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Research Paper

Patented Medicine and the Life of Patients

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ABSTRACT
"The researcher is of the view that, Medicines are for life savings but patents make it otherwise".The aim of this article is to ponder the issues relating to patented medicines (expensive life-saving drugs) and how it is related to the life of patients.In the beginning, the article explains a dispensable phenomena pertaining to patenting of life saving drugs. Pragmatically speaking, in a country like India where the importance of affordable healthcare cannot be underestimated, we need to have a liberal IPR regime, so that even the poor can have access to patented medicines. The article deals with the concept of health economics and some ethical issues relating to it as well.It deals with what does "Ever Greening" mean in the context of patents and especially with regard to the pharma industry.The legal provisions of Section 3(d) Indian Patents Act, 1970 and the benefits that section 3(d) offers by preventing 'Ever-greening' are explained in the article.The article discusses the constitutional validity of the 3 (d) which is in itself a big question? Adding to this, the judgment of Novartis AG vs Union of India has covered all the aspects of the research.The article presents the contemporary position of IPR in India. The Role of State and Right of patentee and whether the patentee discharges his duty or not? The article also proposes the concept of unapproved formulations and the health of people.In the last paragraphs- Right to Health in Indian Constitution and the Importance of access to essential medication are discussed.At last, the paper proposes conclusion, suggestions and some specific recommendations in order to protect the life and preserve the rights of the poor populace of the country who have the right to avail and afford adequate health and medical facilities.

KEY WORDS: *Patents, Ever-greening, Drugs, Patients, India.*

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I. INTRODUCTION

The idea to cover the contemporary issues of medical health and Intellectual Property laws are substituted more likely towards the social-monologue, i.e. focusing on a developing country like India. Today in developing countries, especially India, the enormous predicament we have in the field of health care is the skyrocketing prices of the life-saving drugs that infringe the right to life.

Time and again the importance of generic prescribing has been emphasized, primarily to reduce the cost of drugs. There are two concepts to be understood here, one is generic vs. patented drugs and the other is a drug's "brand name" vs. "non-proprietary name" or "generic name."

Generic drugs work as a key in granting access to affordable medicines that benefit both the health of the patients and the senior citizens.

Non-proprietary name is the name for the active ingredient in the medicine that is decided by an expert committee and is understood internationally.[3] Thus, paracetamol/acetaminophen is the non-proprietary name (generic name) while Crocin/Metacin/Meftal/Tylenol etc. are brand names.

According to WHO "Health is a state of complete physical, mental, and social well-being and not merely the absence of disease or infirmity". Claiming the WHO definition on health is a bad one, Callahan[4]

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[3] Karan B. Thakkar and Gauri Billa, *The Concept of: Generic Drugs and Patented Drugs vs. Brand Name Drugs and Non-Proprietary (generic) Name Drugs,*(May, 05, 2016, 04:00 p.m.), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3770914/.

(1973) criticized the exclusive definition of health tracing the development generated by the WHO. He concluded that health is much more than implications and uses rather we can also conceptualize the abuses which have not been in the meaning of health given by the WHO. Health is an indispensable element of human life that one manages to protect through physical, mental and social aspects of well-being.

Patenting of Life Saving Drugs: Dispensable Phenomena

Pragmatically speaking, the life-saving drugs are emergency drugs that require immediate administration in medical emergency. Medicines which have the potential to sustain life and/ or prevent further complications or the drugs which require immediate administration within minutes post or during a medical emergency are going to sustain a life they are to be freed from the clutches of patents. Since these medicines are quite good in number, they cure variety of diseases and save variety of lives of human being. For example such medicines are-

List of Life-Saving Drugs (LSD's)

Drugs used in Anaplylactic shock	**Drugs used in Myocardial infarction and cardiogenic shock**	**Drugs used in peripheral circulatory collapse**	**Drugs used in status eplipticus**	**Drugs used in acute respiratory failure**
(1) Inj. Epinephrine Hydrochloride (Adrenaline) (2) Inj. Sodabicarb (3) Inj. Dexamethazone Sodium phosphate.	(1) Inj. Isoprenaline (2) Inj. Amino Caproic Acid (3) Inj. Streptokinase	(1) Inj. Dopamine Hydrochloride (2) I.V. Ringer Lactate (3) I.V. Normal Saline	(1) Inj. Phenytoin Sodium (2) Inj. Diazepam. (3) Inj. Phenobarbitone	(1) Inj. Nikenamide (2) Oxygen gas I.P. /B.P

A Need of Liberal IPR Regime

We cannot ignore the fact that today pharmaceutical industry is considered as most profitable industry in the world. The global pharmaceuticals market is worth US$300 billion a year, a figure expected to rise to US$400 billion within three years.[5]

The new problem which arose with the right of patent wanting that the patent should not be opened to all kinds of medicines, has drawn the attention of philanthropists saying that there should not be the medicinal patent era in India. Though as the motivational factor for the inventors the right of recognition for the patent has to be given but it should have limited application by giving patent only to the medicines of the rare diseases. And this can be the most effective way to provide relief to the people.

Secondly, the cost of patented medicines must be generously fixed so that in a country like India where the importance of affordable healthcare cannot be ignored, we can have a liberal IPR regime, so that even the poorer can have access to the patented medicines. The issue contemplated here is to reduce the amount of price of life saving drugs which is used to cure the rarest of rare diseases, especially for the poor populace of the country.

The legal and bureaucratic barrier that restricts new generic drugs from entering the market is a serious concern. The continuous hike in the price of drugs not only affects the elder people but also harms all of us because they subvert the private and public system of ours. In a country like India where the awareness regarding life insurance has not reached to the far flung area it is unwise to think of linking the cost of medicine to the life insurance. There is an urgent need for government to intervene in the process of marking/deciding the prices of life-saving drugs in order to prevent the manipulation of drug prices being done by the pharma industries. It is quite evident that taking such sort of steps would take a lot of time and documentation but are necessary that such steps should be taken to prohibit brand name drug companies from entering into such agreements which affect the price of drugs.

Among the hallmark achievements of the modern civilization is the realization and dissemination of knowledge that rights to life, liberty and security of person are primary, inherent and inalienable for every human who are inhabitant on earth, irrespective of a person's race, nationality, economic status or other man-made discriminations. Article 3 of the Universal Declaration of Human Rights of 1948[6] and Article 21 of the Indian Constitution recognize these rights as fundamental to everybody.[7] The Supreme Court in *C.E.R.C. v.*

[4] Daniel Callahan, The WHO Definition of 'Health', NATIONAL SEMINAR ON LAW, SCIENCE AND TECHNOLOGY, 161 (2015).

[5]Rufus Pollock, *Strong Words from WHO on Pharma Industry*,WHO (Dec. 16, 2016, 04:00 p.m.), http://rufuspollock.org/2016/05/29/strong-words-from-who-on-pharma-industry/.

[6] MODI, A TEXTBOOK OF MEDICAL JURISPRUDENCE AND TOXICOLOGY 181 (24thed. 2012).

[7]*Id.* at 181.

Union of India,[8] held that right to health, medical aid to protect the health and vigour of a worker while in service or post- retirement is a fundamental right under Article 21.

Modern human rights, born in the aftermath of the Second World War and crystallized in the Universal Declaration of Human Rights of 1948, reflect a broader, societal approach to the complex `problem of human well-being. The implicit question behind the modern human rights movement is: 'what are the societal (and particularly governmental) roles and responsibilities to help promote individual and collective well-being?' This form of the question leads to a specific list of actions that governments should not do (discrimination, torture, interference with the free flow of information, prevention of association with other person in society), and basic minimum that governments should ensure for all (elementary education, housing, food, medical care).[9]

The ethics for medical practitioners reveals that it is the privilege of the medical doctor to practice medicine in the service of humanity, to preserve and restore bodily and mental health without distinction as to persons, to comfort and to ease the suffering of his or her patients. The utmost respect for human life is to be maintained even under threat, and no use made of any medical knowledge contrary to the laws of humanity.[10] Moreover, it is the duty of the doctor to tell the available generic drugs to the patients. Chapter 1 of Code of Medical Ethics[11] mentioned in the notification of Medical Council of India provides the duties and responsibilities of the physician in general.

Tussle Between Right of IP (Intellectual Property) of Patentee Vs Right to Life of Others

Pharma industries presenting their art of inventions for the benefit of the people and thus asking returns for their labour and skill in form of patent and naming it as motivation for further welfare of the people are in fact proving the invention unaffordable and beyond the reach of humanity. In fact patent is only the individual centric interest to exercise monopoly right over medicines and earn huge amount out of their work.

Health Economics

The concept of demand and price are inversely proportional to each other and the supply as well as price is directly proportional. Thus if the price of drugs is hiked due to patenting of drugs, naturally the demand will fall. As a result the cost of storage of drugs will rise. Henceforth to overcome this mass storage evacuation they will sell it off to some other country or to less knowledgeable countries in order to regularize their distribution, even if the product is in its expiry period. Consequently this system will give rise to other problems and create more vicious cycle of chaos. In light of this head, it is quite important to discuss the basic contours of Parallel Import, these are imports of a patented or trademarked product from a country where it is already marketed. Thus, Parallel imports can reduce the price of health products and pharmaceuticals by introducing competition. Hence, it can be concluded that the process of parallel import is a way to struck down the problems of expensive drugs, which are at the stake of individual's life.

An Ethical Issue

Since the introduction of the Trade-Related Aspects of Intellectual Property Agreement (TRIPS Agreement, for short) in 1994, the poorer of the less developed countries of the world have had huge problems in getting their medical needs fulfilled properly. The basic purpose of this paper is not to focus towards the patenting and the pricing process of the life-saving drugs but to ensure and highlight the ways and means by which the price of life saving drugs can be reduced and made affordable by poor patients.

A Battle for Patenting Ended In 2013

In the year 2006, the Indian Patent Office first refused patent of Glivec under Section 3(d) of the Indian Patent Act arguing that it was only a modified version of an existing drug, Imatinib, and said that the drug was not at all innovative. Though in the course of the proceeding, Novartis replied filing legal challenges against the Government of India but the final verdict in April, 2013 ended the battle. Indeed, the Supreme Court stated that even if the bioavailability of the drug was improved, it did not demonstrate the enhanced efficacy and the patent could not be granted.

[8]C.E.R.C. v. Union of India, AIR 1995 SC 922.
[9]MODI, A TEXTBOOK OF MEDICAL JURISPRUDENCE AND TOXICOLOGY 181 (24th ed. 2012).
[10]*Id.* at 193.
[11]Code of Ethics Regulations, 2002, Gazette of India, (6th April, 2002), http://www.mciindia.org/RulesandRegulations/CodeofMedicalEthicsRegulations2002.aspx.

Section 3(d) Indian Patents Act, 1970
Section 3. - What are not inventions.-
3 (d) reads as follows:

"the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant".[12]

Explanation: For purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy.

Strictly legally speaking, Section 3(d) of Patents Act came from EU regulations.The courts only look for greater efficacy and any other advantages of a drug and not the role it plays in determining whether "Ever-greening" term applies or not. Section 3(d) of the Indian Patents Act, 1970 prevents "Ever-greening" of a drug. To define the scope of the term "efficacy", the Court has taken help of the medical dictionary and concluded that "efficacy" would mean "therapeutic efficacy". It stated that section 3(d) is a heightened inventive step standard and that the only kind of efficacy that would satisfy section 3(d) is therapeutic efficacy.

Benefits That Section 3(d) Offers By Preventing "Ever-greening"

A drug company develops a new drug and is rewarded with patent rights. The patent stops other producers making the same medicines for 20 years, so the drug company can earn very high prices for 20 years. When the patent ends other producers can come in and compete with each other and make the prices come tumbling down so the medicines become affordable for everyone but a drug company wants more profit so it makes little change in the drugs and asks for another 20 years patent. The section 3(d) works as a safeguard for ever-greening of patents. To prevent ever-greening section 3(d) is available. If this happens then no generic medicine would get a chance to come into the market.

Section 3(d) of Indian Patent Act has been a source of raising debate especially as pharmaceutical companies are considered. The very objective of having Section 3(d) as an amendment clause to Indian Patent Act was to prevent the "ever-greening" of patents. This section sought to prevent ever-greening by disallowing the patenting of a known substance unless an 'enhancement is effected in the efficacy of that substance'. Under this situation there is a surge of patent withdrawals and compulsory licensing.[13]

Constitutional Validity of Section 3(d) of Indian Patents Act, 1970

The case of preventing ever-greening of patents is controverted by mentioning that, the terms such as "enhancement of known efficacy" and "differ significantly in properties with regard to efficacy" are not accompanied by guidelines to define its scope, hence rendering the section 3(d) as ambiguous and random. In 2006, Novartis challenged the constitutional validity of section 3(d) before the Madras High Court in Chennai, in the case of *Novartis AG v. Union of India*[14] arguing that the word "efficacy" in the section was vague. However, dismissing the constitutional challenge, the Madras High Court in 2007 held that the word "efficacy" used in section 3(d) had a definite meaning in the pharmaceutical field, i.e. therapeutic efficacy in the context of medicines. Thus deciding on the validity of Section 3(d), the High Court held that Section 3(d) is constitutionally valid. However, on the other hand Supreme Court of India held that, In view of the findings that the patent product, the beta crystalline form of Imatinib Mesylate, fails in both the tests of invention and patentability as provided under clauses (j), (ja) of section 2(1) and section 3(d) respectively, the appeals filed by Novartis AG fail and are dismissed with cost.[15]

The Contemporary Position of IPR in India

As is evident from the above paragraphs, the product patenting of Drugs and Pharmaceuticals would contribute to increase in the prices of life saving drugs. Once the life-saving drugs become dearer, and inaccessible, the worst sufferers are going to be the people living in the Third World countries, who may not be in a position to spend huge amounts on health care. It may not be out of place here to mention that Article 25 of the Universal Declaration of Human Rights proclaims that everyone has a right to health and medical care. Similarly Article 12 of the International Covenant on Economic Social and Cultural Rights directs the member

[12] The Patents Act, 1970, No. 39, Acts of Parliament, 1970 (India).
[13] Dr. Dhanalakshmi Iyer, *Analysis of Section 3(d) of Indian Patent Act*,(Jan. 15, 2016, 06:30 p.m.), http://ip.com/news/2012/04/analysis-of-section-3d-of-indian-patent-act/.
[14] Novartis AG v. Union of India, (2007) 4 MLJ 1153.
[15] Novartis AG v. Union of India, (2013) 6 SCC 1.

states to recognize and accept the right of every one to the enjoyment of highest attainable standards of physical and mental health.

This Covenant urges the states to take steps to prevent, treat and control epidemic, endemic, occupational and other diseases and create conditions which would assure to all a medical service and medical attention in the event of sickness. Thus, the national governments are under an obligation to give primacy to public health and access of public to sufficient quantities of safe medicines at affordable prices.[16]

A perusal of the Patent Act, 1970 makes it clear that "a patent is granted not for the benefit of the patentee but for the benefit of the public at large". Therefore the Act reflects the legislative intention to maintain a balance between the public interest and individual interest.[17] While granting the patent and making provisions for control and distribution of such drugs.

So, it is suggested that in order to ensure such medicine within the reach of poor people, a suitable amendment should be made in patenting Act. So that companies seeking patent of life saving drugs are obligated to supply such medicines to the government run hospitals in specified quantity and for specific period.

The Role of State and Right of Patentee

A patent is an exclusive right given by the law for two reasons: firstly, to protect the right of the inventor and secondly to make the welfare state responsible and duty bound for the better health of its people.

As per the research carried out by Mr. BS Rawat[18]on life saving drugs in Nov. 2014, some facts have come to the knowledge which proves that the prices of life saving drugs are higher than the normal purchasing power of a person of average income group. This confirms that the prices of life saving drugs are high.

According to an estimate, as many as 4.7 crore people are suffering from heart ailments in India, while 4.1 crore from diabetes. The figures for tuberculosis (TB) and cancer are 22 lakh and 11 lakh respectively. These patients can no longer bank on life-saving drugs they used to as these have been made inaccessible to them in one stroke by "the price decontrol policy of the government". Geftinat, the drug used in the treatment of cancer was earlier available in the market at Rs 5,900 to Rs 8,500. It is now priced in the range of around Rs 11,500. Similarly, the price of medicine Cardice used in the treatment of heart ailment which was available between Rs 92 to Rs 147 is now ranging between Rs 147 and Rs 1,615.The prices for drugs for cancer and diabetes are set to cost 10 times more than they used to cost. This becomes disastrous for the country as a whole. Not only this, even the prices of drugs for treatment of dog bite are also set to rise. This quantum jump in the prices of life-saving drugs has sent shockwaves in the patients and their relatives. Unable to afford these expensive medicines, many of them have no choice but to go without them. This will hamper their treatment and may lead to eventual death. This rise in price thus makes these essential drugs beyond the reach of the common man leaving alone the poor and the underprivileged. Under the present regime too, there is no change in the price rise tendency of the essential commodities which itself makes the life of poorer miserable. As many as 108 life-saving drugs used to treat heart diseases, cancer, TB, diabetes, HIV, and for respiratory diseases are de-controlled.

Whether Patentee Discharges His Duty

The patent granted confers not only certain rights on the patentee but also imposes certain duties and obligations. If the patent is not used and the granted monopoly is abused, compulsory license may be granted to any person who is willing to work the patent or even the patent may be revoked. It is the implied duty of the patentee to work the patent in India in such a manner so as not to deprive the reasonable requirements of the public and also to make the products of patent available to the public at reasonable prices. Further the patentees are restrained from making baseless and unjustifiable threats of an action for infringement of the patent. Similarly every patentee should submit periodical statements to the controller as to the extent to which the patented invention has been worked on a commercial basis in India. Failure to supply such information is made punishable.[19]

Despite these pro people provisions patentee continues to drive home and use profit, frustrating the hope of many needy patients. It is a matter of great concern to be seen seriously and worked out religiously by the organs of the state.

[16] DR. G.B. REDDY'S, INTELLECTUAL PROPERTY RIGHTS AND THE LAW193 (9th ed. 2012).
[17] *Id.*at185.
[18] BS Rawat, *Life-Saving Drugs Cost Up; Patients Stare at Death*, (Jan. 12, 2016, 12:35 p.m.), http://www.drugtodayonline.com/medical-news/nation/1388-life-saving-drugs-cost-up-patients-stare-at-death.html.

[19] DR. G.B. REDDY'S, INTELLECTUAL PROPERTY RIGHTS AND THE LAW 226(9th ed. 2012).

Unapproved Formulations and Health of People

Millions of unapproved formulations and products of fixed dose combinations (FDCs) available in India in three therapeutic areas- analgesia, anxiety/depression and psychosis are unsafe and at times dangerous or even lethal, as in the case of anti-psychotic. With pharma co-vigilance being at a nascent stage and reporting of adverse events being low, the absence of information on adverse effects of even approved FDCs, therefore, does not mean that they are safe. "Unapproved formulations should be banned immediately, prioritizing those withdrawn/banned internationally," Recently it is found that over 73 per cent of the 124 NSAIDs (Non Steroidal Anti-Inflammatory Drugs) (analgesia) FDC formulations marketed in India were unapproved. The unapproved FDC formulations to treat depression/anxiety were 81 per cent and 70 per cent in the case of anti-psychotics. Contrastingly, only 20 per cent of the 25 metformin formulations for diabetes sold have been unapproved.[20]

It shows that the government is not careful towards the health of its people. As the points have been made out with regards to the patented drugs, state should include such drugs within the ambit of watch and warn/ revoke license. So, that people health becomes a matter of concern for all those who are involved in preparations, distribution and administration of such drugs.

Benefits For The Sake of Individuals Life

Definitely, subsequent to the new move, 0.7 per cent of the combined sales of Sun Pharma and Ranbaxy in India will be out of price control. The corresponding figures for Torrent and Lupin will be 1.5 per cent and 0.7 per cent, respectively. Sun Pharma and Ranbaxy gained nearly2percent and GSK Pharma and Davis Lab gained 1 percent each. Glenmark was also up around 1 percent.[21]

Right to Health in Indian Constitution

Right to Health has been recognized as a fundamental right not only in India but in many other third world countries. In so far as India is concerned, even though it is not recognized as a Fundamental Right expressly, the judiciary has recognized the same as a fundamental right under Art.21 of the Constitution which guarantees Right to life and personal liberty. Therefore the right to health care and also access to health care at affordable prices have become universally recognized fundamental right.[22] Rights are recognized to be realized by the people and if such right is infringed by the patentee or anyone else the state should rise to the occasion and ensure the realization of such rights by the person who are in need.

The Importance of Access to Essential Medication

The scope of the epidemic and its likely devastating consequences for socio-economic development has made the issue of access to essential medications a particularly urgent one.[23] Nearly 34 million people in this world are at this moment dying (of AIDS, cancer), because they don't have the purchasing power for health and life. When 34 million people in the resourceful world are falling ill, feeling sick to death, and are dying, that is something not acceptable by a developing country. When life-saving treatments for diseases such as HIV/AIDS or cancer become unaffordable to those who need them, the consequences could be and would be devastating one. In developing countries, especially like India where people pay for drugs out of their own pockets and very seldom have health insurance, the high price of medicines decide the state of life and health.

II. CONCLUSION AND SUGGESTIONS

Having discussed about the need of the hour in above paragraphs, it is concluded that the right to affordable life-saving drugs should be recognized as fundamental right, so that it can be realized through the intervention of court and also the state should come forward for saving the lives of its people, especially those who are suffering from deadly diseases through enacting suitable law making it possible that such medicines are freely and readily available at least in government run hospitals at affordable or minimum price.

It is also obvious that rights and interests of intellectual property rights holders cannot be sacrificed by removing the motivation of high profits because private companies will cease research into life-saving drugs.

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[20] R. Prasad, *India Flooded With Unsafe Fixed Dose Combination drugs,* THE HINDU, (May 21, 2015, 03:30 p.m.), http://www.thehindu.com/sci-tech/india-flooded-with-unsafe-fixed-dose-combination-drugs/article7227916.ece.

[21] Iftikhar Gilani, *Cancer Drug Price Goes up from Rs 8,000 to Rs 1.08 Lakh,*(Feb. 10, 2015, 01:00 p.m.), http://www.dnaindia.com/india/report-cancer-drug-price-goes-up-from-rs-8000-to-rs-108-lakh-2022667.

[22] DR. G.B. REDDY'S, INTELLECTUAL PROPERTY RIGHTS AND THE LAW 192-193 (9th ed. 2012).

[23]Udo Schuklenk&Richard E. Ashcroft, *Affordable Access to Essential Medication in Developing Countries: Conflicts between Ethical and Economic Imperatives,*27 Journal of Medicine and Philosophy 1, 1-2 (2002).

The research can be promoted by the state giving incentives and other relief/concessions to the companies engaged in invention/research of life saving drugs. This mechanism will bring down the cost of invention and thereby make the inventors to have consideration for the state policies of being pro-people. In lieu of these incentives, the prices of drugs could be controlled and made reasonable.

The very aim of giving MNCs incentives and concessions for inventing/researching of life saving drugs is to have concession in terms of price fixing of such drugs and number of years for which they can enjoy the right of patent.

We cannot ignore that The National Pharmaceutical Pricing Authority (NPPA) & Drug Price Control Organizations (DPCO) are working consistently on this issue with many interventions. Discussions, policies and reports on this subject are bearing fruits but as of now they are not enough. The question remains still unanswered as to- who is answerable for the death of the human beings for want of life saving drugs. In the same vein, what is at stake is the affordability and reasonableness of the prices.

In order to protect and preserve the health and safety of the public in general, it is imperative to create a balance between the benefits of the patent holders, industry so that they would enjoy the moral and material benefits as being a creator and inventor of the intellectual property i.e. of a drug, and the right of all human beings to a standard of living who have the right to avail and afford adequate health and medical facilities.

Further, patents used to help the inventors, but now most pharma inventions are done by MNCs so why should we further enrich them.

The Specific Recommendations Are-

1) Linking of Aadhaar cards with medical cards of patients.
2) Direct transfer of subsidies to the patients.
3) State funding on research and development of such drugs.
4) Committee to review the reasonableness and affordability of prices of drugs.
5) Liberally classifying essential drugs into Life Saving Drugs (LSD).