Int J Pharm Bio Sci 2013 Apr; 4(2): (P) 487 - 493

Review Article **Pharmaceutics**

International Journal of Pharma and Bio Sciences **ISSN 0975-6299**

DRUG AFFORDABILITY IN INDIA - POST 2005

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ABSTRACT

Indian pharmaceutical industry so far has reformed globally as a powerhouse for production of drugs after implementation of Indian patent act (IPA) in 1970. After implementation of Trade Related Aspects of Intellectual Property Rights (TRIPS) act on March 23, 2005, India's weak process patent system has been replaced by a strict product patent system resulting in a big question mark on the affordability of medicines. Judicious use of inbuilt flexibilities available in the TRIPS, introduction of utility models and industrial design patents, medical insurance to all, elimination of heavy duties and taxes on medicines and regulation of markups, promotion of generic medicines, improved availability of medicines in the public sector , transparency in the supply chain are the key strategies needed to be implemented and regulated at national level to secure the peoples' rights of access to affordable and quality health care.

KEYWORDS:TRIPS,drug affordability,drug pricing

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INTRODUCTION

India's Pharmaceutical industry is 150 years old with a continuous transition of the patent laws from 1856 till date[1,2]. India has emerged as a global hub for the development of generic drugs after the introduction of Indian patent act (IPA) in 1970[3]. After independence, IPA was put in action obligating 'Process patent' for pharmaceuticals and agrochemical compounds for 7 years. That was a very cost effective and practical approach being adopted by Indian pharmaceutical industry to emerge as a strong generic drug industry producing drugs equivalent to Multinational companies (MNCs) but at affordable prices. IPA allowed Indian pharmaceutical industry to tremendously grow within two decades resulting in the spectacular rise in Indian firms due to their unique and wide ranging technological capabilities. It has been ranked high in the third world in terms of technology, quality and range of medicines. Indian pharmaceutical industry, having 300 large and moderate sized firms and 10,000 small companies has been estimated to produce 8% of the world's drugs in this phase[3]. In 1998, India was ranked 8Th in terms of United States patents obtained[2].Indian pharmaceutical sector made it possible for economically weaker population to access and afford essential medicines because from simple pills to complex medicines needing complex manufacturing techniques, all the drugs were being manufactured by Indian firms, hence changing altogether the scenario from importing the drugs to supplying 2/3 rd of its exports to developing countries. The rapidly growing pharmaceutical industry resulted in rise in India's export share from 0.55% in 1970-71 to over 4% in 1999-2000[3]. But a tremendous pressure on Indian pharmaceutical industry was witnessed after transition from soft IPA to the strict universal intellectual property rights act.

What is TRIPS?

Trade Related Aspects of Intellectual Property Rights (TRIPS) is an agreement which was finalized by World Trade Organization (WTO) in 1994 as an international regimen to control and govern all the intellectual property rights worldwide .It allows the patent protection for 20 years from the date of filing a patent for a novel, non obvious and useful inventions in all fields of technology including pharmaceuticals [4,5]. Duration of one year was given to the developed countries from January 1, 1995 to become TRIPS compliant whereas exemption was given to developing and least developed countries to implement it by 2005 and 2016 respectively. Mail box provision, a means by which patent applications can be filed, and later examined once new patent laws are in effect, was made mandatory for India to file patent claims with effect from 1995 till the practical implementation of TRIPS in Indian pharmaceutical industry [5]. TRIPS act was implemented worldwide to harmonize the international patent protection regimen to attain minimum standards in the pharmaceutical industry. Knowing the fact that no single country can escape from implementing TRIPS, India also being a member country of WTO since 1994 was under obligation to comply with the TRIPS agreement on 23 March, 2005. TRIPS agreement shifted 'Process patent' system to 'Product patent' system[1,3]. Process patent, which refers to the protection of the process/method used by the patent holder, allows other companies to grow by manufacturing same drug but with different manufacturing process .Hence generic equivalents can be produced by different manufacturers leading to competition, more affordability and accessibility but product patent system provides monopoly to the manufacturer for production and sales of specific products for 20 years [5].

Drug Unaffordability ---A Prime Implication Post-TRIPS

Lack of harmony in terms of development of different WTO member countries was a big hindrance to the TRIPS compliance and hence adversely affected various developing countries that could not bear the strict laws imposed by TRIPS. The most important adverse effect

observed after implementation of product patent regimen is high drug prices and lack of consumer welfare which affects the overall health system. Medicines represent a substantial proportion of the cost of treatment of diseases with up to 20-60% expenditure in developing and transitional countries as compared to 18% in countries of organization for economic co-operation and development [6].Medicines in India have become very costly and over priced in post TRIPS phase causing violation of consumers' rights[7]. The rise in drug prices ranging from 26-242 % was observed in a study after introduction of product patent system[8]. The flourishing Indian pharmaceutical industry which was a power generator of affordable medicine suddenly got trapped in strict patent law resulting in a threat for poor people regarding the affordability of life saving drugs in conditions like HIV, cancer, cardiovascular conditions and dementia because of the rising cost[2,9,10]. Special concern is for patients with AIDSs because the second highest number of AIDS patients (4 millions) lives in India after South Africa. Till date, India has been in position to reduce the prices of antiretroviral drugs by 98% because of its substantial contribution in generation of generic antiretroviral drugs[3]. In 2005-6, approximately 350,000 people worldwide, half of all people in the developing world, who received antiretroviral treatment, used drugs produced in India[5]. But after TRIPS implementation, though new drugs for AIDS will be available, legal limitation of MNC s to produce low cost generics will certainly make it impossible for poor people with AIDS to buy medicine and hence will lead to premature deaths in larger number [9]. Unaffordability is of major concern for patients with chronic diseases because in chronic diseases, treatment is for months or years and that too for so many times a day which drastically affects the pocket of payers giving them stressful lives and hence lack of proper treatment[7].

Contributors for drug unaffordability

India is a developing country occupying world's one third of poor population. Medicines constitute 50-80% of health care costs in India. It has been studied in 2010 that out of 1.17billion population of India, only 50 millions are able to afford modern medicine[11]. Reason for high prices of medicines after implementation of TRIPS is attributed to the adverse impact on the technological development of India. Due to scarcity of resources and weaker economy, it is hard to develop new chemical entities, despite the increasing number of disease afflicted patients in India. Also increase in royalties to developed countries can lead to an outflow of economy from developing to the developed [2].Major factors responsible for unaffordability of drugs in post TRIPS phase are patenter monopoly, cut off supply and lack of generic competition[3,12]. Lack of uniform health insurance policies in India is another contributing drawback in Indian health care system which cannot be ignored if we discuss the reasons behind unaffordability of drugs by the majority of Indian population[13].While developed countries cover most of the population under medical insurance, major portion of the population in India is self financing for health care costs[14]. Only less than 4% of total govt resources are contributed to the health system. Out of pocket payments are the primary source of payment resulting in 50-90%of expenditures which is far more than the expended money by consumers in developed countries leading to a huge burden on patient's economy in developing countries like India[4]. In addition, the decaying public health system has also aggravated the problem of unaffordability of drugs in India. Indian health care system includes both public and private sector. Public health care system though constitute 2/3 rd of the health sector, still is unable to provide the basic health care needs to population urging people to seek private health care services which are costlier[7].Strict policies for controlling drug prices is lacking in indian system hence contributing to very rapidly rising prices of modern medicines[14]. Tendency to prefer brand drugs as observed in various studies also increases unnecessary expenditure on costly brand medicines.

Steps to be taken

The right to health is a fundamental right, judicially recognized under article 21 of the

Indian Constitution and drug affordability is a fundamental rule of right to health by any population[15,16] . Drug unaffordability has a direct impact on any nation's welfare and growth. The current issue of unaffordability which has invaded the health care system of India hence needs a major attention in the current scenario of rising diseases.

What is needed

At national level

- Prudent application of flexibilities in TRIPS by incorporation of compulsory licensing, bolar exemption and allowing parallel importation

Compulsory licensing –It refers to the provision of license for the domestic manufacture of the drug by judicial authorities in case of national emergency, on anti competitive grounds [insufficient quantity and heavy cost] and where availability is critical to public health so as to protect the legitimate interests of the patent holder .Under this provision, third party is authorized to make, use or sell a patented drug without the consent of the patent owner.

Parallel importation— It refers to importation of the drug from an organization of other country rather than the manufacturer itself. It can be a helpful step to increase the affordability of drugs because the cost of the drug taken from other distributor will be very low as compared to the manufacturer itself.

Bolar exemption- This provision maintains a clear balance between promoting invention and ensuring that consumers have easy access to cheap generics after expiry of the patent. It allows the manufacturer of generic drugs to use the patented invention to obtain market approval without the permission of the patent holder before patent expiry[3].

- Incorporation of Research exception provision
  Under this provision, researchers can be allowed to use the patented drug for research so as to explore and study the patent drug.
- Strict Price regulations by government on at least life saving essential drugs
  .A transparent formula is needed to keep the price controls effective. Regular revision every two to three years is recommended to access the list of drugs under price control.
- Incentives to Research and Development (R & D) to bear high cost and risks in the development of new drugs.
- Introduction of utility models and industrial design patents so as to encourage domestic enterprises to undertake minor innovations[2].
- Medical insurance to all
  Unfortunately only 11% of Indian population have health insurance out of which only 1% are having effective and adequate insurance for better access to modern health care[2,17]. Hence there is a dire need for effective and uniform medical assurance schemes for raising government's contribution in disease treatment thus increasing drug affordability by every strata of population in India.
- Generic open (GO) license is another proposal where a patented drug or vaccine becomes automatically open to generic production by interested manufacturers for use exclusively in low- and middle-income countries[18].
- Such national drug regulation policies should be implemented which directs the elimination of heavy duties and taxes on medicines and regulation of mark ups[11].
- Transparency in the supply chain can be ascertained through provision of price catalogues with the medicine, internet based price lists, prices published in papers by reputed NGOs so that payers become more aware of the pricing of medicines. This public consciousness can be an important tool to bring down the prices of medicines which are otherwise sold overpriced in the markets lacking transparency.
- Regulation of each component of the supply chain by keeping a check on profit margins of manufacturer.
- Regulating unethical and extravagant drug promotions which lead to hike in drug prices[7,15,19].
- Promotion of generic drug use -
  Both practitioners as well as patients should be encouraged to prescribe/use the generic

equivalents of innovator drugs. As question raised on the quality of generics has been nullified by various studies, utilizing the quality effective generics with low cost can be a simple but effective step to enhance drug affordability[20,21].

- Limiting the medicines in the market as per WHO essential list by weeding out the unnecessary, unscientific and therapeutically useless drugs which add to the cost of prescriptions and hence complicates health recovery.

At international level

- Suspending the evolution of TRIPS to further strict its regulations for the next couple of decades.
- Resisting developed countries' attempts to limit the implementation of TRIPS flexibilities- Enormous pressure is there on low and middle class countries to outlaw TRIPS flexibilities which do not allow such countries to limit the impact of TRIPS.
- Revision of TRIPS to grant provision of flexibilities to developing countries until they reach a certain level of development as per capita income.
- To shorten the time for product patent in developing countries.
- International funding for R &D in developing countries.
- Discriminatory pricing (tiered pricing)
  It follows the rule of equitable pricing of drugs where the price paid in each country is proportional to the average wealth, income or any other economy indicator. According to the tiered pricing pattern, poorer countries have to pay less for the same drug than in developed countries so that difference in consumers' ability to pay is minimized in developing and developed countries. This strategy can make the drug available to poorer of poor who would otherwise be impossible to afford them[2,4].

At pharmaceutical industry level

- Effective limitation of sales to the destination country and setting prices according to price elasticities of demand are recommended strategies to be adopted by multinational pharmaceutical industries.
- Research and development for newer innovations to strengthen health care systems Till now, Indian pharmaceutical industry concentrated on making and marketing the generic versions of drugs without any basic research and development of new drugs. Though it will be difficult for Indian drug industry to suddenly come up with new molecules due to lack of experience and financial scarcity, but Indian companies can enter licensing agreements with MNCs for development of a new molecule. Contract research is another lucrative option open to small and medium enterprises to survive in post TRIPS era[3]. Another comprehensive solution is the research at the level of universities to improvise the global access to medicines[22].

CONCLUSION

There is a need for access oriented drug policy strategies and research based pharmaceutical industries, to meet the target of affordability of drugs by all. High level commitment is needed on the part of the government to implement the ideas into action and afterwards regularly monitoring the policies for effective management of drug pricing strategies. To achieve national goal of affordability, it is highly needed to improve international affordability, keeping in view the fact that major R & D is international in structure and ownership along with the strategic pricing by pharmaceutical industries.

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