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ESSENTIAL DRUGS AND DRUG PRICING – AN ANALYSIS IN THE HUMAN RIGHT PERSPECTIVE

Under the Guidance and Supervision of

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CERTIFICATE

This is to certify that **FATHIMA JAUHAR**, Reg. No: LM0320010 has submitted her dissertation titled, "**Essential Drugs and Drug Pricing – An Analysis in the Human Rights Perspective**" in partial fulfillment of the requirement for the award of Degree of Master of Laws in Public Health Law to the National University of Advanced Legal Studies, Kochi under my guidance and supervision. It is also affirmed that, the dissertation submitted by her is original, bona-fide and genuine.

Date: 11 – 10 – 2021

Place: Ernakulam

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DECLARATION

I declare that this dissertation titled, "**Essential Drugs and Drug Pricing – An Analysis in the Human Rights Perspective**", researched and submitted by me to the National University of Advanced Legal Studies in partial fulfillment of the requirement for the award of Degree of Master of Laws in Public Health Law, under the guidance and supervision of **Dr. Mini S**., is an original, bona-fide and legitimate work and it has been pursued for an academic interest. This work or any type thereof has not been submitted by me or anyone else for the award of another degree of either this University or any other University.

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ABBREVIATIONS

WHO	World Health Organization
WTO	World Trade Organization
UNICEF	United Nations International Children's Emergency Fund
OECD	Organization for Economic Co-operation and Development
UDHR	Universal Declaration of Human Rights
ICCPR	International Covenant of Civil and Political Rights
ICESCR	International Covenant on Economic, Social and Cultural Rights
CESCR	Committee on Economic, Social and Cultural Rights
NPPP	National Pharmaceutical Pricing Policy
NPPA	National Pharmaceutical Pricing Authority
NLEM	National List of Essential Medicines
DPCO	Drug Price Control Orders
TRS	Test Report Series
HRBA	Human Rights Based Approach
IP	Intellectual Property
IPR	Intellectual Property Rights
TRIPS	Trade – Related aspects of Intellectual Property Rights
CL	Compulsory Licensing
UN	United Nations
EU	European Union
GDP	Gross Domestic Product
LMIC	Low - and Middle – Income Countries
LDC	Least Developed Countries
MNC	Multi National Corporation
R&D	Research & Development

GSP	Generalized System of Preferences
ARTS	Anti Retro Viral Therapies
INCB	International Narcotics Control Board
UNODC	United Nations Office on Drugs and Crime
SDG	Sustainable Development Goals
AIDAN	All India Drug Action Network
SCAMHP	Standing Committee on Affordable Medicines and Health
UIP	Universal Immunization Programme
FDC	Fixed Dose Combinations
NGO	Non – Governmental Organization
HIV	Human Immuno – deficiency Virus
AIDS	Acquired Immuno Deficiency Syndrome
TB	Tuberculosis
MRP	Maximum Retail Price
NTD	Neglected Tropical Disease

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CHAPTER – 1

INTRODUCTION

Medicines are the most important and basic element of health. Any system of medicine requires drugs of appropriate standard in order to treat the disease. Medicines have become an inevitable part of the day – to – day life of people. With the advent of different forms of diseases, especially the ones like the current Covid – 19 pandemics, the scope and importance of medicines has increased profoundly.

Access to healthcare services includes accessibility as well as affordability of good quality medicines. Medicines are expected to be available to all persons at any time in order to ensure their health and well – being. For this purpose, the concept of essential drugs was introduced by the World Health Organization back in 1970s. Now, the idea of providing access to health through deliberation of essential medicines has paved way to universal health coverage and the protection of a person's fundamental right to health.

Essential drugs are also intended to make the healthcare services cheap and affordable to all classes of people in the community, thus ensuring equality in access to health. Constant efforts are being made to keep the drug prices under control, at a rate that is reasonable to even the under privileged groups of people. Despite the endeavors, the prices of basic essential drugs are on the rise making the expenditures high, throwing the poor into further poverty.

1.1 SCOPE OF STUDY

Health for all is a universally envisaged principle that is being strived to be achieved by all countries. Universal health coverage can only be achieved when there is profound access to medicines amongst all groups of people in the society. In India, right to health, as envisaged in Article 21, is a fundamental human right recognized by the Constitution of India. Nevertheless, a large number of people around the world are still deprived of access to medicines, especially the weaker sections of the society. The underprivileged community cannot afford to buy medicines for treatment of diseases due to unaffordability. The concept of essential medicines is their last resort to afford and access quality medicines and exercise their basic right to health.

1.2 RESEARCH PROBLEM

The availability of medicines often is a big issue. The availability of medicines is undermined by several factors: Poor medicine supply and distribution systems, low investment in health, and the high cost of medicines. The non-availability of essential medicines in the health facilities is not the only issue; there are problems of affordability and accessibility. Countries face a range of obstacles to achieving this, including rising prices for new medicines, shortages and stock outs of essential medicines.

1.3 RESEARCH QUESTIONS

1. What are the measures in India relating to essential drugs?
2. Whether the existing measures are adequate to address Right to Health?
3. What provisions need to be included to the existing laws to ensure availability of essential drugs?

1.4 OBJECTIVES OF THE STUDY

1. To examine the human rights perspective of access to medicine.
2. To examine whether the existing laws are adequate to ensure affordability of essential drugs.
3. To suggest recommendations that maybe required to be included to ensure accessibility of essential drugs.

1.5 HYPOTHESIS

The rising prices and non-availability of essential drugs as a result of inadequate measures in India does not ensure access to medicine and basic right to health.

1.6 METHODOLOGY

The methodology employed for this study is doctrinal. The Doctrinal study is based on collection of data from primary and secondary sources.

The primary sources of data used include statutes, regulations, declarations, notifications, guidelines and committee reports. The secondary sources of data used are books and websites.

1.7 REVIEW OF LITERATURE

The research is based on primary sources including Reports published by World Health Organization (WHO) such as The WHO Test Report Series, WHO Medicines Strategy and other publications, The Drug Policy 1986, the International Covenant on Economic, Social and Cultural Rights, The National Pharmaceutical Pricing Policy 2015, The Drug Price Control Order 2013 and The Patent Act. Various secondary sources including guidelines issues by World Health Organization, committee reports such as Hathi Committee Report have also been referred to for relevant data.

The research is also widely dependent on electronic resources like online databases such as PubMed, ResearchGate, JSTOR etc. for gathering resources.

1.8 CHAPTERISATION

Chapter I: Introduction

This chapter is an introduction to the overall theme of this study and further gives an idea about the topic. It also includes research design having an objective and scope of the study, research problem, research questions, hypothesis, methodology used to undertake the research and literature review.

Chapter II: Concept of Essential Drugs

In this chapter, a detailed explanation of the concept of essential drugs has been given. The chapter also discusses the application as well as impacts on the implementation of the essential drugs concept.

Chapter III: Regulations relating to Essential Drugs and Drug Pricing

In this chapter, various regulations relating to essential drugs and drug pricing have been discussed. The chapter also studies the implications of these regulations on availability and pricing of drugs. A comparison between old and updated regulations have also been made to observe the changes that have happened in this regard. Finally, the chapter also includes an Indian perspective of drug pricing and control.

Chapter IV: Issues relating to Access to Medicine

This chapter has an in-dept study on the issues related to access of health and medicines. It includes an in-depth understanding of the Intellectual Property Rights aspect of medicines and the scope of compulsory licensing. It also examines the issues related to medicines with regard to IPR.

Chapter V: Human Rights Perspective of Access to Drugs

The chapter looks into the aspect of access to medicines from the human rights perspective. It includes the international framework for human rights and the importance of including access to medicines in the drug policy. It also studies access to vital medicines as part of right to health.

Chapter VI: Loopholes in the Existing Regulations

The chapter discusses the escape clauses in the existing regulations and corresponding ambiguity despite the implementation of laws in this regard. It includes the current scenarios relating to drug pricing and how existing regulations are being misused for business motives.

Chapter VII: Recommendations and Suggestions

This chapter provides suggestions and recommendations based on observations made during the research, which are essential to accomplish the goal of enabling access to health and medicines for all persons in the community through effective implementation of the essential drugs concept.

CHAPTER 2

CONCEPT OF ESSENTIAL DRUGS

People consume drugs even in the remotest areas of the world. These drugs are part of the armamentarium of medical practitioners and healers at all levels and are universally accepted to have and often do have powerful effects. The concept of essential drugs first evolved in a report made to the 28th World Health Assembly in 1975. The intention behind the report was to shoot up the scope and availability of medicines for populations with poor access. As a result of wide consultation, an "Expert Committee on the use of Essential Medicines" was formulated to assist member states in selecting and procuring essential medicines. In order to make the concept more specific, the WHO released an initial model list of essential medicines in 1977 with 205 items.[1] Most products on the list were known to be therapeutically effective and were no longer protected by patent rights. That step, according to the then WHO Program Manager of essential drugs, marked the start of 'a peaceful revolution in international public health'. The WHO's goal of 'Health for All by the year 2000' included regular supply of certain essential drugs as a key indicator to evaluate progress. The Declaration of Alma Ata on primary health care in 1978 identified the provision of essential drugs as a basic element.

[1] https://www.researchgate.net/publication/207423715_Essential_Drug_Concept_and_Rational_Use_of_Drugs (last visited August 30, 2021)

Essential medicines are those that satisfy the priority healthcare needs of the population. These medicines are selected with due regard to the public health relevance, evidence on efficacy and safety and comparative cost – effectiveness.[2] The essential drugs are intended to be available within the context of functioning health systems at all times in adequate amounts, in appropriate dosage forms, with assured quality and adequate information and at a price affordable by the individual and the community. Essential medicines and medical technologies are the nucleus of a health system. The careful selection of a limited range of medicines ensures a higher quality of care, better management of medicines, including improved quality of prescribed medicines and more cost - effective use of quality medicines. The concept of essential medicines has become one of the eight pillars of the World Health Organization's "Primary Health Care" strategy. In implementing of the concept of essential drugs the intention is to make it flexible and adaptable to different situations. Availability assumes not merely the physical presence of the drugs at the pharmacy but also includes economic factors. The purpose of such a model list is evident – to extend the accessibility of the essential drug to those populations whose health care needs cannot be met by the existing system.

The process of selection of essential medicines is very critical. An essential medicine list simply imposed by authorities will not be reflective of the needs of the people nor will it be acceptable. It is therefore very crucial that the selection procedure be transparent and consultative, selection criteria be explicit, selection of these medicines be linked to evidence-based standard clinical guidelines, the list be divided into different levels of care and be regularly reviewed and updated. The lists are flexible enough to accommodate new drugs and newer information on established

[2]Who.int, https://www.who.int/topics/essential_medicines/en

drugs. Nevertheless, in order to achieve the objective optimally, a review of the list at regular intervals is necessary. This is not only because of the advancements in the drug therapy but also to meet the needs of the practitioner considering experience. The WHO revises its Essential Medicines List every two years since 1977, the latest being the 21st EML released in 2019. The WHO also released the Essential Medicines List for Children in 2007. It was updated last in June 2019. A remark suggesting that a drug is complimentary can be seen on both the WHO adult and children's lists. Thus, the "core list" and the "complementary list" are effectively two lists. The core list is a list of the most efficacious, safe, and cost-effective medicines for priority illnesses that a basic health care system would require. Priority conditions are chosen based on their current and projected public health importance, as well as their potential for safe and cost-effective treatment. The complementary list includes necessary drugs for priority diseases that necessitate specialist diagnostic or monitoring facilities. If in doubt, medicines may be labelled as complementary in a variety of circumstances due to greater costs or less appealing cost-effectiveness. The list is significant because it serves as the foundation for national drug policies in over 155 nations, both developed and developing.

The essential medicines list consists of cost - effective and safe medicines, while the pharmaceutical market is flooded with a large number of medicines many of which are of doubtful value. The WHO model list serves as a guide for the development of several national, regional and institutional list of essential medicines. Each country is encouraged to prepare its own National List of Essential Medicines, considering the local priorities and needs. The idea of essential drugs has now been accepted worldwide as a powerful tool that promotes health equity. Its impact is remarkable because essential drugs have proved to be one of the most cost - effective elements in healthcare. The Essential Medicines List help countries to rationalize the

purchasing and distribution of medicines, thus lowering costs to the healthcare system. The idea of essential medicines is very progressive. It focuses on the need to regularly update new medicines selections to incorporate new therapeutic options and new therapeutic needs, the need to ensure drug quality and the need for continued development of new medicines, medicines for emerging diseases and medicines that meet changing resistance patterns. Clinical recommendations and lists of essential drugs, when appropriately designed, implemented, and supported, have been shown to enhance prescribing quality and result in better health outcomes. Once looked at as relevant only in resource-constrained settings, the WHO model of essential medicines is now viewed as equally important to high -, middle - and low- income countries, particularly after the inclusion of new, highly effective and expensive medicines in the most recent years. WHO recommendations are often referred to by many countries while making decisions on health spending. Over 150 countries now have an essential medicines list based on the local priorities and needs of the population.[3]

2.1 SELECTION OF ESSENTIAL MEDICINES

The rationale for the selection and use of a limited number of essential medicines is that it leads to an improved supply of medicines, more rational prescribing and lower costs. In fact, proper utilization of vital pharmaceuticals is one of the most cost-effective methods that a government can implement. The concept of essential medicines is a worldwide notion and can be applied in any country, in both public and private sectors, at primary health centres and in referral hospitals, in urban as well as rural areas. The choice of which medicines are to be considered essential,

[3] Who.int, https://www.who.int/medicines/services/essmedicines_def/en/

however, is a national - level responsibility. Under ideal circumstances, the registration of essential medicines for the public and the private sectors should be based on an evaluation of efficacy, safety and quality assessment. In such instances, the selection of essential drugs takes place during medicine evaluation, approval and registration and hence is applicable to both public and private sectors. The selection of essential drugs is more commonly limited to public sector health facilities however, many private health facilities and health insurance systems have formulary lists that serve a similar purpose. A limited list of essential drugs is prepared as a basis for supplying pharmaceuticals, in each level of health care in the public sector, and for the purpose of training health professionals – the reason which is why such lists should be tightly linked to standard treatment guidelines for clinical health care practices.

There are several reasons to support the use of a limited list of essential medicines. Firstly, basic health services are to be made accessible to everyone before more expensive services are made available to a small, usually urban proportion of the population. Secondly, neither the public sector nor health insurance systems can afford to supply or reimburse all medicines that are available in the market. Hence the list of essential drugs not only guide in procurement and supply of medicines in the public sector but also in schemes that reimburse medicine costs as well as those medicines that make sense for production by local manufacturers. Since the availability of pharmaceuticals in many countries is inconsistent, the regular supply of the products in the essential medicines list would aid in a well improved public health system and also boost the confidence of the general public in the health care system. Many organizations, including the UNICEF and other international non – profit supply agency organizations, have adopted the concept of essential medicines for their supply systems. Thirdly, the use of a limited list of essential medicines could improve the quality of care delivered by ensuring that patients

receive the treatment of their choice as well as similar treatments from different providers because the list represents the consensus of prescribers on first choice pharmaceutical treatments. It also makes the prescribers more familiar with the selected number of medicines. This restricted possibility, in fact, contributes to an improved understanding of the actual benefits and limitations of specific medicines therapy, as well as in detecting and preventing adverse drug reactions. In the fourth place, for countries with scarce funds for health care expenditure, the limited lists of essential medicines act as a boon by promoting quality in care as well as cost control. As a result, the policy, which has now become a universally accepted tool, enables improved efficiency and effectiveness in patient treatment with reduced health care costs. Fifth in the row, it is advantageous to public sector supply programs in procurement and logistics activities because of the reduction in the number of medicines that needs to be stocked, distributed and monitored. Since essential drugs are available with multiple suppliers, increased competition facilitates negotiation for favourable prices. Additionally, the use of limited number of essential drugs creates potential opportunities to achieve economies of scale as larger quantities of the medicine will be required to treat a particular clinical problem. National pharmaceutical programs base their medicine donation programs on the national essential medicines lists, the reason for which is that it is easier to ensure the quality of a smaller number of pharmaceutical drugs. Lastly, the selection of limited number of essential medicines smooths the path for efforts to provide drug information and education, both of which facilitate rational prescribing and use of these drugs. Since objective drug information is very raresome in most developing countries, their provision is considered extremely beneficial by the physicians and other health care professionals. Although the amount of pharmaceutical products for available public health is limited by an essential medicines list, the practical availability and corresponding

drug information, as well as training materials, can be increased. By focusing on these medicines, patient education and the efforts to promote the proper use of medicines by patients can be enhanced. [4]

2.1.1 Criteria for the selection of essential drugs

The treatments recommended and the medications chosen depends on several factors, such as the pattern of widespread diseases, treatment facilities, the training and experience of the available personnel, financial resources and genetic, demographic and environmental factors. The choice of medicines depends highly on the health care staffs' capacity to handle them effectively. Thorough knowledge of the extent of staff training and the availability of support facilities for the potential staff confusion and possible medication errors that may be caused should also be taken in to consideration while choosing the medicines. Each level of health care is important before deciding which medicines need to be made available where. Essential drug selection is an ongoing process that must take into account shifting public health goals and epidemiological conditions, as well as advances in pharmacological and pharmaceutical expertise. It should be accompanied by a parallel effort to provide information, education, and training to health professionals on how to use the pharmaceuticals properly. Additionally, the WHO Expert Committee on the Selection and Use of Essential Medicines employs the following criteria for the selection of essential drugs:[5]

- Only those medicines with sound and adequate evidence of safety and efficacy in a variety of settings are chosen.

[4]Pharmaceutical Management, Part II, Ch 16, Managing Medicine Selection, mds3-ch16-selection-mar2012.pdf (msh.org)
[5] Supra note 4.

- Another major consideration for choosing medicines within the same therapeutic category is relative cost-effectiveness. While contrasting between medicines of similar safety and efficacy, the total cost of the treatment - and not just the unit cost of the medicine - is considered and is compared to its efficacy.
- Other factors such as pharmacokinetic properties and local considerations such as availability of facilities for manufacture and storage also influence the choice of medicines.
- Each selected medicine shall be available in adequate quality in a form for which bioavailability is ensured; the stability under anticipated conditions for storage and use shall be determined.
- Single compound formulations may be preferred for most essential medicines. Fixed - dose combination products may be selected only when such combinations have a proven advantage and special therapeutic effects, safety and adherence or decrease the emergence of drug resistance in TB, malaria, HIV/AIDS etc. [6]

2.1.2 Guidelines for the selection of pharmaceutical dosage forms

The goal of choosing dosage forms and strengths for the pharmaceuticals in the model list is to give countries direction on how to standardize or reduce the number of preparations in their own drug lists. Pharmaceutical formulations are typically chosen based on their broad utility and widespread availability around the world. In many cases, especially when it comes to solid dosage forms, a variety of preparations is available. Tablets are typically less expensive than capsules, but in addition to cost, pharmacokinetics, bioavailability, stability under ambient

[6] WHO Policy Perspectives on Medicines; The Selection of Essential Medicines, Geneva, June 2002, EM6pg_en.pm (who.int)

climatic conditions, availability of excipients, and known local preference should all be taken into account.

Where tablet strength is not standardized, a dosage range is supplied from which appropriate tablet strengths should be chosen based on local availability and need. When precise dosage is not necessary, scored tablets can be used to make dosing more flexible if needed and, in some cases, to provide a handy paediatric dose. Only when particular circumstances require it, are specific paediatric dosages and formulas provided in the list. In many cases, dosage is indicated in terms of a specific salt or ester, while in others, it is estimated in terms of the active moiety, as is standard practice.[7]

2.2 APPLICATIONS OF THE CONCEPT OF ESSENTIAL DRUGS

The World Health Assembly has unanimously accepted the idea of essential pharmaceuticals. It is designed to be adaptive to a variety of scenarios; nonetheless, determining which pharmaceuticals are considered vital remains a national duty. The WHO's Action Programme on Essential Drugs, as well as bilateral agencies, have widely disseminated and promoted the notion of essential drugs at the national level. The concept's broad applicability has now been demonstrated by experience gathered in a number of countries. Most national lists of essential medications are divided into categories to reflect needs at various levels of the health-care system. For community health workers, a relatively small list is usually created, whereas the most complete lists are maintained for large metropolitan and regional hospitals. Many countries

[7] Who.int, WHO Technical Report Series No. 796, The Use of Essential Drugs

have also effectively implemented the model in teaching hospitals and specialized care institutions. The concept has also been applied to drug information dissemination.

Many international and bilateral agencies have embraced the model list, which now includes medication supply and drug rationalization in their health-care programmes. The list's adoption has resulted in improved worldwide coordination in health-care development, and it's also being used to determine if medicine donations are suitable in specific circumstances.

2.3 ESSENTIAL DRUGS AND PRIMARY HEALTH CARE

It cannot be overstated that, in practice, the selection of pharmaceuticals for primary health care must be made at a national level, given the training and duties of those responsible for providing this care vary greatly. Highly skilled personnel can safely utilize a wide range of medications suited for their diagnostic skills, and judgments about the availability of certain pharmaceuticals can only be made after all relevant local circumstances have been considered. The following factors certainly influence the compilation of such drug lists.

(1) EXISTING SYSTEMS OF MEDICINE - The introduction of primary health care facilities in developing nations should not result in a sudden disruption of rural populations' cultural traditions. Traditional healers' work, for example, should be altered and supplemented so that innovation can be successfully integrated into current healthcare systems.

(2) THE NATIONAL HEALTH INFRASTRUCTURE - The location and nature of the first referral facilities determine the type of primary health care service that a country requires. In some nations, the nearest permanently staffed health post is still a day's journey time or more from isolated settlements within its catchment area.

(3) TRAINING AND SUPPLIES - The breadth and constraints of the primary health care system are determined by the quantity of qualified professionals, the facilities available to them, and the supplies entrusted to them. Workers who have had one or more years of vocational training are clearly capable of more than those who have only had a few weeks of intensive practical training. Whatever the circumstances, little can be accomplished unless vital supplies and information are available at all times.

(4) THE PATTERN OF ENDEMIC DISEASE - The incidence of major endemic infections and parasitic diseases may vary from region to region within a country due to climatic, geographical, topographical, social, economic, and occupational factors. To ensure that the most effective treatments are delivered and to get the most out of limited resources, careful planning and, in some situations, epidemiological surveys are essential.[8]

2.4 PRACTICAL IMPLICATIONS OF ESSENTIAL DRUGS CONCEPT

National essential drug lists and national drug formularies, along with clinical guidelines, should serve as the foundation for health professionals' formal education and in-service training, as well as public drug education. They should also be the primary source of drug purchase and distribution in the public sector, as well as drug contributions. Insurance plans frequently employ a limited list of pharmaceuticals for which they will reimburse the price. In industrialized countries, this is one of the most common implementations of the principle of selection. Health insurance is less common in underdeveloped nations, although it is rising, and most plans are based on compensation for critical pharmaceuticals. Given the continuously rising cost of pharmaceuticals in most nations, it is logical to assume that any health insurance programme will

[8] Ibid.

require a drug selection procedure of some kind. Essential drug lists and education about the benefits of drug selection could also be utilized to influence private-sector practice, for example, through basic medical student training and continuing medical education programmes with universities and professional groups.

The essential drugs have profound effects on:

- HEALTH – Effective pharmacological treatment for most major infectious diseases, such as acute respiratory infections, HIV/AIDS, tuberculosis, malaria, and diarrhoeal disorders, as well as major non-communicable diseases such as ischemic heart disease and cancer, is now available.
- COST EFFECTIVENESS OF HEALTH EXPENDITURE - Medicines account for the majority of household health spending in many poor nations, and governmental pharmaceutical spending is second only to personnel costs in most countries. The cost-effectiveness of government and OOP medication spending can be improved, and the health impact can be increased, by focusing pharmaceutical spending on important drugs.
- HEALTH SYSTEM EFFECTIVENESS – Essential drugs are high value commodities. Their availability draws patients to health facilities, where they can also benefit from preventive services. Furthermore, if drug procurements is efficient and transparent, the confidence of governments and donors in a country's health system is increased, and provision of resources encouraged. [9]

CHAPTER-3

[9] WHO Medicines Strategy 2000-2003 Geneva
http://apps.who.int/iris/bitstream/handle/10665/66694/WHO_EDM_2000.4.pdf?sequence=1

REGULATIONS RELATING TO ESSENTIAL DRUGS AND DRUG PRICING

3.1 INTRODUCTION

The pharmaceutical industry contributes significantly to people's health and India's economic prosperity. The pharmaceutical industry is responsible for medical innovation, development, production, and marketing. It is the government's responsibility to ensure the availability of life-saving pharmaceuticals at reasonable rates by taking into account the interests of both manufacturers and purchasers. The National Pharmaceutical Pricing Authority (NPPA) is an Indian agency that regulates medicine prices in order to protect public health.

Every year, out-of-pocket healthcare costs push more than 55 million Indians into poverty. In India, healthcare accounts for less than 1.3 percent of the country's gross domestic product (GDP). Bihar has an out-of-pocket healthcare expense of 80%, while Gujarat has a 50% out-of-pocket healthcare cost. According to the World Bank, the global average is 18.6%. More than 38 million of the 55 million people who fall into poverty as a result of disease do so solely due to the cost of medicine. As a result, price caps are a quick cure for a systemic problem. High drug prices, in fact, have a negative impact on health-seeking behaviour, resulting in increased morbidity. The rise in drug prices is a severe issue all around the world. Orkambi, a fibrosis medication, is no longer available on the NHS in England. The Dutch are grappling with the rising costs of Keytruda, an immuno-oncology medicine. Access to healthcare is getting more difficult as inelastic drug costs force patients to pay more and more as demand grow[10]s.

[10] Regulations and Guidelines Ipapharma.org, https://ipapharma.org/portfolio/regulations-and-guidelines/ (last visited Aug 30, 2021)

Pharmaceutical expenditures accounted for between 11.6 percent (USA) and 18.3 percent (Japan) of total healthcare spending across the G7 countries, according to the most recent Organization for Economic Cooperation and Development (OECD) figures. Global pharmaceutical spending was anticipated to be 1.2 trillion dollars in 2018, up from 1.1 trillion dollars in 2017, and is expected to surpass 1.5 trillion dollars by 2023, expanding at a compound annual growth rate of 3 - 6%. Health care spending has consistently outpaced economic growth in OECD countries in the past, and this trend is anticipated to continue in the coming decade. Health spending in these nations is expected to increase to 10.2 percent of GDP by 2030, up from 8.8 percent in 2018. Given these estimates, health-care economic sustainability is becoming a rising challenge, as most countries rely heavily on public spending[11]. High costs of novel medicines, as well as price spikes of old drugs that are frequently unexplained, have become a source of rising worry. While some high-priced novel medicines provide significant benefits over existing treatments, others only provide minor gains, and retail prices appear to be largely determined by market conditions rather than the cost of development or the significant value provided to patients in terms of improved health outcomes. The costs of branded prescription pharmaceuticals have risen significantly in the United States over the years, with recent estimates estimating yearly increases in list and net prices of 9% and 4.5 percent, respectively, between 2007 and 2018, despite vast variances between drug classes. Another study that looked at price increases for 300 off-patent sole-source medications indicated a nearly 9% yearly increase in pharmaceutical expenditures between 2008 and 2018. Prescription medicine costs can be prohibitively expensive, making treatment and medication adherence difficult for patients. Critical characteristics such as large populations with very low incomes, high out-of-pocket health costs, and relatively fledgling health insurance and payment systems exacerbate the issue in low- and middle-income countries

[11] Ibid.

(LMICs)[12]. Medicines differ from other consumer products in several ways, including the need for expert professional advice, uncertainty in value assessment in terms of disease prevention and/or future health benefits, significant barriers to entry for competitors, and information asymmetry between prescribers and patients, all of which prevent desired interactions between demand and supply. As a result, governments around the world have implemented a variety of actions and policies to increase drug affordability and consumer access[13]. Manufacturer price controls in the form of cost - plus pricing, internal and external reference pricing, manufacturer profit regulation, supply and distribution chain mark-up regulation, tax and tariff exemptions/relaxations, generic medicine promotion, and the use of health technology assessments are some of the most widely used strategies.

3.2 THE UNEXPECTED IMPLICATIONS OF PHARMACEUTICAL PRICE REGULATION

For numerous years, the impact of pharmaceutical price limits on patient health outcomes and social welfare has been a contentious and hotly disputed health policy topic in both the developed and developing worlds. These laws have the potential to reduce drug costs and so enhance affordability and access to medicines, as well as increase patient adherence to their drugs and, as a result, treatment outcomes. Other arguments, on the other hand, warn of far-reaching unexpected negative outcomes. The suffocation of pharmaceutical research and development is of particular concern. Novel drug development is an inherently costly, time-consuming, and risky process, which is sometimes claimed to justify the high prices of branded medicines. Several

[12] Pharmaceutical price regulation and its impact on drug innovation: mitigating the trade-offs Taylor & Francis, https://www.tandfonline.com/doi/full/10.1080/13543776.2021.1876029 (last visited Aug 30, 2021)
[13] Ibid.

studies have repeatedly demonstrated that lower pharmaceutical revenues and profitability lead to lower drug R&D investments, resulting in fewer novel compounds being introduced each year. According to recent estimates, whereas the United States had access to approximately 90% of novel medications published between 2011 and 2018, just 47% of new drugs were available in other industrialized nations with price control mechanisms[14].

Furthermore, in comparison to the United States, the release of these novel drugs was often delayed by more than a year in the latter. According to Golec and Vernon's research, EU pharmaceutical companies cut their R&D investment significantly between 1985 and 2004, resulting in the introduction of 46 fewer medications. While the EU's pharmaceuticals R&D spending was approximately 24 percent higher than the United State 's at the start of this period, it had fallen behind by 15 percent by 2004 Pharmaceutical price limits have been proven to have an increasing impact over time, undermining generic competition and resulting in medicine shortages in regulated markets[15] . Empirical research from low- and middle-income countries reveals that price-control techniques have significant limits. Existing businesses may abandon a product category or reduce production or quality in response to shrinking profit margins. New entrants, on the other hand, may regard the pricing restrictions to be a significant barrier to entrance. These drawbacks have been proven to disproportionately affect the poor and rural customers, who are the two populations in these contexts who are most in need of healthcare. Despite the fact that price limits are intended to increase cost and access to medications, they can, unfortunately, reduce their availability. Empirical research from low- and middle-income countries reveals that price-control techniques have significant limits. Existing businesses may

[14] Supra note 1.

[15] Cost control: drug pricing policies around the world Pharmaceutical-technology.com, https://www.pharmaceutical-technology.com/features/cost-control-drug-pricing-policies-around-world/ (last visited Aug 30, 2021)

abandon a product category or reduce production or quality in response to shrinking profit margins. New entrants, on the other hand, may regard the pricing restrictions to be a significant barrier to entrance. These drawbacks have been proven to disproportionately affect the poor and rural customers, who are the two populations in these contexts who are most in need of healthcare. Despite the fact that price limits are intended to increase cost and access to medications, they can, unfortunately, reduce their availability.

3.3 FACTORS AFFECTING THE COST AND AFFORDABILITY OF PHARMACEUTICALS

Pharmaceutical drug pricing increases often represent increased work stress for medical professionals, who serve as financial counsellors to patients and assist them in managing out-of-pocket spending. Providers or prescribers want to assist patients with medication expenditures, but they frequently lack the necessary information. On their websites, healthcare plan providers try to offer prescription and drug pricing information, however this information isn't always linked to electronic prescription software. A mark-up is described as the additional charges and prices added to the price of a product in order to pay overhead costs, distribution costs, and profit. As a result, rules enacted in the pharmaceutical distribution chain may include wholesale and retail mark-up control, as well as pharmaceutical remuneration. If mark-ups are regulated, it is strongly advised that countries employ regressive rather than fixed percentage mark-ups.

Increased demand for medicines can have an impact on the performance of the health-care system and place a financial burden on individuals and society. As a result, the goal was to look

at the factors that influence induced demand for drugs and come up with solutions to the problem.

The following are some of the reasons that contribute to raise the cost of pharmaceuticals for patients-

- High launch prices, with the drug's price frequently rising over time.
- When market exclusivity ceases, there is insufficient competition.
- The combination of market power, health insurance, and the lack of effective price control incentives.
- Buyers and sellers have unequal bargaining power.
- Expenses for research, development, and marketing, as well as other business expenses.
- Insurance benefit designs that require a considerable amount of patient cost-sharing.
- Patient assistance schemes and other public programmes aimed at making drugs cheaper for patients function poorly.
- Inadequate information is influencing medication decisions.

3.4 A COMPARISON OF DPCO (Drugs Price Control Order) - OLD AND NEW SYSTEMS

Drugs, which are acknowledged as a "essential item," should always be affordable to the general public. In the absence of any regulatory controls, a manufacturer may charge extravagant prices for a drug, which is not only against the public interest but also against the principle of the welfare state. The drug price control order was issued to fix the maximum retail pricing of drug formulations and to combat the exorbitant profiteering in drug manufacturing and distribution.

The DPCO increases the pressure on MNCs in terms of pricing setting, which aids domestic enterprises in doing research. DPCO regulates the prices of numerous multinational corporations' off-patent branded pharmaceuticals[16].

The Drugs Price Control Order of 2013 differed significantly from the DPCO of 1955. DPCO in 1955 was supervised by the Essential Commodities Act, and prices for 74 pharmaceuticals were controlled, but DPCO in 2013 was governed by the National Pharmaceutical Price Authority, and prices for 652 drugs were controlled. The goal of DPCO 2013 is to diversify more areas than in 1955, as it is primarily concerned with profitability and cost-effectiveness.

Because the Government of India has the authority to set the maximum sale price, it can be seen from the beginning of the DPCO Act that there have been numerous swings in prices and percentages in products and net worth, marginal costs, and so on. The NPPA and the government set prices by adopting a formula for retail price of formulation and MRP[17].

A company cannot raise the retail price of pharmaceuticals or promote a new formulation without the approval of the government. In addition, no one is allowed to sell the imported planned formulation. If a manufacturer charges a greater price than the government-set price, the government may be able to recoup the difference. Violations of the Act are also subject to a variety of penalties. Sections 7, 9 and 10 of the Essential Commodities Act of 1955 discuss such penalties, which include imprisonment for a specified period of time as well as the requirement to pay a fine. The Drugs Control Price Order, 2013, is being enforced by the National Pharmaceutical Pricing Authority, the FDA/State Drugs Controller, and the Drugs Inspector of the District.

[16] Nppaindia.nic.in, https://www.nppaindia.nic.in/wp-content/uploads/2018/12/DPCO2013_03082016.pdf (last visited Aug 31, 2021)
[17] Supra note 5.

3.4.1 Mechanisms for Drug Pricing

- Drug prices were previously set by manufacturers depending on their manufacturing costs. However, after the adoption of DPCO (1995), the government set the prices, resulting in the withdrawal of most producers' items from the market and a reduction in manufacturing levels.
- In response to this circumstance, the Indian government introduced DPCO (2013), which classified most pharmaceuticals as essential medicines (NLEM)[18].
- At the store, the final MRP of the medications is increased by 16 percent.
- However, some patient advocacy groups contend that the prior price-fixing method, cost-based pricing, from 1995 is more important than the current market-based pricing.
- iii. The prices are determined by taking the simple average of all marketed goods for that drug with a market share of more than 1%.

DPCO 1995 is a win-win situation for manufacturers because the government has no power over the fixation of drug prices, and drug prices are regulated by a manufacturing cost mechanism. DPCO 2013 has overcome this difficulty by enlisting the government in price fixing through a simple average market price system, through which the majority of lifesaving drug prices are fixed by the government, resulting in a win-win situation for both the producer and the patient. There is no doubt that the Indian customer will benefit the most from the new medicine pricing control order 2013. (DPCO 2013). Some brands' costs could drop by as much as 70%. The policy

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https://www.researchgate.net/publication/263657518_A_comparision_between_old_and_latest_systems_in_DPCO (last visited Aug 31, 2021)

is expected to encompass two-thirds of the Rs.60,000 crore domestic industry[19]. On a short – term and long - term basis, the influence on the industry can be assessed. Large enterprises with well-known brands may be able to weather the storm better, although market share may be lost. The profitability of small-scale production may suffer. Despite the initial cost-effectiveness knock, capacity expansion over the next few years will help businesses improve.

3.5 INDIAN PERSPECTIVE ON PHARMACEUTICAL PRICING POLICY AND CONTROL

Hospitals, medical devices, clinical trials, telemedicine, medical equipment, health insurance, medical tourism, and outsourcing are some of the largest industries in India in terms of revenue and employment. Healthcare delivery includes hospitals, nursing homes, diagnostic centres, and pharmaceuticals, which account for 65 percent of the whole market. The Indian government has decided to open 3,000 medical stores across the country to encourage the healthcare business by providing high-quality medicines at affordable prices. The Indian healthcare market is expected to grow to US$ 280 billion by 2020, up from its present value of US$ 100 billion[20]. The Indian pharmaceutical business is predicted to grow to US$100 billion by 2025, thanks to rising consumer expenditure, fast urbanisation, and more healthcare insurance, among other factors. Furthermore, India's pharmaceutical production costs are far lower than those in the United States and nearly half of those in Europe[21]. In terms of the global medicines industry, India holds a key place. In India, the pharmaceutical business is severely fragmented and has to be

[19] Ibid.
[20] Journals.sagepub.com, https://journals.sagepub.com/doi/pdf/10.1177/0972266120929146 (last visited Aug 30, 2021)
[21] Supra note 5.

consolidated[22]. The government must keep the cost of important life-saving pharmaceuticals under control so that they are affordable to all members of society. At the same time, the government must protect the interests and welfare of India's pharmaceutical companies. According to industry officials, the government of India's recent policy measures in the pharmaceutical sector, such as banning some drugs, controlling prices, and withdrawing tax benefits, may have a negative impact on the growth of the Rs.98,000 crore pharmaceutical market, as well as the consolidation and Make in India Initiative. According to Ms. Menghaney, India's intellectual property policy fails to recognise that IP is a market-driven concept when it comes to treatments for neglected diseases, and as a result, access to drugs will be severely hampered. Under the Indian Patents Act, a compulsory licencing (CL) for a drug can be awarded if it is judged unaffordable, among other circumstances, and the government grants permission to qualified generic drug companies to manufacture it. In the case of CL, India has only issued a patent for a cancer medicine.

The government in India is becoming increasingly concerned about rising patient out-of-pocket expenses, of which a substantial portion is spent on medicine purchases. Drug Price Control Orders and the National List of Essential Medicines are examples of regulations aimed at keeping drug and medical device prices under control. They're designed to lower patient costs and, as a result, make quality healthcare more accessible to millions of people. While pricing laws make pharmaceuticals more inexpensive in the near term, they may not allow patients to obtain them in the long run. Accessibility is determined by availability, and pharmaceutical corporations play a critical role in bringing pharmaceuticals to market. Excessive pricing control diminishes a company's revenue, forcing it to cut back on production or possibly shut down.

[22] Supra note 1.

Firms may also be hesitant to expand into rural areas. Regulations and pricing controls also have a direct impact on medication development R&D investments, which may have a negative impact on future public health. It requires a significant amount of time and resources to find cures for untreated diseases or to develop better and more effective medicine formulations[23]. As a result, pharmaceutical regulation may include a trade-off between cutting prices today and having fewer medications to successfully treat diseases later. As a result, India must strike a balance, as many other developed healthcare markets have, to ensure that its inhabitants have access to high-quality healthcare now and in the future. It may study best practises in both developed and developing countries in order to establish and execute policies that strike this balance.

In India, drug prices are regulated, and the Indian government uses the DPCO to set price ceilings for vital drugs. It is the government's job to protect pharmaceutical companies' interests while also ensuring that vital medications are available to all members of society at a reasonable cost[24]. Pharmaceutical companies in India must establish strategies in accordance with Indian government policy in order to survive and thrive. Pharmaceutical businesses may consider cutting costs in order to comply with the government's drug pricing strategy. To guarantee that medicines remain affordable, the Indian government may look into and focus on other critical elements of the pharmaceutical business, in addition to price policy.

3.5.1 Following are issues with drug pricing regulation in India.

[23] Impact of the Drug Price Control Order on the pharma industry Project Guru, https://www.projectguru.in/impact-of-the-drug-price-control-order-on-the-pharma-industry/ (last visited Aug 31, 2021)
[24] Supra note 14.

- In 2015, the Supreme Court of India ruled that the National Pharmaceutical Pricing Policy 2015 and the Drug Price Control Order 2013 were arbitrary and irrational. It is in response to a PIL alleging that Market Based Pricing (MBP) was never used for price regulation purposes, hence increasing the cost of medications.
- The government was directed by the court to reconsider its market-based medicine pricing policy.
- Only 35% of the general population has access to necessary medicines.
- The profit margins for drug makers and dealers ranged from 10 to 1300 percent = High medicine prices.
- The NLEM only includes 348 pharmaceuticals, leaving out numerous critical medicines that are subject to price controls.
- More life-saving drugs for diseases including HIV/AIDS, cancer, diabetes, and tuberculosis, as well as those used in mental health and non-communicable diseases like asthma and rheumatoid arthritis, are being requested to be included in NLEM.
- Price regulation is ineffectual and unproductive since simple average ceiling prices were higher than market prices in several circumstances.
- It hasn't addressed combination drugs: When a price - controlled drug is mixed with a non – price - controlled drug, the price control is voided.
- In the event of non - compliance with the NPPA's orders, there are no consequences for the companies.
- 90% of doctors do not prescribe generic medications, implying that the idea of programmes like Jan Aushadhi is flawed.

- Malpractices in the distribution network, for which organizations such as the Indian Medical Association and pharmacists' organizations bear significant responsibility.

3.5.2 Policy Measures are Recommended

In India, the number of useful molecules in use is most likely between 800 and 1000. A list that serves as the foundation for pricing regulation must include all of these 800-1,000 compounds. As a result, with 348 molecules, the NLEM 2011 will negate the goal of price regulation[25]. Me-too medications, on the other hand, must have the same price ceiling. Furthermore, any drugs useful for a certain illness, such as asthma or diabetes, must be priced[26]. And, if the government is serious about price regulation and providing inexpensive health care, it must eliminate all other drugs (including nonsensical combinations) from the market, which include medicines with little or no therapeutic benefit as well as a slew of hazardous substances. If combinations of beneficial pharmaceuticals with inessential or useless drugs are not to be completely phased out of the market, they should have the same price ceiling.

All out – of - patent drugs would have to be de - branded, according to the Report. That is, they should only sell under their brand identities. Only paracetamol, not Crocin or Calpol, should be sold as paracetamol. India is the only country with a thriving pharmaceutical sector, with prescription pharmaceuticals supplied under brand names that are no longer under patent. Bangladesh de - branded vital pharmaceuticals in 1982 and was threatened with “sanctions” by governments where multinational corporations (MNCs) are headquartered. However, there has been no exodus of pharmaceutical MNCs from Bangladesh. Only by taking these steps can we

[25] Ukibc.com, https://www.ukibc.com/wp-content/uploads/2018/07/UKIBC-Report-Drug-Pricing-in-India.pdf (last visited Aug 31, 2021)
[26] Ibid.

hope to be ready for a relevant health-care system that cares for its citizens – one in which pharmaceutical firms do not overcharge or advertise irrational medicines and drugs of dubious or no benefit that are not mentioned in any standard pharmacology textbook.

3.5.3 The way forward

- Countries such as Brazil provide free drugs, and India can fall into line over time.
- Medicines or drugs account for 50% of inpatient care expenses and 80% of outpatient care expenditures, implying that a means must be found to ensure low prices without discouraging manufacturers.
- According to a recent assessment by India's Competition Commission, store margins are the primary source of high drug prices. This can be solved by investing in wholesale government procurement, as Tamil Nadu and Rajasthan have done.
- Aside from public procurement, state-run insurance can assist in lowering health-care expenses.
- Andhra Pradesh's Ex - Arogyashree model, which incorporates both public procurement and state-led insurance. The Ayushman Bharat Yojana is a positive step forward.
- It is necessary to raise awareness among both doctors and patients about the benefits of prescribing or using generic medications.
- The government and the community should work together to keep track of spending.
- These changes, however, would necessitate a larger budget commitment for the health sector.

The interaction between medicine pricing and the supply chain, including mechanisms and pharmaceutical price components, as well as the pharmaceutical supply chain, was studied. Manufacturers, market warehouses, distribution centres, wholesalers, and retailers were among the major components of the pharmaceutical value chain discussed. Aspects of the legislative background, such as private healthcare facility and service regulation, tariff exemptions, and external and international reference pricing, were also considered. Finally, factors of patient medication spending, including as out-of-pocket spending and out-of-pocket costs, were examined. Medicine prices are reduced when mark-ups are regulated in the absence of any price management plan. This policy is less complicated to execute than the other options because it just requires a small amount of cost and supply chain information, as well as enforcement specifics. This approach, however, may have a negative impact on availability and access due to price changes.

CHAPTER- 4

ISSUES RELATING TO ACCESS TO MEDICINE

4.1 INTRODUCTION

For decades, the right to health as a fundamental human right—and access to medication as a component of it—has been a topic of discussion. The World Health Organization has also underlined the roles of other parties, particularly pharmaceutical firms, in the fulfilment of this right. This is despite the fact that many corporations see little reason to invest in rare disease drug research and development. In many nations, certain legal systems, such as "patent agreements," blatantly obstruct access to pharmaceuticals. In low-income nations, high brand-name drug prices and the lack of legal generic production can result in catastrophic expenses as well as morbidity and mortality from medicines. We examine the present issues in access to medicine and analyse its legal underpinnings in this article. How societies/governors can hold pharmaceutical firms accountable is also examined in order to look ahead to possible futures and actions that policymakers can take at the local and global levels. Infectious diseases kill approximately 14 million people per year, or about 40,000 people per day. Almost half of the victims are youngsters under the age of five, with the majority being from underdeveloped nations[27]. If the poor had access to medications, most of the premature deaths and incapacities caused by infectious diseases could be averted. In the developing world, family poverty, misallocated

[27] Who.int, https://www.who.int/intellectualproperty/topics/ip/tHoen.pdf (last visited Aug 27, 2021)

governmental funds, and a lack of sanitary infrastructure combine to keep basic medical treatment out of reach for the poor. According to the World Health Organization (WHO), around 3,000 million people in poor nations lack access to basic medicines. The World Trade Organization's (WTO) new patent rules will further restrict impoverished people's access to crucial medications. Granting patent holders trade exclusivity for at least 22 years restricts governments' ability to enable the production, trading, and importation of low-cost replicas (generics) of copyrighted medications. It is not a hypothetical or distant threat. The application of these more stringent criteria has already produced severe challenges for generics producers in emerging countries such as India and Brazil, as well as importers such as South Africa and Kenya. The pharmaceutical industry and governments of certain wealthy countries have criticised them, brought them to court, and threatened them with sanctions. Except for a few specialised drugs such as antiretrovirals for HIV/AIDS, access to vital medicines for the world's poor and vulnerable has made little improvement since 2000[28]. Human rights concepts enshrined in national law can foster an environment conducive to universal access to medications; nevertheless, rigorous study and policy guidance on this topic are scarce. The causes for a lack of access to vital medicines are numerous, but in many situations, high drug prices act as a deterrent to needed treatments. Drug prices that are prohibitively expensive are frequently the outcome of robust intellectual property protection. Governments in underdeveloped countries attempting to reduce the cost of medications have come under fire from industrialised nations and the international pharmaceutical sector. The World Trade Organization (WTO) Trade-Related Aspects of Intellectual Property Rights Agreement (TRIPS) establishes basic requirements for intellectual property protection, including pharmaceutical patents. While TRIPS provides protections to mitigate the negative impacts of patent protection or patent abuse, it is uncertain

[28] Ibid.

whether and how governments can employ these safeguards in practise, as patents increasingly provide barriers to pharmaceutical access. Since the implementation of Trade-Related Aspects of Intellectual Property Rights (TRIPS) in 1995, there has been considerable concern that poor access to essential medicines in developing countries would be exacerbated because strengthening intellectual property rights (IPR) leads to pharmaceutical market monopolies and the delayed entry of lower-cost generic drugs. However, despite substantial inquiry and debate on the subject, there are few empirical studies on the subject. Using data from the World Health Surveys 2002-2003, we explored the influence of IPR on access to medications and catastrophic expenditure for medicines in this study. The Doha Declaration was hailed by public health activists as a significant victory since it prioritised public health over commercial intellectual property and clarified WTO members' rights to apply TRIPS safeguards. However, the Doha Declaration did not resolve all of the issues concerning intellectual property protection and public health. The recent inability of the WTO to resolve the unresolved issue of ensuring the manufacturing and export of generic drugs to non-producing nations may possibly imply that the optimism felt in Doha was premature.

4.2 GLOBAL TRADE ISSUES REGARDING INTELLECTUAL PROPERTY RIGHTS WHEN IT COMES TO MEDICINES

In today's world, there is a perpetual conflict between intellectual property and human rights. Following World War II, international human rights duties began to arise. The WHO (public health), the Universal Declaration of Human Rights 1948 (UDHR), the International Covenant on Civil and Political Rights 1966 (ICCPR), and the International Covenant on Economic,

Social, and Cultural Rights 1966 (ICESCR) are just a few of the international organisations that have a direct impact on IP obligations[29]. There are differences in the protection afforded to IP holders in countries at various stages of development, and developed nations such as the EU and the US have lobbied hard to increase IP rights protection in the international domain via multilateral treaties, of which TRIPS is an excellent example. The issue of compulsory licences for patents has been the most prominent feature, particularly in relation to pharmaceutical products, where there are divergent views between developed and developing countries, which is also one of the main reasons why the Paris Convention revision in the early 1980s did not see the light of day. The public has the right to "benefit from the protection of the moral and material interests resulting from any scientific, literary, or artistic output of which he is the creator," according to Art 3, 15 of the ICESCR, 1976. Patents for pharmaceutical items and treatments are also included. "The States Parties to the present Covenant respect the right of everyone to the best achievable quality of physical and mental health,[30]" according to Art 12. Art 31 of the TRIPS provides for obligatory licencing criteria, and Art 31bis, which was added after the 2003 revision, allows for conditions under which "eligible importing nations," usually LDCs, can import pharmaceuticals from "eligible exporting countries" if certain conditions are met. The scope and conditions under which obligatory permits can be given are also outlined in Article 5(A) of the Paris Convention. During the 1990s, the United States charged exorbitant fees for antiretroviral medicines for AIDS, with South Africa being one of the worst-affected countries. In 1997, the South African government introduced a bill that established conditions to ensure the supply of affordable medicines, which prompted the United States to accuse South Africa of violating the TRIPS Agreement because it specifically allowed the importation of patented medicines into

[29] Intellectual Property Rights and Access to Medicines: International Trade Issues Everycrsreport.com, https://www.everycrsreport.com/reports/R40607.html (last visited Aug 28, 2021)
[30] Ibid.

South Africa , which were then placed on another market with the consent of the patent holder. The whole point was to make it easier and encourage the importation of such expensive patented medications from the cheapest market, a practise known as parallel importation in the EU and Singapore. One of the main reasons made in support of TRIPS was that patents must be "enjoyable without any discrimination" in the sphere of technology, and the South African Bill was perceived as discriminatory towards pharmaceutical patents. The pharmaceutical companies eventually dropped out of the lawsuit in 2001 and settled.

Following this, the push for access to medications sparked a much broader and more extensive discussion about the cost of such drugs and their availability in developing and least developed countries. Developing countries pushed for an interpretation of TRIPS that included dealing with a health crisis at a special meeting of the TRIPS council in June 2001, which resulted in the Doha Ministerial Declaration on the TRIPS Agreement and Public Health, November 2001 , a declaration that asserts developing countries' right to protect their population's health. On August 30, 2003, the WTO General Council facilitated the implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, and there was detailed text laying out rules for "eligible importing members" to secure access to pharmaceutical manufacturing capacity from "eligible exporting members," which affected TRIPS Art 31(f) and laid out conditions for TRIPS Art 31bis and the TRIPS Agreement and Public Health. The World Health Organization's IP agenda addresses such challenges, going beyond patents and drug costs to encompass the role of health systems and innovation in the healthcare industry. The multiple balances envisioned in Article 15 of the ICESCR have become even more difficult to accomplish as a result of economic globalisation and rising privatisation and commercialization of science. These reforms aided in the decrease of antiretroviral treatment prices and provided help to

generic producers in India and Brazil in particular. Because these countries did not recognise pharmaceutical product patents prior to TRIPS, most of these pharmaceuticals were not protected under patent law in either of these countries. Following TRIPS, a few developing countries, including India, with generic manufacturing capability, were required to comply with TRIPS commitments relating to pharmaceutical patents.

The plain packaging legislation for tobacco products and the dispute that developed out of a bilateral treaty between Honk Kong (Philip Morris Asia) and Australia is another example of how Australia tried to strike a balance between public health concerns and IP rules. On jurisdictional grounds, the case was dismissed. The law concerns the best possible mix of basic packaging design features, including as colours, font size, and graphic health warnings (size and layout). Australia enacted the legislation to take advantage of the TRIPS Agreement's flexibilities, such as not prohibiting all uses of the mark and stating that the mark will not be removed from the register for non-use, thus avoiding responsibility under TRIPS' Art 5 C and accompanying Article 19.

Even though multinational treaties such as TRIPS and the Berne Convention strengthen IP holders' rights, particularly in relation to patents and copyrights, there are provisions in place to allow for access to medicines.

4.3 ACCESS TO VITAL MEDICINES IS A PROBLEM

Medicines can account for up to 66 percent of overall health spending in poor nations, and they can be a major source of household poverty, as 50-90 percent of such costs are out-of-pocket. More than a third of the world's population, as well as more than half of the poorest people in

Asia and Africa, still lack access to crucial medicines. According to the WHO, such access should cover therapeutic, physical, and financial components, i.e. it should address priority health issues, be accessible physically, and be affordable to everybody. The availability and price of vital medicines are both major issues for the poor in developing countries[31]. Some believe that, as a result of the WTO TRIPS Agreement's establishment of strong product patents for medicines, costs of crucial treatments may rise even higher, making them even more unaffordable for the poor. This is because patents grant their owner the right to prevent others from making, using, selling, or distributing the product without permission, effectively creating a "legal monopoly." Others, on the other hand, argue that patents now protect only a small number of WHO-designated critical medications. This is almost by definition, because one of the factors utilised in the selection of these pharmaceuticals is affordability. Even with the absence of patents, access to medications will remain limited due to a lack of sufficient purchasing power and infrastructure.

The example of HIV/AIDS in poor nations has brought patents and prices to the fore. An estimated 95 percent of people infected live in developing countries, where the disease shows no signs of slowing off. With more than half of those affected being under the age of 25, this disease is wreaking havoc on the social and economic landscape. Because this is such a new condition, many of the drugs are still under ‘live' patent protection, with ten-year or longer expiration dates. Prior to TRIPS, most developing countries and some developed countries prohibited the patenting of medicines, even if they matched the novel and innovative standards. Almost all of these countries are now WTO members and must implement TRIPS, allowing for the filing of patents for novel pharmaceutical inventions at least as early as 1995, as well as the grant of product patents or similar exclusive marketing rights where applicable. It's worth noting that,

31 https://www.researchgate.net/publication/236676097_Accessibility_and_use_of_essential_medicines_in_health_care_Current_progress_and_challenges_in_India (last visited Aug 29, 2021)

even under the TRIPS regime, patents will only be issued on new, patentable pharmaceutical inventions submitted after 1995. As a result, TRIPS should have no effect on the prices of existing pharmaceuticals on the market, or even those covered by patent applications filed before to 1994 anywhere in the globe, because these markets could remain as competitive as before. The term of a patent is 20 years from the date of filing. Patent owners usually file for patents only in significant markets or in areas where they expect piracy to be a problem. As a result, even when patents are available, not every developing country will request one. Product patents are defended by innovator pharmaceutical companies as a necessary incentive for investment in research and development, despite the fact that they argue, perversely, that the lack of patent protection stifles competition that can lower drug prices because consumers do not benefit from generic entry! True, because of brand loyalty and other causes, no-patent pharmaceutical markets are generally fairly consolidated[32]. TRIPS mandates the availability of product and process patents for pharmaceuticals beginning in 1995, radically altering patent rules in underdeveloped nations that previously permitted such exemptions. In nations where such patents are valid, this shift will very probably result in price increases of up to 200-300 percent for patented drugs, especially for essential diseases like HIV/AIDS. Compulsory licencing or government usage, parallel imports, and price controls, all of which are allowed under TRIPS, could mitigate such negative consequences on affordable access to vital medications. None of these tools are without flaws, and they must be handled with caution. Finally, despite demand from some places, developing nations are not required to go beyond what TRIPS stipulates.

[32] Who.int, https://www.who.int/intellectualproperty/topics/ip/tHoen.pdf (last visited Aug 29, 2021)

4.4 THE RELATIONSHIP BETWEEN THE PATENT SYSTEM AND PHARMACEUTICAL ACCESS

A patent is a type of intellectual property right (IPR) that grants a legal, exclusive right to the invention of a new product, process, organism, design, or plant. It grants the right holder the right to prevent others from creating, using, or selling the protected innovation for a term of 20 years. Patents are the most popular way for governments to support R&D in order to find pharmaceutical treatments and cures for diseases and other disorders. IPR protection and enforcement have progressed from being largely a matter of national concern to a matter of international trade policy. The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) of the World Trade Organization (WTO) established minimal requirements for IPR protection and enforcement[33].

As patent is an exclusive right that grants the patent holder the ability to exclude competing suppliers during the patent's duration. In exchange, the patent holder makes their innovation public, allowing for free use of the information once the patent expires. A patent can be sold, licenced, or transferred just like any other property right. The purpose of patent laws is to incentivize investors to make the large sums required to discover, develop, and bring a novel drug to market. In theory, patent protection serves to secure the continuous development and availability of medicines in the future, as long as markets can pay for the patent holder's research and development costs[34]. When patent systems work properly, they encourage technical innovation by providing a return on investment for the patent holder, as well as the transfer and

[33] Who.int, https://www.who.int/healthsystems/topics/health-law/chapter15.pdf (last visited Aug 27, 2021)
[34] Supra note 1.

diffusion of technology and the availability of generic medications once the patent has expired. However, because patents eliminate competition, they can result in high drug prices during the patent's term. High pricing, along with the magnitude of the demand for specific treatments, may work against the goal of universal access to a national list of essential medicines, particularly in low-income nations. Furthermore, when the market value of the innovation is low, the incentive to invest in research and development in order to bring novel medications to market may be absent. Patents have failed to achieve their goal as instruments of innovation in the case of "neglected diseases" that disproportionately affect poor populations and low-income countries, because both governments and patients lack the purchasing power to create a market that justifies the necessary investment in the first place. To overcome market failure and support research and development of neglected diseases, a variety of alternative policy instruments will be required.

For economic, health and safety, and national security considerations, the US government considers the protection and enforcement of international IPR norms, particularly those for patents, to be an essential priority of US trade policy. As a result, the US has pursued robust IPR regimes through international, regional, and bilateral free trade agreement (FTA) negotiations as well as unilateral trade policy mechanisms such as the Special 301 process and the Generalized System of Preferences (GSP[35]). IPR provisions in trade laws are among the many social, economic, and political elements that can have an impact on public health, including a country's ability to provide health care to its citizens. Patents may have an impact on access to existing medicines and the development of new medicines due to their potential impact on innovation and drug prices. According to the World Health Organization (WHO), around one-third of the world's population, especially those living in poorer parts of Africa and Asia, does not have regular

[35] Compulsory Licensing Of Patents And Access To Essential Medicines - Intellectual Property - India Mondaq.com, https://www.mondaq.com/india/patent/890144/compulsory-licensing-of-patents-and-access-to-essential-medicines (last visited Aug 28, 2021)

access to important medicines. While the United States prioritizes establishing a robust worldwide IPR framework, some members of Congress have raised concern about how to strike a balance between providing long-term incentives for research through patents and addressing the short-term need for inexpensive access to medications. This problem is part of a larger discussion regarding the relationship between trade policy and public health. Incorporating public health concerns into the U.S. trade policy advisory process, developing new U.S. trade policy guidance on public health, considering the implications of the U.S. strategy on IPRs and trade for U.S. access to medicines, and reviewing the range of options used for expanding global access to medicines are all possible issues of interest for Congress.

Legal, ethical, and human rights standards are becoming an increasingly crucial component of providing high-quality medical care. Health care environments are far too often locations of punishment, coercion, or abuses of basic rights to consent and confidentiality for society's most marginalized members, rather than places of treatment and compassion. At the same time, health practitioners may be unclear of how to incorporate ethical and human rights principles into their practice, and they may lack independence, fair working conditions, and due process protections[36]. Human rights in patient care include both patients' and health care providers' rights and refers to the application of general human rights principles to the setting of patient care. It is concerned with systemic concerns and the role of the state[37].

Some critics claim that the patent system is harmful to patients in terms of "Access to Medicine." On the contrary, if technical details of inventions are not published sooner through the patent system, the creation of novel treatments will be inhibited. Without adequate patent protection for ideas, research-based pharmaceutical corporations would be unable to invest large resources in

[36] Ibid.
[37] Supra note 3.

pharmaceutical research and development, stalling the development of innovative treatments and limiting access to them.

4.4.1 Estimates of pharmaceutical price discrepancies due to patents

On the basis of patents alone, there are few accurate estimates of variations in drug prices in underdeveloped nations. Inter-country comparisons of medications with similar composition and presentation are a straightforward and appealing tool that is frequently employed. Such comparisons, however, are clearly flawed since, without more information, it is impossible to assign differences solely to the presence or absence of patents. Even price comparisons between countries with similar economic development levels provide only a limited picture. The more important research would be on the consequences of generic introduction on off-patent medications, for which data is currently unavailable in these nations. Several studies based on data from the US market suggest that when a patent expires, generics enter the market, prices drop significantly and quickly. For example, one study found that with just one generic producer, the average generic/branded price ratio after patent expiry was 0.59, while with twenty generic manufacturers, it was 0.17.[38] This is partly due to the fact that, ironically, the price of the leading brand, which has lost patent protection, actually rises in order to protect total revenues. According to a more recent study, the average retail prescription price for innovator pharmaceuticals from a single source might be 300 percent higher than prescription generic drugs. This author's simulation analysis of the Indian pharmaceutical industry, which controlled

[38] Intellectual Property Rights and Access to Medicines: International Trade Issues Everycrsreport.com, https://www.everycrsreport.com/reports/R40607.html (last visited Aug 29, 2021)

for replacements, revealed similar pricing discrepancies. Under certain estimates, the price increase due to product patents alone might be as high as 250 percent.

4.5 PROGRESS BEING MADE THROUGH INTERNATIONAL CO-OPERATION

Despite major global health concerns, tremendous progress has been made. These examples show how successful ways are being created and implemented, as well as the influence that international collaboration and coordination may have on billions of people's health. For example, between 1990 and 2018, the death rate of children under the age of five plummeted by 59 percent. Since the peak of the HIV/AIDS epidemic in 2004, AIDS-related mortality have decreased by more than 56%, and antiretroviral medication is now available to more than half of all HIV/AIDS patients. In 2017, 81 percent of nations have a cancer-related national action plan, up from 66 percent in 2013, and WHO member states supported a set of steps to strengthen cancer control in 2017. Vaccine programmes are allowing progress toward polio eradication in Haiti, meningitis eradication in 26 countries in Sub-Saharan Africa, and hepatitis B eradication in China. New global health conventions and commitments are helping to set additional priorities, with the goal of inspiring global action, such as the 2017 London Summit on Family Planning and the 2018 UN High-Level Meeting on Ending Tuberculosis, as well as the UN High-Level Meeting on Non-Communicable Diseases. Between 2010 and 2017, the number of persons requiring treatment and care for neglected tropical diseases (NTDs) decreased from 2.03 billion to 1.58 billion, indicating that progress is being made. Because of faster reaction times and the deployment of innovative treatment and vaccine candidates, the Ebola outbreaks in the

Democratic Republic of the Congo in 2018 were contained more swiftly than the West African Ebola epidemics of 2014-2016.

CHAPTER-5

HUMAN RIGHTS PERSPECTIVE OF ACCESS TO DRUGS

5.1 INTRODUCTION

Human rights have the power to change social, political, and legal norms in order to provide more fair access to drugs. The International Covenant on Economic, Social, and Cultural Rights has made the right to health legally binding on the 169 sovereign governments that have ratified it (ICESCR). As a result, these governments are legally obligated to defend and promote health rights through national legislation and policy. The degree of compliance in each country varies according to the position of international law in the domestic legal order, as well as the availability and content of national implementing legislation[39].

The right to health facilities, products, and services, as defined by WHO, includes the supply of critical medicines. State Parties are required to ensure that the right to health is exercised without discrimination, as well as to take deliberate and meaningful actions toward its full realisation, with a focus on vulnerable and marginalised groups. In terms of normative content and legal recognition, the human right to essential medications has improved. These vast deprivations and disparities are caused by existing national and international laws, regulations, and institutions. National supply systems for medicines frequently fail to reach the poor. If they do, the medications are frequently out of reach. Historically, research and development have not addressed the most pressing health needs of the poor. Alternative arrangements are possible, and improvements are desperately needed. Indeed, they are required by legal and ethical obligations,

[39] , https://www.researchgate.net/publication/233570769_Access_to_Medication_as_a_Human_Right (last visited Aug 29, 2021)

particularly those imposed by international human rights legislation. The Millennium Development Goals of lowering infant mortality, increasing maternal health, and combatting HIV/AIDS, malaria, and other diseases all rely on increased access to medications. Indeed, one of the Millennium Development Goals is to deliver "affordable vital pharmaceuticals in developing nations in collaboration with pharmaceutical companies." Importantly, enforcing the right to the best possible health can aid in the achievement of the health-related Goals. Medical care in the case of illness, as well as disease prevention, treatment, and control, are essential components of the right to the best health possible[40]. These characteristics are dependent on availability to medicines.

Because human rights are at the heart of our society, the approach should be implemented into all national health and medicine policies and programmes. National non-governmental organisations (NGOs) should be given the authority to apply pressure on governments to meet their pledges and obligations under the international and national human rights agreements that they have signed and ratified. The human right to necessary medications is a subset of the rights to health and life. The right to health comprises the right to immediate medical attention as well as the right to health-care facilities, goods, and services. The right to health facilities, products, and services, as defined by WHO, includes the supply of critical medicines. State Parties are required to ensure that the right to health is exercised without discrimination, as well as to take deliberate and meaningful actions toward its full realisation, with a focus on vulnerable and marginalised groups.

In terms of normative content and legal recognition, the human right to essential medications has improved. However, finding accommodation with the international trade regime, bridging gaps

[40] Ibid.

in political will, creating incentives for innovation and cheap pricing, and ensuring the availability of appropriate human and financial resources to ensure distribution networks remain challenging challenges. All of these things must be accomplished in order for the right to critical medicines to become a reality for the over two billion people who do not have access to them[41].

As a result, access to pharmaceuticals is an essential component of the right to the greatest achievable level of health. Numerous court rulings, as well as UN Commission on Human Rights resolutions, confirm that access to vital medicines is a key component of the right to health. Some of the instances also show that difficulties of access to necessary drugs are inextricably linked to other human rights, such as the right to life.

Access to medicine is a basic instrument for ensuring health, and it is a basic human right. This right, as well as its tools, are confronted with important difficulties around the world. Pharmaceutical companies have an important role in ensuring health by improving access to medicines. Despite these shortages and obstacles, remarkable efforts have been done up to this point. Major pharmaceutical corporations are contributing billions of dollars to the underprivileged and patients with neglected diseases[42]. Every year, the WHO and the United Nations Human Rights Committee hold multiple meetings to discuss novel approaches to enhance access to medicine in collaboration with NGOs and government agencies. States have also attempted to improve the environment in order to increase the availability and affordability of medicine. However, there is still a great deal of room for progress, as well as a lot of room for change. The fundamental requirement in this direction is more realistic accountability of many actors, including both states and large pharmaceutical businesses. Without this accountability,

[41] , https://www.researchgate.net/publication/233570769_Access_to_Medication_as_a_Human_Right (last visited Aug 29, 2021)
[42] Supra note 3.

there will be no long-term change in the condition, and each step will just serve as a palliative, not a cure. Also, this accountability cannot be achieved automatically or through ethical advice, but rather requires serious legal acts in terms of defining crimes, binding state and non-state parties to increase their cooperation, and creating a safe path for developing countries to access generic medicine by restricting TRIPS and TRIPS-plus agreements. With all of these initiatives, we can be optimistic that long-term goals for improving health and reducing injustice will be met.

5.2 AN OUTLINE OF THE INTERNATIONAL FRAMEWORK OF HUMAN RIGHTS

The right to the best possible level of health, which includes access to critical pharmaceuticals, is firmly established in international law. The World Health Organization's (WHO) Constitution of 1946 and the Universal Declaration of Human Rights (UDHR) of 1948 both specifically affirm the right to health. The right to health is defined as "access to health facilities, goods, and services," according to the 1966 International Covenant on Economic, Social, and Cultural Rights (ICESCR), which has 164 signatories. The Committee on Economic, Social, and Cultural Rights (CESCR) interprets the normative content of article 12 of the ICESCR in General Comment 14 (2000) on the right to health[43]. Although the ICESCR only mandates the progressive achievement of the right to health in the context of limited resources, there are a core set of minimum responsibilities that are not progressive, such as access to necessary medicines. The World Health Organization, several national court rulings, Human Rights Council resolutions, and the Doha Declaration on TRIPS and Public Health all reaffirm access to vital

[43] Access to Medicines and Human Rights Health and Human Rights, https://www.hhrguide.org/2017/06/09/access-to-medicines-and-human-rights/ (last visited Aug 26, 2021)

medications as a human right that must be available "for everyone." While states are primarily responsible for the provision of critical medicines, these obligations are shared with various non-state entities. Pharmaceutical corporations, for example, have human rights obligations, according to the former UN Special Rapporteur on the Right to Health, which include the obligation to take all reasonable steps to make innovative medications "as accessible as possible" to people in need[44]. Furthermore, the UN Guiding Principles on Business and Human Rights, which were unanimously supported by the UN Human Rights Council in 2011, require the private sector to accept responsibility for human rights abuses relating to access to medicines. The international community also owes it to governments with limited resources to assist them in fulfilling their basic responsibilities through international collaboration and aid. In the event of a disaster, the world community owes it to the victims of the disaster to contribute to relief and humanitarian aid by sending medical supplies as soon as possible.[45]

5.2.1 Access to pharmaceuticals is aided by a human rights - based approach (HRBA)

Under this situation, an HRBA recognises all human beings as possessing indivisible, interconnected rights to health and access to critical medicines. A HRBA applies the principles of non-discrimination and equality, participation and inclusion, accountability, and the rule of law to universal access policies, in addition to the duties and entitlements outlined by the WHO and the CESCR. These principles are intended to guide programming and advocacy efforts at all levels, including monitoring and evaluation. A Human Rights-Based Approach to Medicine Access pays special attention to marginalised, disadvantaged, and excluded communities, and

[44] Ibid.
[45] Supra note 1.

empowers all populations to accomplish results through a process that is inclusive, transparent, and responsive. At the policy level, a human rights-based strategy can be used to increase access to medications. The right to health provides a framework within which national health policies and regulations for universal and equitable access can be developed. Positive health outcomes and individual realisation of health rights and access to medicines are possible outcomes. Individual claims for necessary medicines can be supported in national courts by domestic constitutions that recognise access to medicines as part of the right to health. The right to health established by the Kenyan Constitution played a part in enabling lawsuits that ultimately increased access to ARVs for individuals living with and impacted by HIV and AIDS, as described in the concluding section of this chapter. It is enormously empowering for individuals and communities living in relative poverty to reframe their lack of access to health care and basic medicines as a denial of their rights, rather than a failure of government policy. When basic requirements for a dignified life are elevated to the status of legal entitlements, they have the capacity to shift political discourse and social expectations. Reframing health as a human right entail pushing the boundaries of what is feasible, mobilising marginalised communities, raising public awareness, and sparking activism and education. Importantly, applying the human rights framework allows for a clear delineation of different stakeholders' domains of duty, as defined by human rights treaties, guiding principles, and general comments. Under international human rights legislation, states must respect, preserve, and fulfil the right to health, which includes taking legislative, administrative, and budgetary measures to make medications more inexpensive, accessible, culturally acceptable, and of high quality. This requirement that a state "use all available resources at its disposal" to meet its health duties will frequently necessitate a state's employment of all public health flexibilities allowed under international law. Meanwhile,

pharmaceutical corporations must adhere to the Ruggie trinity of protect, respect, and remedy when it comes to human rights. Corporations have a responsibility to (a) avoid causing or contributing to adverse human rights impacts through their own activities, and to address such impacts when they occur; and (b) prevent or mitigate adverse human rights impacts that are directly linked to their operations, products, or services by their business relationships, even if they have not contributed to those impacts. Pharmaceutical companies, in essence, have a responsibility to behave with caution in order to avoid infringing on the right to health. These responsibilities are highlighted when pharmaceutical companies prioritise the enforcement of their intellectual property rights over their obligations under the right to health.

5.2.2 Access to medicines is a crucial part of the right to health.

Health is a fundamental human right that is required for the exercise of many other rights, including the right to development, and for living a dignified life. Realizing the right to health is also a fundamental goal of the state's policies and programmes, independent of their economic, social, cultural, religious, or political background. Nonetheless, for millions of people around the world, full enjoyment of the right to health remains an elusive ideal, owing in part to barriers to access to high-quality, inexpensive, and timely medicines, particularly in poor countries[46]. This is a challenge to human dignity, which is the foundation of all human rights, including the rights of all people to life, health, and development. Access to medications is inextricably related with the human rights ideals of equality and non-discrimination, transparency, participation, and accountability[47]. States must adopt national health legislation and policies, as well as build their

[46] Cdn1.sph.harvard.edu, https://cdn1.sph.harvard.edu/wp-content/uploads/sites/580/2012/10/marks_access_to_essential_medecines-2009.pdf (last visited Aug 29, 2021)
[47] Ibid.

national health systems. Key concerns connected to medicine access must be considered for this purpose, including: sustainable finance, availability and affordability of necessary medicines; price and quality control; dosage and efficacy of medicines; procurement policies and procedures, supply chains, and so on. The issue of access to medicines is a critical component of fully realising one's right to health. Medical care in the case of illness, as well as disease prevention, treatment, and control, is heavily reliant on timely and appropriate availability to quality drugs. Previous commission holders have commented extensively on the factors, barriers, principles, and accountable actors in achieving universal access to medicines[48]. Despite advances, many individuals continue to lack access to life-saving medicines. This is owing to the barriers that obstruct access to high-quality, inexpensive, and timely medicines, which are especially prevalent in underdeveloped nations. This undermines human dignity and the foundation of all human rights, particularly the rights of all people to life, health, and development.

Access to medications is inextricably related with the human rights ideals of equality and non-discrimination, transparency, participation, and accountability. Poverty and the implementation of the right to health continue to be inextricably linked, with developing countries having the highest need and the least access to medications. States must adopt national health legislation and policies, as well as build their national health systems.

The right to vital pharmaceuticals is derived from the human rights to health and life. The idea that lack of access to medications was antithetical to human rights was not considered when the main human rights documents were established, save that access to medicines was one of a number of acceptable elements forming healthcare. Following that, and especially as a result of

[48] The Development Of Human Rights Issues (Access To Medicines) In The Light Of Intellectual Property Rights - Intellectual Property - India Mondaq.com, https://www.mondaq.com/india/patent/906688/the-development-of-human-rights-issues-access-to-medicines-in-the-light-of-intellectual-property-rights (last visited Aug 29, 2021)

the AIDS pandemic, the critical need for HIV positive individuals to be treated contributed to the gradual recognition that access to necessary medications, including antiretroviral therapies (ARTs), was an internationally recognised human right. This argument has been extended beyond HIV/AIDS to include all diseases that contribute to the high rates of death and morbidity in underdeveloped countries. It may be instructive to compare the formation of an implicit derivative human right to water, which was legally recognised by the Committee on Economic, Social, and Cultural Rights in its General Comment on the Right to Water in 2002. Drawing on three key reasons given by the Committee, one based on data, one on logic, and the third on legal construction, the analogy with the right to water is strengthened. First, the existence of the water crisis, which was caused by a failure to ensure access to it, was undisputed and recognised as demanding immediate attention. “Over one billion people do not have access to a basic water supply, and several billion more do not have access to appropriate sanitation, which is the primary cause of water contamination and diseases associated to water,” according to the Committee. Nearly two billion people lack access to basic medicines, and an estimated four million individuals in Africa and Southeast Asia could be saved each year if effective diagnosis and treatment were available[49]. The problem's scale and urgency meet the criteria. The other claim is based on a logical construct that states that water as a human right is an inevitable consequence of the commodity's nature. “Water is a scarce natural resource and a public good essential for life and health,” the Committee argues. The human right to water is essential for living a life of dignity. It is a requirement for the fulfilment of all other human rights. Appropriate medicines are also essential for people's health all throughout the world, and the most basic drugs are a public good. The legal interpretation of existing human rights norms was

[49] Human rights in patient care Biomedcentral.com, https://www.biomedcentral.com/collections/phrights (last visited Aug 29, 2021)

the third reason for establishing the right to water as a human right. Articles 11 and 12 of the International Covenant on Economic, Social, and Cultural Rights are mentioned in the title of General Comment 15, and the Committee explains how these two rights (adequate quality of living and health) are "inextricably linked" to the right to water. The Committee connects the right to water to other human rights, such as the right to life, the right to appropriate food, the right to work for a living, and the right to participate in cultural activities. Similarly, the right to basic medications is inextricably linked to the rights to a decent quality of living, education, food, and shelter. The Committee next discusses the normative content of the right to water in terms of availability, quality, accessibility, and information, and pays special emphasis to issues of discrimination and vulnerable groups, following the pattern of earlier general comments[50]. The Working Group on Access to Medicines divided its findings and recommendations into three key categories: availability, affordability, and appropriateness, with quality and crosscutting concerns of human resources and gender thrown in for good measure. In other words, the human right to essential medicines encompasses the entire range of fundamental and connected elements of rights that treaty bodies address in their general comments. The changes recounted in this chapter indicate that the human right to essential medicines has progressed in terms of normative content and legal recognition, yet finding accommodation with the international trade framework and bridging the gaps remains a difficult problem. Find incentives for innovation and cheap pricing, and ensuring the availability of enough human and financial resources to ensure distribution networks, all of which require political will. All of this must be accomplished in order for this right to be useful to the two billion people who now lack access to life-saving drugs.

[50] The human right to medicines - Sur - International Journal on Human Rights Sur - International Journal on Human Rights, https://sur.conectas.org/en/human-right-medicines/ (last visited Aug 29, 2021)

5.3 HUMAN RIGHTS SHOULD BE INCLUDED IN TO DRUG POLICIES BY THE GOVERNMENT

First, concerns to human rights should be highlighted in relation to the national drug control plan. After that, the national plan should be changed to ensure that the human rights of drug users, manufacturers, and traffickers, as well as their (social) surroundings, are protected. The media has a critical role to play in promoting public knowledge about human rights issues and influencing public opinion. The inclusion of human rights in drug policy will be aided by an integrated, balanced strategy based on the notion of harm reduction. In some areas, political courage will be required to take this strategy. It is also critical that law enforcement and the justice system embrace the new approach in order to ensure that punishments are proportionate and that police personnel do not obstruct treatment and harm-reduction efforts. Donor countries must ensure that their funds are not used to finance the upkeep and training of drug detention centres where prisoners are subjected to physical assault, torture, or treatments for which there is no scientific evidence. Donor states must always exercise due diligence to ensure that their assistance does not facilitate human rights violations.

5.3.1 Suggestions for promoting drug control that is based on human rights

A human rights - based strategy implies a straightforward commitment to prioritising human rights over drug policy goals. Make no mistake: this is a highly divisive issue. This hierarchy was

placed into the introduction when the Guidelines were being drafted. It would, according to one reviewer, "kill the document." Votes are gained by being (shown to be) tough on drugs. Furthermore, drug control is a constitutional requirement for several nations. Addiction is considered as a "evil" that nations have a "moral duty to battle" in international law, and drugs are viewed as a threat to the state's very foundations. Human rights are also a challenge to the unchecked authority that such discourse allows. The UN drug conventions' fundamental goal of "protecting the health and welfare of people" is in no way incompatible with international human rights, yet many human rights violations occur in the name of drug law enforcement. Over time, policy innovation has demonstrated that an effective, evidence-based strategy can contribute to human rights protection while also addressing drug-related harm. What's needed is a shift in goals: aiming for high arrest and seizure rates won't help because we already know they have little effect on the drug market. Enforcement will always be one step ahead of the unlawful market. Instead, we should work to lessen the harm that drug use causes to individuals and communities by setting goals for increased service accessibility, lower overdose rates, and lower rates of blood-borne illness infection, as well as a reduction in drug-related violence. The United Nations' drug conventions must be read in accordance with international human rights law. This will minimise any abuses justified under these accords while also increasing legal backing for desirable aspects of them, such as access to vital controlled medicines and the freedom to expand harm-reduction within the conventions. The United Nations agreements do not make drug use or possession for personal use illegal, and they allow national governments to provide alternatives. These solutions should be promoted by the INCB and UNODC. Given the ineffectiveness of criminalization un reducing drug-related harm and patterns of use, it's difficult to see how criminalising personal use or possession constitutes a proportionate infringement of the right to

privacy or the expression of religions or cultures[51]. However, other aspects of the drug treaties, such as the prohibition of certain traditional, cultural, and indigenous activities, cannot be harmonised with human rights legislation. The states that have signed the conventions must resolve these problems[52]. By virtue of their formation under the UN Charter, all UN entities are required to promote human rights. The UNODC provides "technical assistance" in the area of drug control, such as legal guidance, field missions, and magistrate training. The UNODC has released a guidance note describing its plans to promote and preserve human rights. Our task is to fully realise human rights' revolutionary potential in drug policy while being watchful against their subversion.

CHAPTER - 6

LOOPHOLES IN THE EXISTING REGULATIONS

[51] Novartis.us, https://www.novartis.us/sites/www.novartis.us/files/n_int_050236.pdf (last visited Aug 29, 2021)
[52] Ibid.

6.1 INTRODUCTION

If a well-intentioned law contains a loophole, a variety of unscrupulous approaches can be utilised to exploit it. That appears to be the case with a transparency gap that was designed to keep big pharma in check. According to an article published by The Pharmlot View, a four-year-old legislation requiring drug companies to keep track of and disclose meals purchased for doctors, speaking and consulting fees, and clinical trials is being flouted. Over the last half-century, pharmaceutical advances have made it possible to treat and prevent a wide spectrum of ailments. These advancements were so significant in modern healthcare that they were declared to be a fundamental human right. Fulfilling that right has enormous societal value, but due to its expenses, it poses a huge policy issue. In 2017, global pharmaceutical spending totaled $1.135 trillion, up 56% from 2007. Despite the fact that demand for medications is one of the main drivers of pharmaceutical spending, growing costs are a major source of concern for health-care executives since medicines are increasingly being priced at “unfair” levels.

To maximise the societal benefit of pharmaceutical discoveries, policy must encourage the funding of research and development in areas where there is a significant unmet need while also ensuring that the innovations are widely available. Patents, which limit market power for a set period of time, are one approach to encourage research investment while also allowing competition to bring down prices and therefore enhance access. Patents create a "fair" balance in ideal markets characterised by competition between new and old technologies fulfilling the requirements of fully educated consumers confronted with simple consumption trade-offs under

well-defined budget limitations[53]. In the pharmaceutical industry, problems arise because the perfect economic market rarely exists in healthcare, skewing rewards for, and thus investments in, innovation. Because demand for vital drugs is inelastic, the pharmaceutical industry has the ability to misuse its market position. Consumers of copyrighted medicines, commonly known as patients with medical requirements, may not be able to wait for costs to drop like consumers of conventional items. Patients are also often protected from the cost of treatments, unlike regular customers, thanks to various forms of community finance, most notably public or private health insurance[54]. Companies might take advantage of patients' vulnerabilities and group funding schemes by demanding prices that considerably surpass traditional standards of value for money. The profits generated by these inflated prices far outweigh the costs of pharmaceutical research.

The Indian government has implemented a policy aimed at boosting the availability of vital medications at reasonable pricing. In 2011, the government suggested increasing the number of pharmaceuticals covered by the National Pharmaceuticals Pricing Policy 2011 from 74 to 348. This strategy was updated in 2012 to include 652 regularly used medications divided into 27 therapeutic groups. The implementation of this policy is estimated to result in a price reduction of 10% or more for around two-thirds of the critical medications accessible in the Indian market[55]. Establishing a balance between production costs, profitability, and the affordability of the drug for consumers is a difficult issue for a pharmaceutical firm, with the natural temptation to push the aspect of affordability to the back seat in the pursuit of profit maximisation. Large pharmaceutical companies have frequently been chastised for not doing more to promote the

[53] Loopholes in pharma pricing policy @businessline, https://www.thehindubusinessline.com/opinion/loopholes-in-pharma-pricing-policy/article22995282.ece (last visited Aug 30, 2021)
[54] Ibid.
[55] , https://www.researchgate.net/publication/347624228_Factors_Impacting_Pharmaceutical_Prices_and_Affordability_Narrative_Review (last visited Aug 31, 2021)

availability and cost of vital medicines, particularly in poor and developing nations. This criticism is beginning to have fruit, as some pharmaceutical companies, like GlaxoSmithKline and Johnson & Johnson, are stepping up efforts to ensure the availability and affordability of their products in less affluent markets. These efforts are mirrored in the Access to Medicine Foundation's "Access to Medicine Index," which was issued in 2012 and clearly illustrates drugmakers' response to increased popular demand to deliver affordable pharmaceuticals. The endeavours of the pharmaceutical companies cover a wide range of actions, including differential and reduced pricing, technological transfers under licence agreements, and gifts. This criticism is beginning to have fruit, as some pharmaceutical companies, like GlaxoSmithKline and Johnson & Johnson, are stepping up efforts to ensure the availability and affordability of their products in less affluent markets. These efforts are mirrored in the Access to Medicine Foundation's "Access to Medicine Index," which was issued in 2012 and clearly illustrates drugmakers' response to increased popular demand to deliver affordable pharmaceuticals. The endeavours of the pharmaceutical companies cover a wide range of actions, including differential and reduced pricing, technological transfers under licence agreements, and gifts. This occurred prior to the implementation of the National Pharmaceuticals Pricing Policy in 2011, when 27 of the 74 price-controlled medications were withdrawn. In such a case, price control initiatives would be counterproductive.

Inadequacy of access to vital drugs is indicative of deeper issues with the organisation, financing, and delivery of healthcare services. Most poor countries, including India, lack access to medications in the public sector, which is continuously lower than in the private sector. When public-sector drugs are unavailable, patients are obliged to purchase more expensive private-sector medications or forego therapy altogether. Because public healthcare institutions frequently

give drugs at a low or no cost, they are especially crucial for ensuring that the poor have access to medicines. In addition to overall shortcomings in health-care system performance, four drug-related variables must be met in order to ensure that individuals have access to medicines whenever and wherever they are needed. To choose medicines, rational selection processes should be used, based on national or local essential drug lists and treatment guidelines; prices should be affordable by governments, health care providers, and consumers; and impartial and continuous financing for health care medicines should be ensured through adequate funding and unbiased prepayment mechanisms, such as government revenues or reinsurance. Failure to complete any of these processes will jeopardise people's access to medicines. As a result, the problems of lack of access to quality drugs that primarily affect developing countries are low-quality and counterfeit drugs; a lack of availability of essential drugs due to varying production or exorbitant cost; and the need to conduct field-based drug research to determine optimum utilisation and development for new drugs for the developing world.

India is a global leader in the production of generic medications. However, it is also claimed that a substantial population lacks access to basic medicines. The majority of research indicate that the mere presence of a NEML will be mostly ineffective until procurement and delivery systems for essential medicines are enhanced. The importance of NEML implementation in the acquisition of high-quality medications, regular supply, and price regulation, as well as the strengthening of indigenous manufacturing capacity, should be underlined. To improve the trust of the health-care system, vital drugs must be made available on a regular and widespread basis.

Simultaneously, small domestic generic drug producers may be motivated to raise the pricing of their low-cost pharmaceuticals closer to the authorised price-cap level, resulting in an increase in

the average price of drugs. Without a doubt, this would have a severe impact on customers, particularly in smaller communities across the country.

6.2 DRUG PRICING STRATEGIES AROUND THE WORLD: CONTROLLING COSTS

Despite the fact that the expense of pharmaceuticals has been the subject of intense scrutiny around the world, there is little agreement on the best balance between maintaining industry innovation and guaranteeing appropriate access to effective therapies. This special feature examines five case studies from around the world that illustrate various medication pricing strategies and policies. The question is how much we value innovative medications and how much we are willing to pay for them. The solutions to these two questions are frequently diametrically opposed[56]. There is little doubt that medical research advances are of incalculable benefit to society, and that high-quality medicines and healthcare interventions are critical components in improving people's lives all around the world. This value is recognised in the United Nations' (UN) Sustainable Development Goals, which include a target to offer "access to safe, effective, quality, and affordable essential medicines and vaccinations for everyone" as part of the third objective to ensure healthy lives and promote well-being for all[57]. It has not been easy to provide widespread access to current medical innovations anyplace on the planet. Even in the wealthiest countries, finding a balance between rewarding creative drug makers and meeting the demands of budget-strapped health systems is a hot topic of debate, whether strong government-level pricing controls are in place, as in the UK, or a more free-market approach, as in the US.

[56] Cost control: drug pricing policies around the world Pharmaceutical-technology.com, https://www.pharmaceutical-technology.com/features/cost-control-drug-pricing-policies-around-world/ (last visited Aug 31, 2021)
[57] Ibid.

The stakes are much higher in underdeveloped nations, where medications can account for up to 60% of healthcare costs and the vast majority of individuals pay for prescription drugs out of pocket. The dearth of widely available novel treatments has a significant influence on public health. According to the World Health Organization, developing cohesive national pricing policies that best serve the health of a country's people while maintaining a healthy economy is a critical strategy of increasing access. On its website, the UN health agency stated, “Strategies for measuring, monitoring, and regulating pricing are vital for improving access to medicines.” “There isn't a single solution that works for all systems. However, all systems must encourage equality in new product access by ensuring that medical innovations are accessible and collaborating with a viable pharmaceutical business that responds to public health needs.”

6.2.1 The Patent Act and DPCO (Drug Price Control Order)

The All India Drug Action Network (AIDAN) filed a suit in the Delhi High Court challenging the Drug (Prices Control) Order 2013 and the Drug (Prices Control) Amendment Order, 2019. The precise allegations concerned DPCO 2013's paragraph 32, which is the list of exemptions, and the 2019 Order's revision to it. Paragraph 32 of the DPCO 2013 exempts new pharmaceuticals patented under the India Patents Act, 1970 from price restriction, creating an unprecedented relationship between the Patents Act and drug costs. This post outlines the petition and explores the implications of patented medicine price control systems[58].

While the 2019 DPCO revisions came after the NITI Aayog suggested exempting price limits for some categories of medications, the Department of Pharmaceuticals (DoP) moved autonomously

[58] A_comparision_between_old_and_latest_systems_in_DPCO,https://www.researchgate.net/publication/263657518 (last visited Aug 30, 2021)

in making changes to the Order. These revisions surprised everyone, even the NITI Aayog, because there was growing concern about the affordability of life-saving drugs, and this move actually makes price control more difficult. While the DoP made this modification, the NITI Aayog appears to be taking over the regulation of pharmaceutical prices in the country. While the NITI Aayog's specific role as a policy think tank remains unclear, its recommendations skew the balance between industrial expansion and healthcare access while pretending to strike the perfect balance. Furthermore, the establishment of the Standing Committee on Affordable Medicines and Health Products (SCAMHP) significantly erodes the NPPA's jurisdiction to control medication prices, which is already being eroded by the DPCO.

Apart from the inconsistency between these clauses, the petition indicates that the narrow language of DPCO 2013 and 2019 makes it unclear how this exemption connects with the 20-year patent period granted by Section 53 of the Patent Act, 1970, or why a connection was made at all. While previous DPCOs included limited exemptions and the government retained the authority to grant them, the 2013 and 2019 Orders make no mention of this.

According to the petition, there is no reason for linking the Patent Act and the DPCO. This relationship is unprecedented and goes against the DPCO, NLEM, and NPPP's policy instructions[59]. The question is whether or not the policy is intended. The purported link between the exemption and innovation is debatable, as it appears archaic in a vibrant and highly competitive drug market like India. Only the NPPP mentions competitive medicine pricing in order to broaden options and stimulate innovation among these three strategies. Even still, the connection between the Patents Act and DPCO remains a mystery.

[59] Delhi HC Issues Notice on Petition Challenging Price Control Exemptions for Newly Patented Drugs SpicyIP, https://spicyip.com/2020/02/delhi-hc-issues-notice-on-petition-challenging-price-control-exemptions-for-newly-patented-drugs.html (last visited Aug 30, 2021)

However, with the National Pharmaceutical Pricing Authority (NPPA) lately investigating cases of pharma corporations self-invoking Paragraph 32 of DCPO 2013, it would be interesting to see what additional regulatory recommendations are provided.

The DPCO increases the pressure on MNCs in terms of pricing determination, which aids domestic firms in doing research. DPCO controls the prices of many of the MNC's patent branded pharmaceuticals. The Drug Price Control Order is an initiative launched by the Government of India to protect people's health and the profits of Bulk Drug makers. It has controlled and covered practically all sectors of the pharmaceutical industry[60]. Under this Order, the National Pharmaceutical Pricing Authority has played a critical role. It has said unequivocally that it is the responsibility of the government to develop drugs that are both lifesaving and cheap to the general public. However, the influence on the industries might also be taken into account by this Order, both in the long and short term. This would have a significant impact on small businesses and result in market segment losses for giant corporations. However, the Drugs Price Control Order of 2013 would help the industries grow and become more cost-effective in the coming years.

6.2.2 According to health experts, drug price rules are skewed in favour of the pharmaceutical business.

Two recent reports have claimed that drugs are still not accessible and inexpensive for inhabitants of the country, indicating failure of the National Pharmaceutical Pricing Policy (NPPP) of 2012 and the Drugs Price Control Order (DPCO) of 2013. The Public Health

[60] Drugs Price Control Order (DPCO) Lexlife India, https://lexlife.in/2020/04/21/drugs-price-control-order-dpco/ (last visited Aug 30, 2021)

Foundation of India (PHFI) and the Institute for Studies in Industrial Development, both situated in Delhi, produced research that pointed to regulatory inadequacies in drug pricing. According to one of the papers, "Drug Price Ceiling," DPCO coverage is currently limited to just around 17% of the pharmaceuticals prescribed and promoted in the country. As a result, roughly 82 percent of medicines are not covered by the programme, resulting in excessive prices. "Clearly, the pharmaceutical industry's interests have taken precedent above the interests of patients," the report states[61]. The second study, titled "Access to Medicines," expressed worry about medicine pricing and illogical use. The findings collectively show that, despite being the "pharmacy of the global south," India has created a system in which its own inhabitants must pay exorbitant prices for pharmaceuticals.

6.2.3 Prescriptions and usage that are irrational are a source of concern.

The irrational use of drugs is a major worry, according to the second study, "Access to Medicines." "Not only are dangerous and inessential drugs produced and sold in the country, but irrational prescription, dispensing, and use of these medicines is also widespread," the research states. It also points out that, despite being one of the world's leading vaccine producers, India has the highest child death rate. This is owing to the Universal Immunization Program's ineffective outreach (UIP)[62]. Furthermore, non-UIP vaccinations and combination vaccines are effectively sold to the general population by private pharmaceutical companies. “DPCO does not regulate combination vaccines and medications (which comprise two or more active

[61] Drug pricing policies bent to favour pharma industry, allege health experts Downtoearth.org.in, https://www.downtoearth.org.in/news/drug-pricing-policies-bent-to-favour-pharma-industry-allege-health-experts--43721 (last visited Aug 30, 2021)

[62] Medicines Affordability and Pricing Who.int, https://www.who.int/teams/health-product-and-policy-standards/medicines-selection-ip-and-affordability/pricing-financing (last visited Aug 31, 2021)

pharmacological ingredients).” “This has become a way for producers to avoid legal entanglements in setting prices for their products,” Selvaraj explained. In India, fixed dose combination medications account for nearly half of all drugs. Though specific figures are unavailable, the figure is usually between 5% and 12%[63].

6.2.4 Drug companies take use of legal loopholes to protect their brand names.

According to a report by the National Institute for Health Care Management, drug corporations are utilising legal loopholes to extend patents for their most valuable brand-name drugs and postpone the arrival of cheaper generics into the market.

According to the paper, intellectual property laws introduced over the last two decades have increased the average patent life of new pharmaceuticals by at least 50%. Patent protections were supposed to encourage innovation, but they have resulted in higher pricing for consumers and larger profits for brand name manufacturers. Patents for brand-name medications now last an average of 14-15 years, up from eight years in the early 1980s. According to the research, drug firms have taken use of legal loopholes to extend the active life of patents covering their most profitable drugs, preventing cheaper generics from entering the market. “Congress has passed a lot of legislation, all of them well-intentioned, but they've been a huge bonanza for the pharmaceutical industry,” said Nancy Chockley, president of the non-profit organisation that put together the report. “The current system appears to be out of balance, and it is costing the United States billions.”

[63] Ibid.

The report was harshly criticised by the Pharmaceutical Research and Manufacturers of America, the leading industry trade body. “The sponsors' self-serving aim is to lower patent terms for medications to save money for themselves,” the report's president, Alan Holmer, said, citing the fact that the non-profit group sponsoring the report receives some funding from managed care corporations. The research is released at a time when Congress is debating ways to reduce prescription costs, particularly for the elderly and those without insurance.

6.2.5 The patent system is being abused, resulting in excessive drug prices for people.

The patent system exists to protect innovators' intellectual property. Some brand-name drug corporations, on the other hand, frequently try to patent characteristics of drugs that aren't truly innovative. Some companies try to bury generic and biosimilar medicine competition indefinitely by repackaging previous inventions in later patents. Because of the costly expense of challenging meritless patents, these "patent thickets" stifle competition by deterring rivals from joining a market[64]. Another challenge that generics and biosimilars researchers face is that some brand-name pharmaceutical businesses often maintain patents in reserve. This strategy allows them to threaten generic and biosimilar businesses with legal action, perhaps resulting in significant damages liability later on. Congress may pass legislation requiring brand drug corporations to assert all relevant patents as soon as possible, allowing generic drug and biosimilar medication producers to cut through the patent tangles more quickly.

[64] Abuse of the patent system is keeping drug prices high for patients | Association for Accessible Medicines Accessiblemeds.org, https://accessiblemeds.org/campaign/abuse-patent-system-keeping-drug-prices-high-patients (last visited Aug 30, 2021)

CHAPTER – 7

RECOMMENDATIONS AND SUGGESTIONS

The Indian government research group NITI Aayog's Three Year Action Agenda (2017-18 to 2019-20) made an important observation: "A balanced approach to regulation is essential to achieve the twin objectives of access to medicines and a thriving pharmaceutical industry." There is a trade-off between cheaper prices and quality medicine and breakthrough drug discovery on the one hand. As a result, Drug Price Control Orders should be separated from the National List of Essential Medicines[65]." This indicates that policymakers are aware of the constraints that private healthcare providers, such as pharmaceutical companies, face.

Pharmaceutical companies are testing various funding options to see if they might reduce the cost of pharmaceuticals and medical devices for patients. In the case of a developing country like India, some policy ideas for ensuring medicine affordability without jeopardising future innovations might include-

- Patented drug costs should be determined through price discussions by the regulator. It's possible that this is based on the market pricing of similar patented pharmaceuticals in other countries, which is a standard procedure in many countries. Prescription medicine costs in the Netherlands, for example, have been based on wholesaler pricing in Belgium, France, Germany, and the United Kingdom since 1996.

- The use of reference pricing is a possibility. The regulator should establish a reference price, which is a price above which customers will not be compensated for drug costs. Bundled pricing, also known as the Diagnostic Related Grouping (DRG) method, has

[65] Pharmaceutical price regulation and its impact on drug innovation: mitigating the trade-offs Taylor & Francis, https://www.tandfonline.com/doi/full/10.1080/13543776.2021.1876029 (last visited Aug 30, 2021)

become the norm in various nations. This concept provides a set payment amount for a procedure that an insurance company will make to a hospital. For reimbursement purposes, this method classifies probable diagnoses into more than 20 major body systems and subdivides them into about 500 groupings. Hospitals make money if they spend less than the DRG, and they lose money if expenses rise.

- Many governments are implementing medication regulations and price limits as a policy tool. RAND (2008) evaluated pharmaceutical industry rules and their impact on industry revenue in 19 countries (OECD and USA) from 1992 to 2004. It shown that not only did rules exist in these countries previous to 1992, but that several of them even created new legislation. As a result, controls on the pharmaceutical business are found to be the standard rather than the exception among countries, while the strength and scope of laws vary.

- The supply of suitable human resources is a key necessity for ensuring the availability and accessibility of important medicines. At various referral levels, sufficient numbers of qualified and competent health care clinicians and technical health care employees should be recruited.

- Increase generic drug production promotion and reduce barriers to uptake.

- For vital drugs, generic substitution plans are being implemented. It is critical to speed up the implementation of a scientifically sound system of generic medicine interchangeability, which would make it easier to implement comprehensive policies to promote the use of generic medicines.

- Ensure that critical drugs are readily available in public health care facilities.

- When deciding whether or not to include a drug in a benefit package offered by the National Health Insurance, the government, or commercial insurers, or when setting the level of payment, economic evaluation must be taken into account. New Zealand, for example, has employed cost-utility analysis (which measures the cost per quality adjusted life year) as a key analytical technique in its medication subsidy administration[66].

- Medicines policy of a Country has to be updated.

- It's also crucial to consider the difference between in-patient and outpatient treatment expenditures. Hospitalization costs are frequently the source of ballooning hospital bills, and these must be considered when determining price ceilings. Increased health literacy and self-care awareness can considerably aid in the prevention of noncommunicable chronic diseases such as heart disease, cancer, and diabetes. Because OTC (Over-the-Counter) drugs are essential for self-care, they are not subject to price limits in most countries. The Indian government is also being requested to lift price limitations on OTC medicines and allow manufacturers to determine their own rates for non-prescription

[66] Ibid.

drugs that are not paid based on market conditions. More businesses will enter the market and invest as a result, assuring the supply of OTC drugs, proper pricing competition, and future innovation.

- Policymakers may also want to consider e-linking R&D expenses to the drug's final price. This can be accomplished through a government-funded arrangement in which corporations are rewarded for bringing a new medicine or formulation to market.

- In order to combat neglected diseases, innovation must be fostered. The pharmaceutical industry should be rewarded for researching and treating neglected diseases. This will reduce the prevalence of diseases that are costly to the economy.

- Consumers would benefit in a clear and concrete sense if drug prices were negotiated and unreasonable price increases were limited. Furthermore, these reforms would begin to address long-standing health inequities, such as the increased likelihood of complicated medical needs and differential pharmaceutical access for women, people of colour, and persons with disabilities. The impact of lower drug costs would be felt at the pharmacy, in premiums and out-of-pocket expenses, and, eventually, in people's health and well-being.

- The issue of healthcare access must be addressed through true Public-Private Partnerships, which assist the health sector in leveraging both the big state sector's assets and the cutting-edge technologies that the private sector delivers.

- Finally, countries should collaborate and encourage the exchange of knowledge concerning policies and their effects on pharmaceutical pricing.

Essential medication prices are regulated by the central government in India under the Essential Commodities Act of 1955. The goal of price caps is to make pharmaceuticals more affordable and available to everyone. This is essential since a substantial portion of the Indian population finds it difficult to afford pharmaceuticals, which account for a significant portion of out-of-pocket healthcare spending. The National Pharmaceutical Pricing Authority (NPPA) was established in 1997 with the mission of fixing or revising pharmaceutical product prices, enforcing the DPCO (Drug Price Control Order), and monitoring the pricing of controlled and decontrolled pharmaceuticals. DPCO now has a list of 851 medication formulations that can have their pricing restricted. This policy only applies to a certain dosage. The average price for all brands supplying a certain drug with more than 1% market share is the ceiling price. If a drug's price is below the ceiling price, it can only be raised after a year. Patented medications and fixed-dose combination (FDC) pharmaceuticals, however, are exempt from this provision.

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