

# Drug affordability in india—an analytical review

## Abstract

“Health is wealth”. Leading a healthy life is a boon because if one ailment attacks our body, all other related ones follow. The present scenario of globalization has changed the food and lifestyle of people, leading to several diseases. This increases the susceptibilities to higher degree of diseases. Greater the severity of any disorder, greater is the cost of its treatment. It has made many patients sleepless in nights leading to misery and penury. Not every person in India is ready to afford for the medicines which he/she has to take on account of the disease attacked. The jobless society in India with lots of economic recession decreases the purchasing power of medicines. An average family man’s budget is mainly for his essentials of living and what is left out-of-pocket is only spent for medicines. Public health outlets are set under each State Governments so that even poor people could easily access the medicines for free of cost. In spite of this system, certain drugs are not available through these outlets. No anti-cancer drug is available in some Government hospitals. This condition prevails due to the following fact: A researcher inputs rigorous techniques and formulates a new drug and obtains patent for it. For the patent period of 20 years, only those who officially possess the license manufacture the medicine resulting in the high cost of medicines. They are the contributors for drug unaffordability not only in developing countries like India but also in developed countries like the United States. It must be understood that drugs are not just marketable commodities but lifesaving essentials researched and formulated with an intention to help the needy. It’s very objective gets defeated if it is priced beyond the reach of the consumer.

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**Abbreviations:** WTO, world trade organization; TRIPS, trade-related aspects of intellectual property rights; GATT, general agreement on trade and tariffs; USFDA, united states food and drug administration; NGOs, non-governmental organizations; GIPAP, gleevec international patients assistance program; AIDAN, all india drug action network

## Introduction

The right to health is a human’s basic right under the Article 21 of Indian Constitution.<sup>1</sup> What is the meaning of leading a tedious life where we earn a lot of money and not able to maintain a healthy body? Today’s lifestyle leads us to many incurable diseases. The cost of treatment for such diseases is unimaginably high. This keeps us away from the availability of drugs. The question of drug access and drug prices has become particularly important after India changed over a regime that recognizes process patents for medicines to product patents, since 2005.<sup>2</sup> The effects are more acute in the case of drugs to treat HIV/AIDS, cancer, diabetes and psychiatric conditions.<sup>3</sup> It is true that in India we don’t have any strong patients and citizens organization to fight for patients rights. Hence our Government’s intervention is definitely required in this case as it is in the larger interest of public. The following topics cover the reasons behind, current status and the steps taken by our Government for the improvement of drug affordability.

## Background of patent

The World Trade Organization (WTO) was formally established in 1995 to reduce trade barriers between countries of the world. As a part of WTO’s rules in the area of public health, an Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) was made and it awarded a minimum of 20 years protection from the date of filing the patent. This gave patent for both the manufacturing process and the product obtained. This differs from the General Agreement

on Trade and Tariffs (GATT) which protected only the manufacturing process and permitted the production of generic equivalents of brand drugs using slightly different manufacturing process. India was not in compliance with TRIPS until 2005. On account of facing enormous international pressure, India changed its Patent Act, 1970 in accordance with TRIPS in 2005. Following the agreement, India had been required to establish a ‘mailbox’ where patent application could be filed between 1995 and 2004 by the Indian Patent Office. During this ten year period, over 4000 drug patent applications were filed. It is interesting to note that only a few hundred New Chemical Entities have been developed, which indicates that the majority of the other applications are already known and have been slightly modified. Exclusive Marketing Rights were granted only to those companies introducing truly new invented drugs.<sup>4-7</sup>

## Overcoming limitations of trips

There are three key mechanisms as listed below by which the potential impact of TRIPS can be avoided:

### Compulsory licensing

A judicial authority within a country can issue a license for the domestic manufacture of a drug which is still under patent, without the agreement of the patent holder with an acceptable royal payment. This is possible only when the availability of the drug is critical to public health or on grounds of anti-competitive practices like excessive cost of the drug.<sup>8-10</sup>

### Parallel importation

This can happen when a country imports a drug from an organization in another country rather than purchasing it directly from the manufacturer to obtain it at a cheaper rate because pharmaceutical companies sell drugs at different prices in different countries based on the standards of living.<sup>11</sup>

## Bolar exception

This allows generic manufacturers to conduct research and development for a generic equivalent of a brand drug which is still under patent. Hence after the long research they can begin production and sales of the drug immediately after the 20 year patent of it is expired.<sup>12</sup> These mechanisms led several low- and middle-income countries to amend their patent legislation to implement compulsory licensing and parallel importation legally. But enormous pressure has been exerted primarily by the US Government on those countries not to explicitly allow those practices which limit the impacts of TRIPS. This agreement is termed as TRIPS-Plus. For example, South Africa was withheld from passing the Medicines and Related Substances Control Amendment Act in 1997 which allowed compulsory licensing. In addition to that, US withdrew preferential tariff treatment on some South African exports. These sorts of actions in the nation level would definitely affect the poor people of the country who are in lack of resources and medicines.

## Amendments in the indian patent act

The Indian Patent Act was revised by the Indian Patent Office in 2005 because of the fact that India is the world's leading supplier of generic medicines, with two-thirds of its exports going to other developing countries like Africa. Further in the crisis of epidemics, India had decreased the cost of anti-retroviral drugs for AIDS by as much as 98%. The salient features requiring the need for amendments in the Act include the following:

- The Patent Act allowed the manufacturers to apply for patents on new-use products. For instance, a drug that already exists but is found to treat a different disease other than that which it was developed for. This process is called as Evergreening of patent where an already existing patent is repeatedly extended beyond the 20 years time period to prevent the generic production of the drug.
- It would not permit the export of compulsory licensed medicines from India to other countries. To import generic drugs to India, the importing country must itself have a patent of the brand drugs and have granted a compulsory license for the generic drugs.
- Compulsory licensing would be allowed in India only under exceptional cases when there is a national emergency like in the case of epidemics.<sup>7</sup>

## The scope of compulsory licensing

Under Section 84 of the Indian Patent Act, any person can send an application to the Controller-General of Patents for a compulsory license after the expiry of three years from the date of sealing of patent on the following grounds—non-fulfillment of reasonable requirements of the public or non-availability of the invention to the public at a reasonable price. Even the TRIPS and Doha Declaration provide for compulsory licensing at specified circumstances. India's use of the compulsory licensing provisions under its patent law for the first time to make the patented anti-cancer drug Nexavar available at affordable prices is the turning point in curbing the mounting cost of drugs. The patent for Nexavar was held by Bayer, the German-based company. The cost of this brand drug for 120 tablets is Rs.2.84 lakhs per month dosage. But when it comes under compulsory licensing the cost would be Rs.8,880 or the same dose till the expiry of the patent

till 2021. Indian Patent Office for the first time offered compulsory license to Natco Pharma, an India-based company by sending Bayer's monopoly for Nexavar allowing chances to sell the drug cheaply to Indians from March 12, 2012.<sup>7-10</sup>

## Impacts on indian health system

India has less than 4% of total Government resources being allotted to health services. In United States, an unskilled worker must work for 10 minutes to buy 10 tablets of Paracetamol. While in India, a daily wage worker will have to work for at least one hour. The most interesting thing in this statistics is that Paracetamol is the cheapest drug in the world. India being a developing country with an unstable economy is affected to a greater extent. The grant of patent to the drugs which are essential for the treatment of severe diseases led to their higher costs. Though it prevented companies from copying drugs it resulted in elevated drug prices. It is estimated that India will join the league of the top ten global pharmaceutical markets in terms of sales by 2020 with the total value reaching \$50 billion. Several Orders were passed by the Indian Government to freeze the elevated prices of medicines. Pricing system for medicines was brought in 1962 which consisted of Drug (Display of prices) Order, 1962 and Drug (Control of prices) Order, 1963. Later in 1995, Drug Prices Control Order provided a detailed and clear list of price controlled medicines. It additionally eradicated medical attender's corruption which was common in those days. Apart from this, Pharmaceutical Policy in 2002 was given for controlling prices of non-essential, harmful medicines which included about 30 to 34 drugs like Analgin and Phenylbutazone tablets. But drugs used in the treatment of HIV/AIDS, animal bites (for example, rabies) fall outside price control.<sup>13</sup>

## Current status of drug prices in india

In our country, health care is the second most leading cause of rural indebtedness after dowry. The first choice of a patient is to go to a private practitioner and spend out-of-pocket expenditures. A doctor never prescribes one medicine for a disorder and the treatment may continue for many months. Patient will never hesitate to buy them at any cost to seek immediate relief. A notable part of it is that doctor prescribes only his/her brand of medicines as an outcome of drug company-doctor interface. These are unethical practices to promote drugs and the ones who are affected are mere poor patients.<sup>14-18</sup> Some examples of drugs with high cost are listed in the Table 1. Small scale Schedule M manufacturing company which manufactures medicine at the following rate is given in Table 2. The above mentioned costs are much lower when compared to the market prices of other manufacturers. This shows the same drug being sold at different cost by different manufacturers.

**Table 1** Name of the drugs with high cost

S. No.	Name of the drug	Disease to treat
1	Dexorange	Anaemia
2	Glimepiride	Diabetes
3	Abciximab	Angina Pectoris
4	Epoeitin Alfa	Chronic Renal Failure
5	Interferon Alpha-2a	Leukemia
6	Etanercept	Arthritis

**Table 2** Name of the drugs with low cost

S. No.	Name of the drug	Disease to treat
1	Albendazole 400mg	Worm Infection
2	Amlodipine 5mg	Angina Pectoris
3	Atenolol 50mg	Angina Pectoris
4	Enalapril 5mg	Angina Pectoris, High Blood Pressure
5	Fluconazole 150mg	Allergies

### Drug cost maintenance in india

The Indian market is highly competitive in bringing the cheapest brand to people. It is also described as the free market where irrational medicines from human placenta, animal liver, etc., are sold at higher prices. It is noteworthy that doctors always relate the quality of the drugs to the cost of the drugs. The brand leader sells the highest priced medicines. In contrast to this, highly sold drug is under price control to afford people. For example, Chloroquin is less in cost than other anti-malarial drugs. A State Government has stated in Lok Sabha Session (2005–2006) that high prices of antibiotics, Cetrizine, anti-cancer drugs were referred to National Pharmaceutical Pricing Authority and it has conveyed helplessness in curtailing the high prices. The tender prices are about 1–3% of the retail market prices. In Tamil Nadu, Albendazole 400mg is bid at Rs.0.35 per tablet by the Government but in the market it is sold for Rs.12 per tablet. Few other examples are anti-hypertensive drug Enalapril which is Rs.72.9 in the private but sold for Rs.21.1 under Government procurement. Similarly a bronchi-dilator Salbutamol is sold for Rs.72.9 in the private but under Government it is sold for just Rs.10.5.<sup>14–18</sup>

### Expiry of patents

Ongoing expiry of pharmaceutical patents on a range of blockbuster drugs is the onset of opening the market to cheaper drugs in countries like India and China. Patent protection was absent for the drugs produced during the period 1972–2005. Those drugs were universally manufactured by many pharmaceutical at that time. There was a lag in the enormous production of medicines because, those who held the patent were only able to manufacture. Between 2011 and 2012, many drug-makers lost patent protection on their best selling product. As more and more patents expire, Indian industries could start seeing major profits with their generic versions. Once the protection expires, the first company to challenge the patent gets an exclusive right to sell the copy for 180 days for even one-fifth of the original price in order to gain the market. After 180 days, even more companies start selling them for even cheaper rates. Drugs like Lipitor, an anti-cholesterol tablet manufactured by Pfizer for \$6.4 billion per year lost its patent on November, 2011 and Ranbaxy has won approval from the United States Food and Drug Administration (USFDA) to sell Lipitor's generic version in the US market for desired price. Some other notable examples of this case are Eli Lilly's anti-psychotic drug Zyprexa, Johnson and Johnson's Levaquin and Concerta, Pfizer's Viagra and Protonix, Merck's anti-asthma drug Singular. The Hyderabad based Dr. Reddy's Lab has launched Olanzapine tablets, the generic version of Zyprexa in September 2011. Another Pfizer drug which was sold for \$393 billion in United States to be made by Ranbaxy is Caduet.<sup>19–22</sup>

### Evergreening of patent

Revised protection for an already patented product for another

period is termed as Evergreening. The amendments of Indian Patent Act in 2005 aim at preventing Evergreening. At present, a Swiss drug-maker Novartis has filed a case in Supreme Court to protect its anti-cancer drug Gleevec. This Gleevec is found to be the new version that is expected to increase the efficacy and bioavailability by 30% but it is still the basic drug molecule Imatinib mesylate which was patented in 1990s. By this it is challenging Indian Patent Law by making patent extensions or new patents based on minor changes to preparation. Though several Non-Governmental Organizations (NGOs) have long argued that poor patients in India should be given cost effective drug, the outcome of this case is going to affect India's entire drug industry in context of unaffordability.<sup>23–26</sup>

### Initiatives for drug affordability in other countries

In USA, health maintenance organization indirectly regulates the costs of the drugs. By the Affordability Care Act, United States guaranteed access and affordability for all the democrats of America. The Swiss pharmaceutical company Novartis has started the program Gleevec International Patients Assistance Program (GIPAP) which provides \$1.7 billion worth drugs to patients from 2002 for free of cost. Another drug-maker Roche has initiated women's cancer program Prayas to provide better access to Herceptin for women below the poverty line. Also Merck has approved to sell its anti-diabetes drug Januvia in India at a price lower than its US market price. Nobel Laureate Joseph E Stiglitz has advocated a medical prize fund to spur innovation with large rewards for discoveries like vaccines and small rewards for others similar to the existing formulations. This may reduce the cost of the generic drugs to a certain extent.<sup>10,27–32</sup>

### Private motives for drug affordability

In India, only 14 patented drugs have entered into the market. In other countries, the population is not directly affected due to several public health schemes and insurances. But Indians have to face them directly because of the absence of the health care insurance system. Even the TRIPS is silent over the price control. Dr. Yusuf Khwaja Hamied, Chairman, CIPLA Ltd., has announced that it slashed the prices of its anti-cancer drug Nexavar by 75% in India. By this we can afford the drug for Rs.6,840 per month which is cheaper than the Natco prices who sell them at Rs.28,000 per month. It also came up with the first AIDS medicine in 1990s, AZT with one-fifth of the price of the brand drug. He has also shaken up the global pharmaceutical industry by offering it for \$1 per day to the AIDS patients. On August 30, 2012, New-Delhi based Ozone Pharmaceuticals has announced a uniform pricing levels for its blood pressure, cardio-vascular, diabetes medicine portfolio for Rs.2 per day across the dosage and strength, says the Chairman.<sup>33–35</sup>

### Steps suggested for easy accession of drugs

Indians consume about Rs.56,000 crore worth medicines through private chemists.<sup>36</sup> This shows the wide gap between Government procurement of drugs. Among the top selling 300 brand drugs in the ORG only 36 were price controlled.<sup>37</sup> The following points can be recommended from the citizen's side to avail the medicines more easily:

- Unethical practices of drug companies with the doctors must be removed.

- b. Strict watch on prices of lab investigations, medical procedures and surgical operations rate to prevent corruption.
- c. Limiting new drug approvals and only those with therapeutic, safety and cost advantage should be permitted.
- d. Regular provisions of Essential Medicines Prices should be done for the period of every 2–3 years.
- e. Prices of drugs must be regulated based on the therapeutic class, pharmacological action, efficiency and potential of the drug.
- f. Creation of a single regulatory agency to look into drug pricing, control and quality issues as soon as possible.
- g. A differential taxing/subsidy approach could be mulled with a higher tax exemption to patent holding company.

## Conclusion

About 2 billion people i.e. one-third of the world's population lacks access to essential medicines. In India, nearly 40% live below the poverty line. In India, All India Drug Action Network (AIDAN) has actively ceased the rising cost of essential drugs to a measurable extent. Modern pharmaceuticals played a significant role in increasing average life expectancy at birth in India from little more than 40 years in 1960 to the average of about 67 years today. For developing India, we need to resolve the conflicts between drug price controls, innovation and affordable health care. Drug affordability to a patient is the absence of economic barriers to avail them and it does not include explicitly consumer's willingness to pay for it. It is absurd that high prices of some of the modern drugs under the guise of Intellectual Property Rights will fool no one. At present India has the highest number of USFDA approved pharmaceutical manufacturing facilities. India exports \$1 billion worth medicines to other countries. Resources are needed to be utilized for the growth and not for exploitation. Considering several contributors for drug unaffordability and other factors, I wish to express that appropriate specific measures and actions are needed to be taken in time so as to improve our society and our India that will lead to the betterment of every citizen.

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## Conflict of interest

The author declares no conflict of interest.

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