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BRIDGING HEALTH DISPARITIES: A COMPARATIVE STUDY OF ACCESS TO GENERIC DRUGS IN SPECIAL REFERENCE TO INDIA AND VIETNAM, WITH FOCUS ON COVID-19, AIDS, AND CANCER

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ABSTRACT

According to the World Health Organization, approximately 2 billion people lack access to essential healthcare services. This alarming statistic highlights the urgent need for global action to address health disparities. Nations must therefore collaborate to develop sustainable solutions that ensure equitable access to healthcare, particularly for marginalized and under served populations. The study further confirms that health inequities are exacerbated owing to the limitations of advanced healthcare technologies with significant gaps in infrastructure and skilled workforce. The Indian situation indicates that innovative solutions to address the increase in cancer rates are critically required, yet high costs restrict access to advanced treatments like immunotherapy. Similarly, in Vietnam, the lack of quality pathology labs and limited availability of radiation therapy centres further complicate cancer care. The study advocates for a multifaceted approach, including enhanced distribution of generic drugs, financial support for research, and policy reforms to ensure equitable healthcare access, collectively aimed at bridging the gap in health disparities in both countries.

Keywords: *Health disparities, Generic drugs, Cancer care accessibility, India, Vietnam, Intellectual property rights*

I.INTRODUCTION

The various diseases that have surged in recent years encouraged several shifts in the global health landscape including COVID-19, AIDS, and cancer. These health crises continue to overwhelm the healthcare systema and facilities, and have also further intensified systematic health inequities, especially in low- and middle-income countries. Access to essential medications, especially generic drugs, is crucial for effective disease management and prevention[1].As such, in this study, the investigation of these facets of regulatory frameworks, healthcare system, and socio-demographic factors-influencing access to medications, was aimed at yielding findings that can inform policy reforms and improve health outcomes for vulnerable populations.

A. Background

Health disparities relate to variations in health outcomes as well as the affordable and readily availability access to quality healthcare services among different population groups. It is therefore observed that these disparities depend on socio-economic factors, geographic location, and systemic inequalities within healthcare systems[1)]. In the context of India and Vietnam, significant disparities exist in access to cheap and generic medicines that play a crucial role in the treatment of various chronic diseases as well as in the prevention, control and management of public health emergencies. According to the World Health Organization (WHO),the use of generic medicines is crucial for achieving universal health coverage while also simultaneously reducing health inequities[2]. However, several challenges hinder the effective distribution and utilization of these medicines in both countries.

The Indian pharma industry faces a multifaceted and restrictive regulatory environment, which leads to delays in drug approvals particularly pertaining to market entry for new generic products. However, many a times the cost of the branded medicines are prohibitive and this leads to many patients seeking alternatives from other sources, while the supply of quality generics remains inconsistent. For instance, in Vietnam, though the government seems to have devised ways of enhancing access to generic medicines, issues such as; lack of sufficient facilities, poor awareness of the generic options, and restrictive regulatory framework, present themselves as barriers. These

factors contribute to a cycle of health inequity, whereby the vulnerable groups continue to suffer from the effects characterized by inability to access affordable medications.

B. The Impact of COVID-19, AIDS, and Cancer on Healthcare Access

The current landscape of healthcare access has been worsened by the COVID 19 pandemic, and has further revealed vulnerabilities in health systems worldwide[3]. Ideally, both in India and Vietnam, the pandemic has strained the health care system; and shifted focus away from other acute health matters; and disrupted the global chains thus leading to adversely affecting the availability of essential medications in the markets[4]. The emphasis on dealing with COVID 19 has resulted in delaying the resources and efforts dedicated to other diseases, including AIDS and cancer, which require ongoing care and access to medications. The convergence of these health crises is a clear indication that there is need to have strong health policies that will provide equality in access to medications.

AIDS continues to be an important public health issue in both countries as millions of people continue to get affected and need antiretroviral therapy (ART) to manage their conditions[5]. It is important for people to note that access to generics versions of such vital life-saving medications is important if the treatment must be followed strictly[6]. Nevertheless, fear of stigmatization, discrimination and the general poor health care facilities puts a damper on the availability of ART particularly in the rural areas level[7]. Similarly, cancer care in India and Vietnam has issues like expensive care and treatment, restricted availability of specialized services and lack of awareness about the generic cancer medications. It is vital to search for new solutions in oncological treatment due to the fact that it combines variables that complicate the issue of access to affordable treatment[8].

C. Objective of the Study

i. To Analyze the Regulatory Frameworks Governing Generic Drugs

One of the main research questions of this study is to evaluate the regulatory framework of generic drugs, especially concerning the approval and distribution of generic medicines in India and Vietnam. The existent policies and regulations must be comprehensibly examined to identify the gaps and areas for improvement. This analysis will consider the various procedures that are associated with the approval of drugs, the specific role of National Drug Authorities and the impact of Intellectual Property Rights on the availability of generic medications in a country. By analysing these factors, the study aims to provide potential recommendations for improving the regulatory environment for the promotion of generic drugs access.

ii. To Assess the Socio-Economic Factors Influencing Access to Medications

Another significant aim is to evaluate the socio-economic factors regarding the accessibility of the medications in both countries. This encompasses the analysis of effects brought about by income, education, and geographic distribution on access to essential medicines. The study will explore how these factors contribute to health disparities and identify potential interventions to address them. The policymakers thus ideally should develop targeted strategies to improve access to generic drugs for vulnerable populations.

iii. To Evaluate the Role of Healthcare Infrastructure in Medication Access

The study also aims to evaluate the role of healthcare infrastructure in facilitating or hindering access to medications. These include an evaluation of the distribution of the healthcare facilities, health personnel, and the systems of procuring and delivering health commodities. Poor infrastructure plays a role in long and erratic medication delivery, stock shortages as well as poor health. The study aims to compare the healthcare infrastructure in India and Vietnam with an intention of discovering how access to generic drugs may be improved by pointing out the areas of strength and weaknesses of the respective health systems.

iv. To Propose Policy Recommendations for Improving Access to Generic Drugs

Finally, this study seeks to provide recommendations that can enhance access to generic drugs in India and Vietnam. Such recommendations are expected to stem from the outcomes of the paper's analysis of regulatory frameworks, socio-economic variables, as well as healthcare facility development. As a result, the study seeks to contribute to the ongoing efforts to reduce health disparities and promote equitable access to essential

medications. The recommendations will be focus on enhancing regulatory processes, increasing awareness of generic options, and strengthening healthcare systems to ensure that all individuals have access to the medications they need.

Thus, the issue of accessibility to generic drugs is a paramount concern that defines the health prospects in India and Vietnam, and which becomes more paramount in the presence of contemporary chronic diseases that include COVID-19, AIDS, and cancer. This study aims to shed light on the challenges and opportunities related to access to medications, with the ultimate goal of informing policy reforms that can improve health equity. Thus, it is possible to work towards a more equitable healthcare system that ensures equitable opportunity for every individual to receive the care they need by addressing the regulatory, socio-economic and infrastructural barriers to access.

II.LITERATURE REVIEW

A. Historic Context of Generic Drugs: Evolution and Impact of Health Disparities

The history of generic drugs can be traced back to 1950s when use of thalidomide by pregnant women to treat morning sickness resulted in tragedy. The incident led to the development of strict regulatory changes for approving generic drugs. The Hatch-Waxman Act passed in the USA in 1984 with an objective of promoting generic drugs provided huge growth in the development of generic industry. Thus, in the countries like USA, UK, Netherlands etc., generic drugs got popular due to high pricing freedom given to branded drug manufacturers. However, in mid and low-income countries, generic drugs gained popular quickly due to extremely cheap prices. Generic drugs played an instrument role in ensuring health equity by providing affordable alternatives to branded drugs. Thus, generic drugs gained momentum at different time in different countries but they shared a common objective of ensuring access to healthcare at a cheaper rate.

B. Global Health Disparities

As per the WHO, developing and underdeveloped countries account for 90% of the global burden of diseases with merely 12% of global spending on health. Most of the Asian and African countries are struggling to provide basic healthcare facilities and more than 60% of the spending is done from out of pocket. Socio-economic factors such as poverty, lack of education, lack of government funding for healthcare etc. contribute to health disparities. Just as disparities exist at a global level, it exists within the countries, with poor, minority and marginalised being most deprived. Thus, to reduce health disparities, effective intervention is required from the states by forming policies based on a multifaceted approach comprising clinical care, health promotion, workforce education and research.

III.ACCESS TO GENERIC DRUGS IN COVID-19

A. Overview of the Global Response

The sudden occurrence of the black swan event i.e., COVID-19 left everyone in shock. A sudden rush in the market caused by the panic led to a huge shortage of health products such as generic medicine and vaccines **(1)** which caused huge challenges in ensuring equal access to healthcare products and vaccines in all countries **(2).**

1. Vaccines and Treatment

In 2020, due to the sudden effect of COVID-19, deaths began to multiply coupled with the fact that the global supply chain of drugs got disrupted. Initially, countries all over the world witnessed huge competition due to scarcity of drugs, stockpiling of generic drugs and export bans. For example, in the first phase of COVID-19, generic drugs such as paracetamol and morphine were used for treating people with COVID-19 months. However, within two months of the occurrence of COVID-19, the countries witnessed a shortage of adrenaline, insulin, paracetamol and morphine. Countries like the United Kingdom, Austria etc. were forced to ration these generic drugs to one packet per person[9]. Medical systems in all the countries including the United States, India, Italy, Vietnam etc. faced shortages of essential commodities such as ventilators, oxygen cylinders for critically ill patients and Personal Protective Equipment (PPE), N-95 masks, sanitisers etc for medical professionals. The situation is worst in mid and low-income countries[10]. The WHO survey stated that almost 10 African countries did not have

a single ventilator or mask to fight against COVID-19. In countries like Mozambique, Ethiopia, Kenya and Zimbabwe only 35-50% population had access to COVID-19 health products[11]. War-affected countries like Libya, Sudan, North Korea saw the devastation in the pandemic due to the lack of basic testing kits for diagnosing COVID-19[12].

Talking specifically about vaccines, the high-income countries paid huge sums of money in advance to manufacturers such as Serum Institute of India and Pfizer for purchasing 80% of the production. The high cost of the vaccine made it impossible for low-income countries to buy the vaccine. Further, the manufacturers did not also prioritise them because of bulk orders they got from high-income countries, thereby further aggravating the situation in low-income countries.

2. Challenges in distribution and accessibility

As discussed in the previous section, countries all over the world witnessed competition over scarce medicines, stockpiling of generic drugs and export bans. Thus, various nations such as the US passed the Defence Production Act to ban the export of generic drugs and health equipment' required during the COVID-19[13]. Studies have indicated that if vaccines were distributed equally among all the nations in 2021, the healthcare system could have prevented 6,00,000 deaths. Some of the major reasons for the uneven distribution of vaccines across the countries include:

- **Financial divide**: High Developing Countries entered into advance agreements with the vaccine manufacturers for the purchase of the dosages which led to the unfair distribution of vaccines among different countries. They gave advanced orders of about 4.2 billion vaccine dosages which constituted 70% of the total dosages available in 2021. Over 80% of the Pfizer vaccine dosages were bought by the US, UK, Australia, Japan, etc[14]. Further, even if the vaccine dosages were available, they were highly-priced. This made it impossible for low-income countries to afford vaccines. For example, Pfizer's vaccine was priced at $39 per course, and Moderna's vaccine was priced at $64 to $74. Thus, we must say that the affordability of the vaccine became a huge issue for low-income countries, thereby increasing health disparities.
- **TRIPS as a barrier:** Developing the COVID-19 vaccine involved huge financial resources. Therefore, the vaccine was first developed by the multi-national pharmaceutical companies in high-income countries due to the huge financial support by the government. Most of the pharmaceutical companies filed an application for patent. Granting patents means companies can charge higher prices to recoup the cost of research and development, thereby making it difficult for mid and low-income countries to afford vaccines. Further, mid and low-income countries faced a shortage in developing vaccines due to the accumulation of resources in high-end countries. Therefore, countries like India and South Africa put forth proposals at the World Trade Organisation meeting for waiver of the TRIPS Agreement about COVID-19 vaccine to ensure the availability and accessibility to all nations[15]. Since most of the vaccine manufacturers belong to High-Income countries, such a proposal was strongly opposed by high-income countries such as the US, UK, Switzerland, Norway, Australia etc. Later on, the US and the UK agreed for the waiver of the Intellectual Property Rights for the COVID-19 vaccine and WTO passed TRIPS waiver of IP rights for COVID-19 vaccine.

B. Comparative Analysis

In this section, the author attempts to make a comparative analysis of the policies adopted by Vietnam and India in ensuring healthcare equity during COVID-19.

1. Policies and strategies adopted by the healthcare system

India

The government introduced the liberalised pricing and accelerated COVID-19 vaccination strategy to ensure that testing facilities and vaccines are available to all sections of society. The government ensured the participation of the private sector to ensure better allocation of COVID-19-related facilities. On March 21, 2020, the central government released a guideline wherein testing facilities provided by private hospitals were capped at Rs. 4500[16]. Further, the government made it mandatory that vaccine manufacturers had to supply 50% of the production to the government of India[17]. The companies are free to supply the remaining 50% of the dosages to any state government or non-government bodies. Further, the government monitored the prices charged by private hospitals for vaccines and stated that private bodies can charge up to Rs. 250 per dosage.

Vietnam

Like most countries, Vietnam also took active steps to develop its vaccine to reduce reliance on any other country. The Ministry of Health took various measures to implement vaccination activities. Initially, they identified 11 priority groups for vaccination. Till September 2021, only 32% of the population was vaccinated[18]. However, due to the rising COVID-19 cases, the government recognised the right to vaccine as a fundamental right and started an extensive vaccination campaign wherein 100% population above age 18 received at least one dose of vaccine by 2021[19]. The success in Vietnam was attributed to the government's quick decision to promote technology transfer for research. Further, the Vietnam government also ensured that vaccines were distributed equally among all provinces with priority given to those provinces that were the centre of the epidemic. The Ministry in collaboration with Meta Corporation also organised various campaigns to create public awareness on vaccination.

2. Success and failure in ensuring access

India

We must say that the government took various measures to boost domestic production of the COVID-19 vaccine. The government invested huge financial resources in research and development conducted by Serum Institute, Bharat Biotech etc. in developing vaccines. Even though India took various initiatives to ensure access to vaccines, it failed to tackle the needs of the 130-crore population. The failure of the government to ensure the availability of vaccines in every part of the country is attributed to the restrictive stance of the government in promoting the production of home-grown vaccines through compulsory licensing. In the press release dated May 27, 2021, the government made it clear that the manufacturing of vaccines will take place only by 6 companies under the coordination of Dr Reddy's Lab and supervision of government supervision[20].All the talks with Bharat Biotech and other companies also took place under government supervision. Thus, the government ensured that domestic production of the vaccine took place only by government companies or under government supervision. The government specifically denied the use of the provision of Compulsory licensing under Section 84 of the Indian Patents Act, of 1970[21]. Such a stance of the government was contrary to its request made before the World Trade Organisation for waiving TRIPS for COVID-19 medicines. The decision of the government to restrict the production of homegrown vaccines that are Covaxin and Covishield to two companies proved counter-productive due to the huge shortage of medicines[22]. Thus, it becomes imperative for the government to take immediate steps to promote the manufacturing of vaccines by entering into **compulsory licensing agreements** with other manufacturers. This is one of the best possible ways through which the government can tackle the vaccine shortage at a wide scale.

Vietnam

Like various developing and under-developed countries, Vietnam faced various challenges such as corruption in healthcare due to hoarding of medical equipments' such as masks, sanitisers, ventilators etc. and high prices of vaccines at the international level etc. However, Vietnam set a huge example to developing and underdeveloped countries for successfully tackling the COVID-19 situation through its effectively and timely policies. Vietnam's success in handling COVID-19 is attributed to the early information received during the first phase of COVID-19. However, in the second phase, when the situation went out of control, the government formed effective policies to increase vaccination. Further, the Vietnamese government is not hesitant to adopt compulsory licensing policies if the need arises, as the government was ready to adopt the same during the 2005 bird flu crisis[23]. However, fortunately, the government was able to meet the vaccination needs through its effective policies.

IV.ACCESS TO GENERIC DRUGS IN AIDS

A. Historical Perspective

The first case of AIDS was reported in the 1930s in animals in West Africa. In 1981, the first case was reported in human being in the USA and the disease was informally known as gay plague. However, awareness about AIDS/HIV gained momentum in 1985 when the first international conference on AIDS took place in the USA[24]. Initially, the treatment of AIDS was restricted to high-income countries or richer sections of society. As scientific

advancement took place, governments all over the world took the initiative to develop antiretroviral medicines to increase their availability.

1. Role of Generic Drugs

With the growth of the generic sources supplying antiretroviral medicines, the developing and underdeveloped countries witnessed growth in AIDS/HIV treatment. The primary reason for accelerating such growth is based on the fact that generic anti-retroviral medicines are cheaper than originator medicines. Over a while, enormous development took place in the research on antiretroviral medicines. In 1987, the first drug zidovudine was developed to treat AIDS/HIV. Thereafter, many more drugs such as NRTI, NtRTI, NNRTI, protease inhibitors, integrase inhibitors etc. have been developed to increase the reach of medicines to low and middle-income countries as well[25].

2. Progress made and remaining challenges

Till 1996, only 13% of the total patients who needed highly active antiretroviral therapy were able to afford it. However, the scenario changed drastically with the development of generic medicines in the 2000s. As per the WHO report, generic drugs for HIV/AIDS saved around 4.8 billion people in 2020 and33.7 billion in the last 10 years[26].The absence of intellectual property claims in generic drugs also resulted in the advancement in the manufacturing of antiretroviral drugs through technology transfer to developing and underdeveloped countries. The availability of generic drugs helped in transitioning AIDS from a deadly disease to a manageable disease. However, there are certain challenges due to which the accessibility of antiretroviral drugs in mid and low-income countries is still a question. Studies indicate that transmission of AIDS/HIV is mostly concentrated in people who are addicted to drugs, involved in homosexuality, prostitutes, transgenders, refugees and prisoners in mid and low-income countries[27]. Providing access to treatment to these sections of the society becomes an issue due to the state laws that criminalise, discriminate and stigmatise these sections of the society. Apart from the structural barriers, the cost of antiretroviral is still high and people have to purchase from the private market in middle and low-income countries. Thus, the affordability issue for AIDS/HIV is not yet resolved fully.

B. Comparative Analysis

In this section, the author attempts to make a comparative analysis of the affordability and availability of antiretroviral medicines **(1)** and their impact on healthcare disparities **(2)** in India and Vietnam.

1. Affordability and availability of antiretroviral drugs

India

Till 2000, antiretrovirals were not accessible to more than 5.13 million people due to the high cost associated with it. Considering the pathetic situation of AIDS treatment, Indian manufacturers played an exceptional role in providing antiretroviral drugs patients across the world at affordable prices. In 2008, the reports suggested that 96 of the 100 countries were purchasing generic antiretroviral drugs from Indian manufacturers[28].

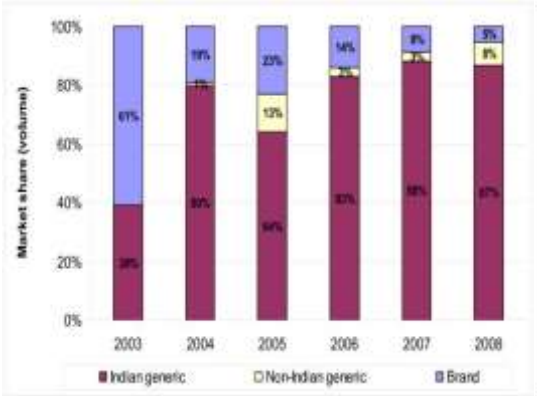

Image 1[29]

Image 2[30]

As we can see from the images, the demand for Indian antiretroviral drugs increased exponentially. Such a move was possible because Indian manufacturers were able to bring down the cost of the drug to one-tenth of the

originator prices at the global level. Further, the absence of patent claims for generic drugs also helped in developing improved versions of antiretrovirals at cheaper rates. The government also took a progressive step in promoting technology and information sharing to mid and low-income countries to avoid the risk of non-availability of antiretrovirals due to limited resources.

Vietnam

In 2003, every province of Vietnam reported AIDS cases, with the greatest number of cases in provinces like Quang Ninh, Ho Chi Minh City and Hanoi. In Vietnam, 50-60% of the total reported cases occur in drug-injected people, people involved in homosexual activities, prostitutes, etc[31]. Despite the huge number of cases in Vietnam, antiretroviral therapies were not easily available in Vietnam. The government primarily relied on international funding for the antiretrovirals due to the lack of domestic funding for the government to promote antiretrovirals. In 2003, the government provided antiretrovirals to only 50 people at $5000 per person per year, thereby making it unaffordable for the middle and poor sections of society[32]. To boost production, nine antiretrovirals were registered in Vietnam in 2004, but most of them were imported, thus making it unaffordable for the poor section of the society. Till 2007-8, only one domestic company manufactured antiretrovirals, and it was not able to fulfil the demand. Even though the price of domestically produced antiretrovirals is lower than that of imported dosages, it is higher than the average price of generics available in the international market. Therefore, to make antiretrovirals more accessible, the government of Vietnam took a major step in 2022 by including HIV under Social Health Insurance. Such a measure has significantly boosted the availability of antiretrovirals to almost 60-70% of the population[33].

2. Health Disparities

India

As we discussed in the previous section, we must say that India played an important role in ensuring the accessibility of AIDS medicine at a global and national level by providing cost-effective products post-2000[34]. Despite being the market leader of generic drugs in the pharmaceutical industry, news reports indicate that some states have faced acute shortages of antiretroviral medicines at public healthcare centres in the last few years. Some of the factors that contributed to the shortage include non-participation of drug manufacturers such as Cipla in government tenders due to delay in payment, black marketing of the antiretrovirals, corruption at the hospital levels, selling of antiretrovirals to private entities at a higher price by the government entities etc[35].
As we all know, more than 40% of the population in India belongs to the poor strata of society[36]. Therefore, the artificial shortage of dosages created internally due to internal factors aggravated the health disparities as people could not afford to buy antiretrovirals from the private sector. Thus, there is an urgent need for the government to take steps to ensure better availability of antiretrovirals.

Vietnam

As discussed in the previous section, the affordability of antiretrovirals was a big issue in Vietnam due to which it was available only to privileged people in the country. Even if antiretrovirals were available, people were reluctant to use them because of the low education rate, lower income, and social stigma attached to AIDS[37]. All these issues created significant barriers in providing timely access to HIV treatment to poor strata of society that are more prone to disease due to social factors such as lack of sanitation facilities, low living standards, etc.
Thus, the government of Vietnam needs to promote domestic production of drugs to make it accessible and affordable. The government should increase the import or production of generic drugs as they are cheaper than to originator drugs. The government can also adopt various policies such as an increase in imports to increase competition that will put pressure on domestic producers to reduce prices. Further, the government can also help in price reduction by waiving off taxes, duties etc. paid on finished and raw materials.

V.ACCESS TO GENERIC DRUGS IN CANCER

A. Evolution of Cancer Treatment

1. Role of Generic Medicines in Cancer Treatment

The treatment of the cancer comes with a huge financial burden. Pharmaceutical companies have developed various branded medicines to treat the cancer. However, these medicines are inaccessible and unaffordable for the low and mid income countries. Thus, generic medicines have been developed as an effective alternative to provide treatment. Generic versions of branded medicines such as vinorelbine, erlotinib, cetuximab, and cisplatin played a major role in increasing access to cancer treatment by bringing the cost to a significant level.

2. Challenges in ensuring equitable access

Even though significant advancements took place in developing cancer therapies and treatment, access to cancer medicines remains the major challenge in mid and low-income countries due to the following reasons:

- **No incentive:** One of the major reasons for the shortage of generic drugs for cancer is that the incentive to continue production and research for better innovation decreases when the cost of the drugs goes down. For example: The United States hospitals have reported that pharmaceutical companies have stopped making generic drugs for cancer because of the little profit involved in it[38].
- **Lack of funding:** Cancer medicines are available at the same price for high, mid and low countries at a global level. Low and mid-income countries like African and Asian countries are overburdened with cancer funding due to the lack of financial resources, thereby causing significant health disparities among nations due to affordability[39].
- **Shortage of generic alternatives:** Several branded anti-drug dosages do not have generic medicines as alternatives. Reports suggested that, unlike other diseases, the availability of generic drugs for cancer is comparatively less due to the complexities involved in it[40]. Thus, the complexities involved in cancer care require innovative approach especially in developing and underdeveloped countries to minimise the huge cost involved in cancer therapies. However, various factors such as lack of funding, lack of treatment guidelines, lack of manpower etc. pose significant barriers to the development of generic cancer drugs.
- **Complex regulatory reviews:** It is often reported that manufacturers of generic cancer drugs are involved in poor quality, manufacturing and storage processes. This becomes a significant issue for cancer drugs with a small therapeutic index. Thus, regulators all over the world are involved in extensively scrutinizing the products before launching them in the market. This has caused substantial delays in providing timely treatment to the underprivileged sections of the society.
- **Social Stigma:** Social stigma attached to cancer disease due to cultural beliefs in certain sections of society causes delays in getting effective treatment.

B. Comparative Analysis

1. Availability and affordability of cancer drugs

India

In India, private hospitals provide cutting-edge specialised care for cancer, however, the high costs involved in the treatment make it unaffordable for 80% of the population[41].Thus, the Public Healthcare system plays a major role in providing treatment for cancer to larger sections of society. However, the public sector is crippled with various challenges such as infrastructural barriers, shortage of health experts, and advanced technologies which often leads to disparities in the availability and quality of cancer treatment in different sections of society. To minimise disparities in the availability of cancer care in India, the government has taken the following steps:

- **Jan Aushadhi Scheme:** The government started the Jan Aushadhi Scheme in 2008 wherein generic drugs are provided at cheaper rates in government-designated "Jan Aushadhi Kendra"[42]. Even though such a move was commendable, the survey conducted in 2022 indicated that only 3 essential drugs were available at the Jan Aushadhi centre.
- **Price Rationalisation:** To curb profiteering in generic cancer drugs, the National Pharmaceutical Pricing Authority imposed price rationalisation for 42 anti-cancer drugs to make cancer treatment affordable for weaker sections of society[43]. The pharmaceutical companies reported that government notification led to a 90% cost reduction in cancer drugs. For example, the price of Erlotinib was reduced from Rs. 9999 to Rs. 891. Similarly, the price of Pemestar was reduced from Rs. 25,400 to Rs. 2509[44].

Vietnam

Like many mid and low-income countries, Vietnam faces significant challenges in providing cancer care treatment. As per a 2016 report, 9 out of 63 provincial hospitals did not have any facilities for cancer treatment[45]. In 2018, Vietnam reported 1,64,671 new cancer cases and 1,14,871 deaths due to cancer. Talking about cancer drugs, only 1 drug was available in Vietnam out of 42 drugs available globally[46]. Thus, health experts mainly rely on generic drugs for cancer care, however, the palliative care system is often struggling with the lack of drugs like morphine due to the lack of domestic production and sometimes shortage at the international level.
Another significant problem in Vietnam regarding cancer care treatment is the lack of quality pathology labs. As per the study, only 48% of the total cancer patients received treatment in Vietnam[47]. Based on the statistical data available, the author believes that the government needs to take immediate steps to promote domestic production of cancer drugs to deal with the cancer crisis.

2. Innovations and health disparities

India

According to the ICMR Report of the National Cancer Registry Program, India reported 1.39 million cases of cancer in 2022 with a reported causality rate of 19 to 20 lakhs in 2022[48]. The number of cases is expected to rise to 1.57 million by 2025. This expected surge in cancer cases requires innovative efforts to deal with a health crisis.
In the last few years, advancements in anti-cancer technology have taken place to provide effective treatment with a high survival rate. Immunotherapy and radiotherapy are two advanced technologies that have been developed for specific cancer cases. Various Oncologists like Mr Chaudhary suggested that these two techniques significantly increase the survival rate of patients[49]. However, a study conducted by Tata Memorial Centre indicated that immunotherapy is available to less than 3% of patients due to the high cost attached to it[50].Thus, the government needs to adopt a multifaceted approach comprising financial assistance for research and development, social awareness and effective policies for the distribution system of generic drugs etc. to provide an equitable cancer care treatment.

Vietnam

As the number of cases is increasing, health experts and government started focussing on bringing technological improvement in cancer care. Modern techniques like immunohistochemistry, molecular analysis and radiation therapy centres have been established in the last few years to fight against cancer. However, as per the Vietnam National Cancer Institute Report of 2016, many provincial hospitals in Vietnam did not have radiation therapy centres[51]. The advanced technology is confined to private hospitals which is not affordable. Thus, the accessibility of advanced technology to cancer patients is still limited and is only available at very few centres. Such lack of accessibility to advanced healthcare technologies coupled with poor infrastructure, lack of skilled workforce and financial resources contribute to health disparities in cancer care.

VI.CHALLENGES AND BARRIERS

A. Regulatory Challenges

1. Intellectual Property Rights

The government all over the world provide patents in the health sector to promote innovation and allow companies to recoup the cost of research and development through profits. However strong patent regime for the pharmaceutical sector acts as a barrier to ensuring access to medicines. As per the study conducted by Duggan, Goyal and Borell, strong pharmaceutical product patents led to a 67% increase in the prices of drugs in India[52]. Thus, the Trade-Related Aspects of Intellectual Property Rights (TRIPS) obligates Member states to include minimum intellectual property rights protection for pharmaceutical products in their national laws through various measures such as compulsory licensing, health emergencies and bolar exemption etc. Various countries like Thailand and Brazil introduced a strong compulsory licencing regime by giving compulsory licences to 7 drugs to improve access to generic drugs in the 2000s[53]. Thus, governments need to maintain a balance between promoting innovation and ensuring access to medicines.

2. Drug Approval Process

The lack of trust of healthcare professionals in generic medicine is the biggest hurdle in promoting the use of generic medicines, especially in mid and low-income countries. Developed countries like the USA and the EU have strict registration procedures. The regulatory authorities conduct bioequivalence studies and strict quality checks before approving generic drugs[54]. Thus, strict regulatory approval mandates helped countries in increasing the use of generic drugs by addressing fears and doubts about it. On the other hand, the lack of strict regulatory procedures to approve generic drugs in developing and underdeveloped countries like African countries and Pakistan etc. creates apprehension in the minds of physicians about the effectiveness and quality of generic drugs due to which healthcare professionals are reluctant to prescribe generic drugs[55]. Thus, it is necessary that the government form policies to make the drug approval process transparent and quick. The registration process and report of bioequivalence studies conducted by regulatory authorities must be demonstrated to health experts.

B. Economic Challenges

1. Affordability and Pricing Mechanisms

Countries all over the world are struggling to ensure the availability of essential medicines to the poorest and neglected sections of society. Prices of medicines are based on various factors such as procurement prices, tariffs, supply chain costs etc. However, studies conducted by Harvard and the Centre for Global Development reported that generic medicines are expensive in less developed countries as compared to developed countries. The lack of a robust mechanism to control the prices of generic drugs in less developed countries allows manufacturers to incur profits, thereby limiting the accessibility of generic drugs. Thus, the Drug Price Control mechanism should be revamped wherein the government must revise the price of essential drugs every year by negotiating prices with pharmaceutical companies to encourage healthy competition in providing access to cheaper medicines[56].

2. Economic Disparities affecting access

The economic disparities and health disparities are interlinked with each other. Increasing income disparities in countries like India, Vietnam, the USA, the UK etc. make lower lower-income section of society more vulnerable[57]. The overburdened public health care system is grappling with an issue of less funding, thereby making it difficult to fulfil the needs of society. As a result, lack of financial resources to get proper healthcare led to poor health, high mortality rates and suffering.

VII.Success Stories and Best Practises

According to the WHO, generic medicines should be promoted as a part of the National Medicine Policy to achieve a sustainable healthcare system by eliminating health disparities. To achieve such an objective, various nations adopted different policies to make healthcare affordable and accessible. In this section, the author attempts to highlight best practices adopted by states to promote generic medicines.

A. Case studies

Finland: In Finland, the government made generic substitution mandatory through a policy decision in 2003. Under the said policy, pharmacists have to give the cheapest interchangeable substitute of the prescribed medicine[58]. Initially, consumers were hesitant to take substitutes however cost effectiveness and recommendations from pharmacists played a major role in creating awareness about generic drugs. To ensure the quality of the generic drugs, the Finnish Medicines Agency releases a list of medicines that can be easily substituted with generic drugs with equally effective results every quarter[59].

Sweden: Like Finland, Sweden also has passed a law on mandatory generic substitution in 2002[60]. As per the policy, the community pharmacy shops have to provide the cheapest generic interchangeable medicine available. To make the process of generic substitution streamlined, the Swedish Medical Products Agency released a list of branded medicines that are interchangeable with generic medicines. Reports suggested that mandatory generic substitution systems have reduced health disparities by significantly bringing down medicine prices[61].

United States: In the United States, pharmacists play an important role in promoting the use of generic medicines. Most of the states in the country have generic substitution regulations. Some states made an active law wherein generic substitution is mandatory for pharmacists unless it is specifically prohibited by prescribers whereas some states allow generic substitution without having any special law. At the federal level, the FDA makes

active efforts to boost the confidence of health professionals by encouraging them to prescribe generic drugs or cheaper branded drugs initially rather than branded expensive drug[62].

B. Best Practices for ensuring access to generic drugs

Learning from the experience of countries that have successfully implemented generic medicine systems, we must say that the government plays a crucial role in forming policies and plans to aware health care professionals and consumers about generic drugs. Some of the steps taken by governments all over the world include:

1. National Drug Authorities must lay down a comprehensive system to examine and inspect generic medicines before registration to ensure better equality and effectiveness of the drugs. For Example: In the USA, the Food and Drug Administration follows a rigorous registration process to ensure the quality and safety of generic medicines[63].
2. Cooperation between all healthcare professionals such as doctors, pharmacists, physicians etc. is necessary to promote generic drugs. If pharmacists give generic drugs but prescribers oppose them then it becomes difficult to build the trust of consumers in generic drugs.
3. The government must organise awareness programmes from time to time to inform stakeholders about the safe use of generic drugs. For example: In Japan, the government conducted the "Action Programme for Promotion of the Safe Use of Generic Drugs" to address the concerns of experts and consumers regarding the use of generic drugs[64].
4. National Drug Authorities should release a list of interchangeable products to help healthcare professionals avoid errors that may occur due to inappropriate generic drugs. For example: In the USA, Sweden and Finland, the government releases a list of interchangeable generic drugs periodically[65].
5. The government should monitor the prices of generic drugs from time to time and form guidelines on the same. In some countries, prices of generic drugs were higher than expected prices due to various factors such as corruption. For example: In Australia, the government made it mandatory for healthcare professionals to disclose the prices of generic medicines in comparison to branded drugs[66].

VIII. RECOMMENDATIONS

A. Policy Recommendations

A well-developed regulatory framework on health care products plays an important role in promoting accessibility and affordability among all sections of society. Studies reported that mid and low-income countries have very loose or no regulatory framework on generic drugs. Most countries did not include generic drugs within national medicine policies. Thus, there is a need for countries to adopt robust frameworks on generic drugs to increase their access.

1. Improve Generic Drug Regulations

Some of the measures that can be taken to improve generic drug regulations include:

- Various scholarships indicate that states that have made generic substitution mandatory performed well in ensuring the availability of generic drugs. For example: 11 European Union countries passed mandatory laws on generic substitution[67]. In the USA, 14 states made mandatory laws on generic substitution whereas 5 states forbid the prescription of generic medicines. In Japan, the government passed a law to instruct all national hospitals to use generic medicines. This measure helped Japan increase the use of generic medicines from 0.2% to 7.5% in a year[68]. It is often observed that states with laws against generic medicines suffer from huge health disparities. Thus, mid and low-income countries should adopt laws on mandatory generic substitution.
- As discussed earlier, governments in mid and low-income countries need to make laws to implement efficient drug approval processes like developed countries to demonstrate that generic medicines are at par with originator medicines[69].
- The prices of generic drugs should also be fixed through government notifications to avoid any discrepancies in pricing. For example: Australia releases a ceiling price for all generic medicines to make it affordable for poor strata of the society[70].

2. Strengthening International Collaborations

The WHO urged nations to collaborate on research and information sharing to increase access to generic drugs worldwide[71]. Pharmaceutical companies all over the world need to collaborate to promote technology transfer and knowledge sharing for the manufacturing and distribution of generic drugs in low- and mid-income countries. In 2015, the European Medical Agency announced its decision to collaborate with regulatory authorities outside the EU to share information on generic medicines[72]. Such a move will help pharmaceutical companies from mid and low-income countries to manufacture medicines in their own country at a cheaper rate.

B. Practical Recommendations for Healthcare

1. Enhancing Distribution Networks

Since the Public healthcare system is overburdened across the world due to a lack of infrastructural facilities and advanced technology, the public–private partnership (PPP) offers a seamless solution. The partnership helps in strengthening healthcare by ensuring effective local production due to favourable support provided by the government coupled with the advanced technology and knowledge provided by the private sector. For example: In India, various states like Rajasthan West Bengal introduced the PPP model by establishing price medicines shops in public hospitals to improve the distribution of generic drugs[73].Under partnership contracts, the state government offered land to manufacturers and distributors for establishing a shop at a very less rent whereas manufacturers and distributors provided efficient technology and distribution systems to boost the production of medicines[74].Thus, the PPP model is considered the most efficient method to strengthen healthcare.

2. Promoting Education and Awareness

Studies and scholarships indicate that misconceptions about the quality and effectiveness of generic drugs are one of the primary reasons for the negative attitude of stakeholders in promoting generic drugs in mid and low-income countries. Thus, the government should make active efforts to educate people about the advantages of generic drugs. Various countries like New Zealand, Japan, Sweden etc. hold public discussions among policymakers, regulatory authorities, physicians, doctors and pharmaceutical companies to discuss about use of generic drugs[75].Further, public campaigns must be organised to aware customers of generic drugs so that they are not hesitant to purchase generic substitution.

IX.CONCLUSION

Though access to medicine forms an integral part of right to health, the study conducted through this article suggest that accessible and affordable health care remains out of reach for larger sections of the society especially in pandemic situations like COVID-19, AIDS and cancer. Lack of education, poverty, structural barriers, sexual orientation, unequal allocation of resources etc. in mid and low-income countries aggravates health disparities[76]. Such health disparities cause significant deaths and morbidities due to non-availability of timely healthcare.[77]Thus, growing health disparities presents a unique opportunity to global health leaders, policy makers, health organisations, pharmaceutical companies to collaborate and form policies to address the healthcare inequities. As highlighted above, author believes that promoting generic drugs as a substitution to branded drugs will make healthcare system affordable and accessible[78]. Various measures such as improving drug regulations, creating awareness among doctors, physicians and customers etc. must be taken by government to make the healthcare equity reality globally.

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