CHAPTER-7

CONCLUSION & SUGGESTION

7.2-SUMMARY OF DISCUSSION & CONCLUSION:

International intellectual property protection, which started in nineteenth century in Europe as a form of inter-governmental co-operation, evolved along with technological changes and across different economies and cultures. In the second half of twentieth century, IPRs were used as one of the major instruments of competition among companies. The TRIPS Agreement was adopted in the context of the late twentieth century, when IPR concerns were much more important for developed countries to sustain investment in technologies. There is no fast or ready-paved road to sustainable and inclusive development in this world. Any widening and strengthening of the ambition of national development strategies will need to be accompanied by institutional changes.

In this knowledge economy, economic, social and cultural development of nations and societies now depend more upon intellectual resources rather than other material or natural resources. Harmonization of intellectual property rights started very long back at Paris Convention, for industrial property. TRIPs Agreement is an unprecedented international agreement in terms of its coverage, scope, specificities and enforceability. This formally recognised the need for effective and appropriative means for the enforcement of intellectual property and this can be seen in the harmonized intellectual property laws.

At the General Agreement on Tariffs and Trade (GATT), it was agreed that “Economic development and social progress should be the common concern.

357 Hiroko Yamane, interpreting TRIPS, Globalization of IPR and access to medicines, Hart publishers oxford and Portland Oregon 2011, p no 518
of the whole international community, and should, by increasing economic prosperity and well-being, help strengthen peaceful relations and cooperation among nations⁴⁷. "Hence, though, the TRIPS patent system envisaged in the TRIPS Agreement has multidimensional implications particularly for developing countries. This WTO agreement is being debated world-wide in developing and developed countries and also in many important international organizations. While the transnational corporations are concerned with high profits, the general public seeks easy access to medicines at affordable prices. The need is for a balanced patent system which would satisfy the aspirations of all the stakeholders including the general public. To a considerable extent this has since become possible for developing countries due to clarifications provided in the Doha Declaration on TRIPS Agreement and Public Health.

Patent as a form of intellectual property, is playing crucial role in the development of countries. As inventions produce goods to society and through these inventions, has brought major changes in the world. India has worked within the framework of WTO and the global trade order. At present, TRIPS compliance is a reality. It is best to make use of the flexibilities within the TRIPS and to be cautious when moving forward. India lags behind with other countries such as Korea, China, Russia, etc., in utilizing its existing local, global knowledge and technology resources. But, India is improving its productivity through the effective absorption of existing knowledge, increase in FDI, national and international collaborations and technology licensing. India was failed to absorb global knowledge through technology licensing, severe paucity of skilled workers, and an educational system that is not

compatible with changing industry requirements are the main causes for the not so –promising situation in India.359

Indian pharmaceutical industry driven by knowledge, skills, low production costs and international quality products has witnessed robust growth in the recent years. India's entrepreneurial pharmaceutical manufacturers are now beginning to leverage benefits from the introduction of the nation's product patent system on January 1, 2005. At the same time, a number of the country's largest pharmaceutical companies are attaining global-player status as existing markets expand, and new ones open up, for high quality, affordable generic drugs. Indian firms have embarked on an unprecedented shopping spree of overseas acquisitions to establish themselves in these highly lucrative markets and boost their capacities, as demand continues to grow. Partnerships will also play crucial role for Indian firms' development in their home market.

Multinational companies that have re-entered the market since the new product patent system is introduced to seek out the domestic industry's skills and infrastructures to boost their research and manufacturing activities in the subcontinent and also open up this vast, virtually untapped market. However, India's market development will depend, more than anything, on government moves to increase the population's access to medicines, which is now extremely limited. Further price controls are not the answer; Indian prices for essential drugs are already the lowest in the world.

It has unprecedented opportunities to expand in a number of fields. The domestic industry's long-established position as a world leader in the production of high-quality generic medicines is set to reap significant new benefits as the patents on a number of blockbuster drugs are scheduled to expire over the next few years. In addition, more and more governments

worldwide are seeking to curb their soaring prescription drug costs through greater use of generics. These opportunities are presenting themselves not only in India's traditional wealthy client markets such as the U.S. and European Union nations but also in emerging economies with vast populations such as Africa, South America, Asia, and Eastern and Central Europe. There was anticipation with regard to pharmaceuticals that, TRIPs implied patent amended act will surely affect pharmaceuticals in India and in turn will affect right to life of all the Indians. But, these Indian pharmaceutical industries were not much affected by it, because of the Government policies and effective utilization of generic medicines. These industries famous as manufacturing location for multinational drug manufacturer is quickly spreading into other areas of outsourcing activities and spreading its wings to other key areas also. This untapped domestic market is also highly attractive to the pharmaceutical MNCs, which recently have returned to India in large numbers (many had left when the regime allowing process patents only was introduced in the early 1970s). Now, MNCs and domestic companies are starting to work together, utilizing each other's strengths for their mutual benefit. For the foreign firms, this includes not only the Indian companies' research and manufacturing capabilities and their much lower operational cost levels, but also comprehensive marketing and distribution networks operating throughout India's vast territories.

With regard to availability of medicines in India, and prices of essential drugs, bulk drugs of the indigenous industry, its growth, production, innovation and strengthening of capacity depends upon drug policies in India. Presently drug policy of the government as implemented through drug control order and the abolition of industrial licensing as well as allowing of foreign investment in the country. Now the latest policy of drugs also envisages control over prices of drugs on the basis of economic criteria, as represented in the market share
of different companies in the context of total market sales turnover of various drugs.

In the year 2000, further liberalization in the economy was effected, in the light of which, Foreign Direct Investment (FDI) in the pharmaceutical sector was brought in the automatic route and the limit raised up to 100%. All drugs where unit price did not exceed Rs. 2.00 were also excluded from the ambit of price control. There were also exemptions given for drugs developed through indigenous R&D, New Delivery Systems. It may be noted that various drug policies adopted from time to time have tried to cope up with the challenge of striking a balance between the at times varying requirements of enabling industry to grow and at the same time ensuring affordable and reasonably priced medicines to the consumers, particularly the poorer masses. This balancing of diverse and conflicting interests is indeed a difficult task, as is the reconciling of short term interests with long term goals and concerns. Hence right to health as a human right is not neglected in India.

The Government is therefore seized with the goal of enabling industries growth with attendant socio-economic benefits along with balancing the declared objective of providing better health care including making available essential medicines at reasonable prices to all. 360

The national health laws and policies on health care, national pharmaceuticals and research and development policies have an intense correlation with the national patent system. None of these laws and policies can be framed and successfully implemented in isolation. The primary objectives of co-relation should be to help in the smooth implementation of these policies and application of patent laws. An extremely careful approach is therefore

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360NPPP 2012, available at ministry of fertilizers and chemicals web, government of India
necessary in framing these laws and policies.\textsuperscript{361} According to the latest data, the cumulative drugs and pharmaceuticals sector has attracted USD 11,304.91 million worth foreign direct investments (FDI) during the period 2000 to 2013. Our industry would continue to experience strong growth as structural growth drivers continue to remain impervious. The Indian Pharma sector exports target has been set to US$ 25 billion by 2016. Generics will continue to dominate the market while patent protected products are likely to constitute 10 per cent of the pie till 2015. Global demand for generic drugs from Indian companies is booming as developed nations battle rising healthcare costs. As a result, generics companies are increasingly focusing on expanding presence in relatively under-penetrated markets (i.e. France, Spain & Italy), branded generic markets of East Europe and niche areas like complex generics, OTCs etc. About 40\% of the generic and over-the-counter drugs sold in the U.S. are from India.\textsuperscript{362}

Indian healthcare is dominated by private players and there is no regulatory authority overseeing the functioning of health service providers so as to ensure equitable access to healthcare for all people. With liberalization of health services, there is a need to devise domestic regulatory laws and institutions to meet the social objectives. Optimum utilization should be made of available resources. Efficient procurement policies have a significant bearing on ensuring the right medicines in sufficient quantities procured at lowest price to secure the maximum therapeutic value to the largest number of beneficiaries with the available resources.

\textsuperscript{361} B.K.Kealya, Review of Patent Legislation In India, Srilanka, Indonesia and Thailand, measures to safeguard public health, SEA-HSD-275 Distribution: General , World Health Organization,Regional Office for South-East Asia,New Delhi, September 2004,pp 54

\textsuperscript{362} WHO, FICCI and Dept. of pharmaceutical joint Report, India pharma summit 2013-14, Position Paper, Enhancing India’s Global Medicines pp..6( available at www.ficci.com/spdокумент/20378/position paper IPS.2013-14, accessed on May 22 at 11.30am)
The new National IPR Policy envisages IP as an integral part of India’s overall development policy. It will integrate and create synergies with IP related aspects of various sector specific policies. It will provide a roadmap for holistic, effective and balanced development of the IP system in India.

It is expected that there would be a steady evolution of patent jurisprudence in India. Patent filings too have gone up by 10.56% from 2008-2009 to 2013-2014. Over 75% of patent filings are by foreign entities and so there is a need for concerted action to be taken to increase filings by Indians.

To have strong and effective laws with regard to IP rights that are consistent with National priorities and international obligations and which balance the interests of rights owners with public interest. It is one of the main objectives of our new upcoming IPR policy.

Through, Make In India policy of the government, it is a initiative by the Government to transform India into a world class manufacturing hub is predicated on fostering innovation and creativity by generating, protecting and utilizing intellectual property assets

The regulation of prices of drugs in the National Pharmaceuticals Pricing Policy 2012 would be on the basis of essentiality of drugs \(^{363}\). The regulation of prices of drugs in the National Pharmaceuticals Pricing Policy 2012 would be on the basis of regulating the prices of formulations through Market Based Pricing (MBP) \(^{364}\). This is different from the earlier principle of regulating the

\(^{363}\)The Hon’ble Supreme Court in its Order dated 10.03.2003 in SLP No. 3668/2003 (Union of India Vs. K.S. Gopinath and others) has also emphasized the need to “….. Consider and formulate appropriate criteria for ensuring essential and lifesaving drugs not to fall out of price control…..”

\(^{364}\)Under Marked Based Pricing, the pricing would be based on widely available information in the public domain as against individual manufacturer level production costing data which would result in more transparent and fair pricing.
prices through Cost Based Pricing (CBP)\textsuperscript{365} under the Drug Policy 1994. The key principles for regulation of prices in the National Pharmaceuticals Pricing Policy 2012\textsuperscript{366} have to be fully utilized in systematic way.

In India, with regard to availability and affordability of medicines, Central and State Government institutions follow one or more of these arrangements for public procurement: (i) Central Rate Contract System, (ii) Pooled Procurement either by the government or through an autonomous corporation (iii) decentralized procurement, and (iv) local purchase. The Tamil Nadu Medical Service Corporation (TNMSC) set up in 1994, is a pioneer in the current drug procurement and distribution system. The success of the TNMSC lies in its centralized drug procurement and distribution system supported by a computerized system of drug management. \textsuperscript{367} it also supervises that Contracts are awarded to only those manufacturing units, which have a Good Manufacturing Practices (GMP) certificate of the WHO and should ideally have a minimum ceiling of annual turnover. Similarly, in other states are also

\textsuperscript{365} Under Cost Based Pricing as the controlled prices of formulations of a particular API are determined on a “lowest common denominator” basis, they tend to be clustered within a narrow band. This allows virtually no space for a new entrant to come in at an uncovered price point. As a result, production activity and competition in the product segment tend to stagnate. This is neither good to the consumer-patient nor for industry growth

\textsuperscript{366} (1) Essentiality of Drugs
(2) Control of Formulations prices only
(3) Market Based Pricing

\textsuperscript{367} The TNMSC has set up warehouses at all district headquarters from where supplies are provided to hospitals and other health facilities. A passbook system has been introduced where the entitlement of each facility is given in monetary terms. The institution can obtain any drug in the approved list if funds are available in the passbook. The TNMSC has also developed a unique Drug Distribution Management System (DDMS) which is put to use in effective monitoring of procurement and distribution of drugs and supplies. Under this system, each district warehouse is linked by computer to the central computer in the Head Office. Receipt and issues of drugs have been computerized resulting in instantaneous adjustments to the stock position. This has facilitated movement of drugs from one warehouse to another based on needs, thus avoiding shortages. Usually States adopt a ‘two-envelope system’ (technical bid and price bid being sent in separate envelopes). This system ensures a speedy and transparent mechanism in procurement of drugs.
following this method. The direct benefits flowing from the TNMSC model seem to support lower prices contributed by competitive bidding and bargaining power.

In the line of availability of medicines, generic prescription patterns, supply-chain management must for low-cost drug availability. The aim of JanAushadi was to supply quality generic drugs at rock bottom prices by removing the several intermediaries between the drug maker and consumer. As there was an over-dependence on pharmaceutical Public Sector Units (PSU), this is not reaching public sufficiently

In damage control mode, the Government roped in non-government organisations, tinkered with the revenue model, etc., but prescription patterns continued to trip-up the plan. Unless medicines are prescribed by generic names, it will not drive patients to buy these chemically similar versions of branded products. In fact, the revenues these shops make in a month are comparable to what a regular chemist makes in a day.

Our constitution makers was much aware about the public health or right to health that’s why they imposed liability on Stat by incorporating some provision (Article 38, 39(e) 41, 42, 47, 48A ) of Directive Principles of State Policy.

368Karnataka and Rajasthan, however, follow a decentralized system. In the former, a major part of drug procurement, accounting for 60%, is sourced by zilla panchayats at the district level while the remaining 40% is sourced by government medical stores. In Rajasthan, in the order of priority, drugs are procured from public sector units (Rajasthan Drugs and Pharmaceuticals Ltd.) Tenders are invited only for those drugs not supplied by Public Sector Undertakings and Small Scale Industries.

369The phenomenon of stable or declining prices due to centralized tender procurement of drugs. A simple comparison of drug price is carried out here, involving the procurement system in Delhi and Tamil Nadu, of drugs from different therapeutic categories with similar strengths and pack sizes. The analysis reveals that drug prices have tended to decline gradually or even steeply in some cases, during the period 1996-2003. The tender prices are not only declining but the analysis in the earlier section shows that even the initial price quoted is well below the market price, indicating a wide drug price difference
While the Medical Stores Depot under the Ministry of Health and Family Welfare has seen gradual reduction in its handling of procurement and storage of drugs meant for a few States and paramilitary forces, drugs required for the new policies like (CGHS) and different National Health Programmes (NHPs), the Central Government either provides financial aid or supplies drugs to States through centrally procured arrangements.

Indian pharmaceutical industry is sound and has diversified its market also. It has also seen increased R&D expenditure because of patent cliff. Patent cliff will have serious implications on the future of the pharmaceutical industry. Apart from obvious implications for the consumer, such as cheaper drug options and over-the-counter accessibility, the pharmaceutical companies will face a great deal of change from the current model of the industry. Consolidation of pharmaceutical industries has also increased and

370 Under the Central Government Health Scheme) are procured through the Hospital Services Consultancy Corporation (HSCC). Under the CGHS, orders for both generic drugs and proprietary drugs are placed through the HSCC. As expected, the price difference between generic and proprietary drugs is extremely high. It is a matter of concern that the Government of India, which brings out as Essential Drugs List covering only generic drugs is actually procuring and dispensing proprietary drugs for its employees under the CGHS scheme. The total value of proprietary drugs is many times the value of drugs purchased by generic name. Second, the price difference not only results in sub-optimal utilization of resources but is also a major drain on Central Government resources. This discrepancy should be resolved and only generic drugs should be procured and distributed. There is no quality check on proprietary drugs whereas generic drugs are procured from prequalified bidders whose products are also subjected to sample testing.

371 The domestic drugs industry, which is valued at Rs 1.6 trillion (US$ 25.87 billion) at present, according to Care Ratings, is also expected to grow in the local market with aggressive rural penetration by drug makers, increased government spending on health, and growing health awareness among people. India exports pharmaceutical products to more than 200 countries. Pharmaceutical exports are expected to cross the Rs 1 trillion (US$ 16.17 billion) mark this year. "The growth would be around 15 per cent and is driven by formulation exports," said Dr PV Appaji, Director-General, and Pharmaceutical Export Promotion Council (Pharmexcil). During 2013-14, pharma exports stood at Rs 90,000 crore (US$ 14.55 billion). Out of this, the share of formulations was 71 per cent.

372 As the patent cliff is approaching, Indian pharma companies have increased their R&D expenses. The companies are spending more to establish niche product portfolios for the future.

373 Rizwan Ahmed, patent cliff implications for the pharmaceutical industry (available at www.triplehelex.blog.com), accessed on 25th Feb2015, at 1.30pm.
has become important feature of the industry. The recent deals viz; Sun pharma acquiring Ranbaxy, Wyeth and Pfizer merger, Strides selling its injectable arm and so on are the classic cases.

However, in order to encourage basic research in pharmaceuticals there is a need for substantial financial support from the government. Introduction of GDUFA (Generic drug User Fee Act) in the US during July 2012 too, had a negative impact on pharma companies in India. Voluntary licensing has the potential to be a trend setter as it ensures protection of intellectual property for patent holders and simultaneously ensures access to medicines, a balance the industry has been striving to achieve. Alternative to voluntary licence is the compulsory licence, which is not prominent in India. Innovation without expanded access to the fruits of innovation leads to underservicing of public health needs, while increasing access to the existing pharmacopoeia without encouraging the development of new medicines and technologies does not address emerging threats to health. Developing-country access to affordable medicines can be facilitated by certain flexibilities allowed under the Agreement on the Trade-related Aspects of Intellectual Property Rights (TRIPS). The issuance of compulsory licences has proven to reduce the price of medicines.

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375 Ibid

376 As per this Act, the generic companies are required to pay user fees to USFDA, for application of drugs and manufacturing facilities. This fee will be utilized by USFDA to engage additional resources in order to speed up the approval process. While the drug filling fees was applicable since some time, from Oct 2014 even plant inspection fees have come into effect.

377 Ibid, Essential medicines were available in only 57 per cent of public and 65 per cent of private health facilities in 2012. Prices of medicines are about 3.3 to 5.7 times the international reference prices and many treatment regimens are priced far above the WHO affordability benchmark.

378 Discussed in detail in 5th chapter
In Indian context with nacto securing India’s first and to date only compulsory licence in 2012 to launch generic versions of Nexavar, Bayer’s drug for liver and kidney cancer.

As reported at various international forums, despite a greater awareness within the private sector regarding the need to increase access to affordable essential medicines in developing countries, medicines remain costly, insufficiently available at dispensing facilities and often unaffordable. Increasing access to medicines and the technology needed to produce them, while encouraging further innovation, requires a better understanding of the linkages between policies on public health, innovation, intellectual property and international trade. Greater international cooperation on policy formation in these areas is needed urgently.  

Essential medicines remain insufficiently available in developing countries, especially in low- and lower-middle-income countries. The average availability of generic medicines in public sector health facilities in the group of sampled countries was 57 per cent. In private sector facilities, the average availability was 65 per cent. Availability was extremely low in a number of countries. Another factor to consider is the difference in prices between originator brand medicines and generic medicines. In a sample of low- and lower-middle-income countries, it was found that originator brand

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379 MDG8, the global partnership for development, the challenge we face, MDG Gap Task Force Report 2013. UN Report, page no 59

380 During the period 2007-2012, medicine price and availability data from national and subnational surveys were undertaken using the standardized World Health Organization/Health Action International (WHO/HAI) methodology WHO/HAI Measuring medicine prices, availability, affordability and price components, 2008 (Geneva, 2008), available from http://haiweb.org/medicineprices/.

381 Availability is assessed as the percentage of facilities stocking the medicine on the day of data collection
medicines were priced four times higher than the equivalent lowest-priced generic medicines, on average.\textsuperscript{382}

The World Medicines Situation Report 2004 of the World Health Organization (WHO) pointed out that approximately 67\% of the population lives without an access to essential medicines.\textsuperscript{383} India is reckoned among theglobal leaders in the manufacturing of generic medicines. However, it is also held that the largest number of populace in India is living without having an access to basic medicines. \textsuperscript{384} For meeting the requirements of medicines at reasonable prices as also for strengthening of the indigenous manufacturing capacity and capability, the Government has, over the years, formulated policies and issued drug price control orders from time to time. Currently, National Pharmaceuticals Policy has been drafted with key objectives of price regulation of the essential medicines, availability of good quality medicine, higher investment for increased production, emphasis on drug research and development and promoting good manufacturing practice in domestic pharmaceutical companies\textsuperscript{385}.

WHO has conducted many studies with regard to availability of medicines and suggested new methods. Adopting ERP (external reference pricing) system\textsuperscript{386} in the country, for availability and affordability of medicines for all.\textsuperscript{387} Using health technology assessment system for analysing, whether new medicines provides any additional benefit compared with current price of

\textsuperscript{382}Based on information provided by WHO/HAI available at www.who.com
\textsuperscript{385} NPPP2012
\textsuperscript{386} ERP is applied at the point when the company seeks authorization for marketing the product in the country.
\textsuperscript{387} WHO, hai global, pharmaceutical pricing policies and interventions, policy brief number, 1 feb2014
medicines. Eliminating sales tax on the medicines. Regulation of Distribution mark-ups are the additions to the medicine manufacturer’s or importer’s supply price to cover the costs of wholesale and retail activities, including overheads, distribution costs and profit margins for wholesalers or other distributors and retailers.

Health insurance systems can reduce prices paid by consumers for medicines and increase access and use. They also have potential to improve the use of medicines through active purchasing and management. Insurance agencies’ defined populations of members give them volume and financial leverage to negotiate better prices from the pharmaceutical industry. Insurance agencies’ contracts with providers can be structured to promote rational prescribing and dispensing. The insurance benefits package can be designed to encourage proper use of medicines by consumers. Multi-faceted medicines management strategies are needed to control expenditure prevent fraud and promote cost-effective use of medicines, combining selection, purchasing, and contracting and utilization management strategies. Effective monitoring systems and audit are vital.

With more than 5,000 players, this sector is the largest exporter of branded generics and has almost two-thirds of its exports directed to highly regulated markets, such as the US and Europe. Any restriction on brands may restrict its

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388WHO,hai global, pharmaceutical pricing policies and interventions, policy brief number, 2feb2014
389WHO,hai global, pharmaceutical pricing policies and interventions, policy brief number5, feb2014
390WHO,hai global, pharmaceutical pricing policies and interventions, policy brief number
3Regulation of mark-ups in the pharmaceutical supply chain, feb2014
391WHO,hai global, pharmaceutical pricing policies and interventions, policy brief number, 2, feb2014
current annual growth rate of 17 per cent, and the industry’s exports may fall short of the expected $25 billion revenues by 2015.\textsuperscript{392}

The introduction of new laws,\textsuperscript{393} however, may not allow companies to charge royalty or brand-value on their drugs, which will lead to value erosion in the already competitive drug market. Large conglomerates will face stiff competition from private labels, which may prompt them to relinquish key cost heads, such as R&D, to ensure their sustainability (in terms of price competition).\textsuperscript{394}

The National Pharmaceutical Pricing Policy, 2012, seeks to evolve a formula to fix the maximum retail prices of 348 essential drugs and also decide on the span of control. The draft policy, unveiled by the department of pharmaceuticals in October last year 2014, proposes to cap prices. Government of India should take initiatives, such as improving market access to pharmaceutical companies through increased medical coverage, to help companies’ write-off losses on value by volume, similarly like ACA\textsuperscript{395} reforms in U.S. However, in India, healthcare coverage penetration lags by approximately 15 percent, with virtually no future promotion plans by the government.

Judiciary has the difficult task of striking a fine balance in interpreting the national patent law provisions. India has adopted a balanced approach towards patent law. It has also committed to protect innovation while promoting the larger goal of welfare of its citizens. It is expected that there would be a steady evolution of patent jurisprudence in India. Patent filings too have gone up by 10.56% from 2008-09 to 2013-14.

\begin{itemize}
\item \textsuperscript{392}ibid
\item \textsuperscript{393}New plans of health ministry of India in 2012 October
\item \textsuperscript{394}See supra note 362, page no3
\item \textsuperscript{395}Affordable Care Act 2010
\end{itemize}
Intellectual property consciousness is on the increase amongst the creators and innovators leading to the development of strong intellectual property culture. India shall continue to strike the right to balance between protection of innovation and larger goal of betterment of society. Knowledge behind these intellectual property rights is the main drive for development and knowledge owned is transformed into knowledge shared.

Presently, Indian pharmaceutical industries are estimated to be growing at an annual rate of 14%. The industry has been in tremendous progress in terms of infrastructure, development, technology base and the wide range of products manufactured. India possess about 360 USFDA approved drug manufacturing units in the country.

India is fully conscious of its international obligations and has always abided by them. But at the same time, it has protected the national interest and has also balance the rights of patent owners and their obligations to society.

India’s statutory framework of patents is robust, effective and balanced. It is in consonance with national development priorities, while being in conformity with international treaties, conventions to which it is a party.

VII- SUGGESTIONS AND RECOMMENDATIONS

The research undertaken has revealed the following to overcome the prevailing deficiencies in this area of study. It is well known that India is emerging as a world leader in generic pharmaceutical production, supplying 20% of global market for generic medicines. India accounts for 8% of global production, and is exporting to over 200 countries. However, the following measures needs to be undertaken by the government.
A- SUGGESTIONS

1. Ensure the quality of generics by the appropriate government at the threshold itself.

2. Clinical trials of the drugs must be conducted observing all the norms and technicalities, holding a proper documentation and registration process.

3. A ban on branded drugs and of undifferentiated generics will have impact on the patients / consumers; the regulatory body should monitor the effects and implement the best.

4. The Government of India although has done work should take initiatives, such as improving market access to pharmaceutical companies through increased medical coverage, to help companies’ write-off losses on value by volume, similarly like Affordable Care Act reforms in U.S.

5. Multi-faceted medicines management strategies are needed to control expenditure to prevent fraud and promote cost-effective use of medicines, combining selection, purchasing, and contracting and utilization management strategies. Effective monitoring systems and audit are vital.

6. The Medicine availability in the government sector needs improvement. The Employee State Insurance hospitals are better stocked but have scope for further improvement as well.

7. One of the important components of a pharmaceutical product is the active pharmaceutical ingredient. (API). Good-quality Active Pharmaceutical Ingredients (APIs) are inevitable for the production of good-quality medicines Ensuring the quality of the API greatly contributes to achieving the objective of building the quality, safety and efficacy into the product

8. The essential drug list of government sectors should include the drugs recommended in the World Health Organization as the core list of drugs.

9. An efficient and computerized central purchasing system and decentralized Distribution by warehousing in each district (based on Tamil Nadu State Model) has the potential to improve availability at Government facilities, should be adopted and improved universally, is the need of hour.
10. Indian manufacturers have several strengths such as availability of qualified personnel, strong R&D capability, strong vertical integration of generic pharmaceutical industry, including R&D and innovation and process design. There is however enough for scope for improvement in the areas of GMP systems which might range from several areas like strengthening Quality Management Systems, premises and equipment, control of materials, documentation and laboratory systems etc. The necessary measures that can be taken by providing policies, resources, setting standard protocols, training requirements for the stakeholders and monitoring supply chains for consistency by conducting internal audits.

11. The retail pharmacies need better stocking facilities with, antiretroviral drugs and Drugs for mental illness as they are major health problems.

12. Purchasers of Indian medicines and importing countries need to be assured about quality in international standards, including GMP.

13. There is a need for up-gradation of SMEs to WHO- GMP, USFDA/EDQM/PICs and other International Standards. CGMP requirements serve as the primary regulatory safeguard over drug manufacturing and must be followed by companies to ensure manufacturing quality.

14. In the changing regulatory landscape, there is a need to strike balance in the regulatory regime and the growth of clinical trial industry, keeping in view the need for closer cooperation for ethical and transparent conduct of clinical trials in India. In addition, there is a need to address other challenges as well, like harmonization of regulatory requirements for clinical trials including capacity building of the regulators, registration of clinical research organizations as well as clinical trial sites in India, certification of Good Clinical Practice benchmarked clinical investigators,
strengthening of clinical trial inspections, registration of Institutional Ethics Committees, and strengthening of Clinical Trials Registry of India.

15. Generic prescription needs to be encouraged so that retailers can also stock low priced generics.

16. Teaching and training in generic prescription can begin during undergraduate education and should be continued for practicing Physicians, which will help to resolve many problems.

17. Consumer awareness needs to be increased in generic medicines, so that it creates the demand, which will drive the retail pharmacies to stock low priced Generics.

18. There should be ceiling on profit margins, especially on essential and scheduled medicines. It can be a defined percentage of manufacturing prices. The MRP should include local tax as for any other consumer item and prices should not vary according to demand. Greater consumer awareness is required for checking and paying the right Price based on MRP.

19. The list of medicines under drug price control order should include the medicines on the National Essential Medicine List (EML) and their prices should be monitored on the ongoing basis and methodology should be transparent and published.

20. The multimedia campaign would also address the myth that low priced medicines are not good or efficacious and only the costly medicines are good or superior.

21. The Jan Aushadhi Campaign a self-sustaining business model not dependent on government subsidies or assistance. The government should monitor and also assist at necessary level of implementation in order to have quality medicines at affordable prices for a good hygienic life.

22. Government has taken initiatives. The cluster development scheme in Pharma sector, started recently by the Department of Pharmaceuticals is for upgrading the existing common facilities and also for setting up new
common facilities in clusters. The details of the scheme are available on the website www.pharmaceuticals.gov.in.

**B- RECOMMENDATIONS**

1. It would be better to follow the US quality control system, executed through the Food and Drugs Administration department and of CDC in our system also.

2. The existing clusters in the sector need to have common facilities.

3. Mega parks and setting up of new clusters in the API segment are the need of hour.

4. There is a need to focus capacity building endeavors for both regulators and manufacturers in India.

5. Creation of a Pan-Indian database of approved products and licensed manufacturers.

6. Promote greater engagement in international programmes of inspection, organize joint inspections and promote sharing of inspection reports among international and national inspectors.

7. Review of existing Indian GMP (schedule M + guidelines) and risk-based suggestions for most urgent additional guidelines to converge interpretation and practice to international standard should be considered.

8. There is a growing need to promote research and innovation in India with focus on assuring treatment access at affordable prices for diseases prevalent in our country.
9. Impetus for creating clusters of innovation for both pharmaceutical and biologic segments and reducing regulatory complexity for biosimilar & vaccines.

10. We can adopt our neighbouring countries approach towards the development of national industry. Ex, korea

11. National Skills Development Council started from May 2013 will address the skill needs of biotechnology, pharma R&D, clinical trials and pharmaceutical manufacture sub sectors need to be utilized appropriately.

12. The research and education system has to be strengthened up for specific requirement of the sector. NIPER (National Institute of Pharmaceuticals Education Research)

13. Policies to encourage innovation need to reflect 'technology push' (advances in Knowledge and their applications) or 'market pull' (social or economic market opportunities Incentivizing innovation).

14. Building R&D excellence and accelerating commercialization of research by developing regional industry clusters, encouraging and raising the quality of R&D through public investment and encouraging public private partnerships including product development partnerships (PDPs).

15. Ensuring access to financial capital for companies: This includes private investment in investment funds and companies, especially in innovative, technology based companies.

16. The challenge for the development of biosimilar arises from the fact that biologics are more complex than small molecules and chemically synthesized
drugs. Regulatory pathway to be more focused and aligned to scientific basis for vaccines and biosimilar registration in the country.

17. Several initiatives have been launched by the Government to give impetus to the thriving biotech industry. Department of Pharmaceuticals is working on several projects through National Institutes of Pharmaceuticals Education and Research. The Biotechnology Industry Partnership Programme (BIPP) has been launched by the Department of Biotechnology (DBT) to support high-end biotechnology research programmes capable of generating globally recognized intellectual property. It specifically focuses on transformational research and development.

18. The DBT has also drafted the National Biotechnology Regulatory Act in order to set up the National Biotechnology Regulatory Authority (NBRA) to regulate the biotechnology segment and reduce regulatory overlap. Biotechnology Industry Research Assistance Council (BIRAC) a Section 25 'Not-for-Profit Company' of Government of India has been set up as Department of Biotechnology's interface agency, which serves as a single window for the emerging biotech industries.

19. Support mechanisms are required for promotion of pharmaceutical industries.

20. The existing public private partnerships should be strengthened by exploring opportunities in pharmaceutical field.

21. Scope of compulsory licensing should be broadened by including affordability.