Anti-competitive practices and healthcare sector in India

Sumit Agarwala
Research Scholar, Faculty of Law, JECRC University, Jaipur

Dr. Namita Jain
Assistant Professor, GD Goenka University, Haryana

Abstract---Health is the basic human right and an important indicator of the nations’ commitment towards the health of its citizen and hence every country strives to increase the health standard and provide basic medical facility to all. This right to health is an outcome of various legal sanctions, both internationally and of countries specific. The right to health is enshrined as a basic human right internationally. The right to health is an inclusive right, extending not only to timely and appropriate health care, but also to the underlying determinants of health as per (Report of Committee on Economic, Social and Cultural Rights). Though the Constitution of India does not expressly recognize the Right to Health as a fundamental right under Part III of the Constitution (Fundamental Rights), it is considered as an inseparable part of the Right to Life. Article 23. As a result, the child labour and human trafficking are prohibited in India. This article aims to analyse the impact of fast-changing lifestyle, habits, stress, COVID-19 pandemic and other factors on public health in India. It is more sensitized since last two years.


Introduction

Health is the basic human right and an important indicator of the nations’ commitment towards the health of its citizen and hence every country strives to increase the health standard and provide basic medical facility to all. This right to health is an outcome of various legal sanctions, both internationally and of countries specific. The right to health is enshrined as a basic human right internationally as under:
1. **Background of Study:**

The right to health was first articulated in the WHO Constitution (1946) which states that: “the enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being.... The preamble of the Constitution defines health as: a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity.” ("WHO Constitution (1946)"

The 1948 Universal Declaration of Human Rights mentioned health as part of the right to an adequate standard of living (Article 25). It was recognised as ‘a human right’ in 1966 in the International Covenant on Economic, Social and Cultural Rights, Article 12: “1. The States Parties to the present Covenant recognize the right of everyone to the enjoyment of the highest attainable standard of physical and mental health. 2. The steps to be taken by the States Parties to the present Covenant to achieve the full realization of this right shall include those necessary for: (a) The provision for the reduction of the stillbirth-rate and of infant mortality and for the healthy development of the child; (b) The improvement of all aspects of environmental and industrial hygiene; (c) The prevention, treatment and control of epidemic, endemic, occupational and other diseases; (d) The creation of conditions which would assure to all medical service and medical attention in the event of sickness.” ("Article 12, International Covenant on Economic, Social and Cultural Rights")

The Committee on Economic, Social and Cultural Rights, a body composed of independent experts in charge of monitoring the implementation of the Covenant, provided a broad interpretation of article 12 of the Covenant (General Comments No.2014) (Report of Committee on Economic, Social and Cultural Rights, n.d.): The right to health is an inclusive right, extending not only to timely and appropriate health care, but also to the underlying determinants of health, such as access to safe and potable water and adequate sanitation, healthy occupational and environmental conditions, and access to health-related education and information, including on sexual and reproductive health (Paragraph 11).

2. **Scope and Significance of Study:**

In Consumer Education and Research Centre v. Union of India (AIR 1995 SC 922), it was held that right to health and medical aid to protect the health and vigour of a worker, both while in service and post-retirement, is a fundamental right under Article 21. Therefore, the State must care for the health of the public at large and the Central Government and various State governments have, rightfully and proactively, taken various measures to contain the entry and spread of the COVID-19 pandemic.

The right to health is relevant to all States: every State has ratified at least one international human rights treaty that recognises the right to health. In India, the right to health, which is a natural result of promoting public health, has been safeguarded under the Constitution of India in multiple ways. The Constitution of India does not expressly recognize the Right to Health as a fundamental right under Part III of the Constitution (Fundamental Rights). However, through
judicial interpretation, this has been read into the fundamental right to life & personal liberty (Article 21) and is now considered an inseparable part of the Right to Life. Article 23 of the Constitution of India also indirectly contributes to protecting the Right to Health as it prohibits human trafficking and child labour. The Supreme Court of India had from time to time reiterated that right to health is a fundamental right.

3. **Objectives of Study:**

- To study the history and background of right to health in the world and India respectively
- To examine the present scenario of healthcare sector in India
- To explore the legal foundation of right to health
- To analyse the possibilities of violations of best practices and guidelines and its impact on public health in India

4. **Review of Literature:**

In *Francis Coralie Mullin v. The Administrator, Union Territory of Delhi* (AIR 1981 746), the Supreme Court held that “life” in Article 21 means a life with human dignity and not mere survival or animal existence (Right to life has an extensive scope, including the right to livelihood, better standard of life, hygienic conditions in the workplace, & right to leisure). The right to one’s own health is an essential and inalienable component of one’s life. In addition to this, Article 21 should be read in conjunction with the directive principles of state policy in order to have a complete understanding of the nature of the obligations that are placed on the State in this regard.

The Directive Principles of State Policy (DPSP), enshrined in Chapter IV of the Constitution of India, require the State to, among other duties,

1. promote the welfare of its people (Art.38);
2. protect their health and strength from abuse (Art 39(e);
3. provide public assistance in case of sickness, disability or “undeserved want” (Art 41);
4. ensure just and humane conditions of work; and
5. raise nutrition levels, improve the standard of living, and consider improving public health as its primary duty (Art 47).

In addition to the DPSP, a few more health-related rules may be found in the 11th and 12th Schedules. These provisions are included as issues that fall under the purview of Panchayats and Municipalities, respectively. These responsibilities include but are not limited to, the provision of clean drinking water, adequate
medical care and sanitation (including hospitals, primary health care centres, and dispensaries), the promotion of family welfare, the advancement of women and children, the promotion of social welfare, and other similar responsibilities.

In Bandhua Mukti Morcha v. Union of India (AIR 1984 SC 812), the Supreme Court held that “although the DPSP are not binding obligations but hold only persuasive value, the State should duly implement them. Further, the Court held that dignity and health fall within the ambit of life and liberty under Article 21.”

In Paschim Banga Khet Mazdoor Samity v. State of West Bengal ((1996) 4 SCC 37), the scope of Article 21 was further widened as the Court held that it is the responsibility of the Government to provide adequate medical aid to every person and to strive for the welfare of the public at large.

In the case of Parmanand Katara v. Union of India (AIR 1989 S.C. 2039), the Supreme Court held that every doctor at a government hospital or otherwise has the professional obligation to extend his services with due expertise to protect the life of a patient.

6. Discussion and Analysis

The government of India has strived to provide the best and cost-effective medical services to its marginal class of citizens and the effect of this can be seen in the fact that India's overall performance in terms of life expectancy, child survival and maternal mortality has improved steadily over the recent years (Health and Family Welfare Statistics in India 2019-20, n.d.) which is visible from the table below.

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<tbody>
<tr>
<td>1</td>
<td>Crude Birth Rate (Per 1000 Population)</td>
<td>25.4</td>
<td>23.8</td>
<td>22.1</td>
<td>20.8</td>
<td>20.2</td>
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<tr>
<td>2</td>
<td>Crude Death Rate (Per 1000 Population)</td>
<td>8.4</td>
<td>7.6</td>
<td>7.2</td>
<td>6.5</td>
<td>6.3</td>
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<tr>
<td>3</td>
<td>Total Fertility Rate (Per women)</td>
<td>3.1</td>
<td>2.9</td>
<td>2.5</td>
<td>2.3</td>
<td>2.2</td>
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<tr>
<td>5</td>
<td>Infant Mortality Rate (Per 1000 live births)</td>
<td>66</td>
<td>58</td>
<td>47</td>
<td>37</td>
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If the Health and Family Welfare Statistics in India 2019-20 report is analysed on other parameters of rural-urban divide, caste based, gender-based health indicators, a lot still needs to be done to bring India to the global standards of developed nations. Since 2016, the healthcare sector in India has experienced a Compound Annual Growth Rate of approximately 22 per cent throughout its expansion. At this rate, it is projected to reach 372 billion US dollars in 2022. In terms of revenue and employment opportunities, the healthcare industry has become one of the essential parts of the Indian economy.

The healthcare industry overtook the education sector as the fifth largest employer in 2015, directly employing 4.7 million people. According to projections made by the National Skill Development Corporation (NSDC), the Indian healthcare industry has the potential to provide an additional 2.7 million employment between 2017 and 2022, which works out to more than 500,000 new position annually. Hospitals, medical gadgets and equipment, health insurance, clinical trials, telemedicine, and medical tourism are components of India's expansive healthcare sector, including medical tourism. It is anticipated that these market segments would diversify due to the increased preference for preventative healthcare shown by an ageing population with a growing middle class. The increasing prevalence of lifestyle diseases in metropolitan areas, such as high cholesterol levels, high blood pressure, obesity, an unhealthy diet, and excessive alcohol consumption, is driving up the demand for specialised care services.

COVID-19 will catalyse long-term changes in attitudes regarding personal health and cleanliness, health insurance, fitness, nutrition, and health monitoring and medical check-ups. These demographic and epidemiological trends are already in motion. Additionally, the pandemic has hastened the implementation of digital technologies, such as telemedicine. Public-Private Partnership (PPP) models are becoming more prevalent and are receiving rising attention in India's healthcare industry. The relative cost competitiveness of the country and the availability of skilled labour are both contributing factors that make it an increasingly popular location for medical value travel. In terms of policy, the Indian government is now engaged in extensive structural and ongoing changes to bolster the country's healthcare system. Additionally, the government has declared measures conducive to attracting Foreign Direct Investment (FDI).

India's Foreign Direct Investment (FDI) regime has undergone significant liberalisation. At this time, foreign direct investment (FDI) is permitted up to one hundred per cent under the automatic route in the hospital sector and the manufacturing of medical devices. This means that the non-resident investor or Indian company does not require India's government approval for the investment. In the pharmaceutical industry, the automatic route allows for foreign direct
investment (FDI) of up to one hundred per cent in greenfield projects and up to seventy-four per cent in brownfield projects. India has become one of the emerging economies with the quickest growth rate over the past two decades. As a result, it has been receiving significant amounts of foreign direct investment (FDI), which has increased from USD 2.5 Billion in 2000-01 to USD 50 Billion in 2019-20. Nearly the past few years, investors have shown a heightened interest in the healthcare industry in particular. As a result, the value of transactions in this industry has increased from USD 94 Million (2011) to USD 1,275 Million (2016), representing an increase of over 13.5 times. All of these elements present several opportunities for financial investment in India’s healthcare sector when taken together. (NITI Aayog, n.d.)

The Indian health sector has registered appreciable growth in recent times and attracted considerable private investments. It is one of the fastest growing segments of the Indian economy, and expected to record a three-fold rise, growing at a CAGR of 22% between 2016–2022 to reach US$ 372 billion in 2022 from US$ 110 billion in 2016. (Report of Indian Brand Equity Foundation, n.d.). The following chart shows the growth of Indian health care sector.

Healthcare Sector Growth Trend (US$ Billion)

<table>
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<th>Year</th>
<th>Healthcare Sector Growth (US$ Billion)</th>
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<tr>
<td>2014-15</td>
<td>62.6</td>
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<tr>
<td>2015-16</td>
<td>60.6</td>
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<tr>
<td>2016-17</td>
<td>58.7</td>
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<td>2017-18</td>
<td>48.8</td>
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Healthcare services in the country are characterised by a profound contrast in performance between the private and the public sectors. While the upsurge in private participation in this sector would continue to meet the demand of the increasing populace, government needs to assess and adjust its role in this emerging environment. Through the initiation of the National Rural Health Mission (NRHM) in 2005, a number of states have made progress with provision of quality healthcare services to its citizens. However, a number of challenges remain in the sector, especially since a large number of Indians still remain outside the reach of healthcare services (WHO, 2008), and many who are somehow able to access these services are further impoverished.

Each year, some 150 million people worldwide face financial catastrophe due to spending on health and according to a 2010 study, more than one third of them live in India. (Berman et al., 2010) (Shahrawat & Rao, 2011) The number of Indians falling below the poverty line (BPL) due to health spending may run as high as 63 million people: almost 7% of the nation’s population. This total is on
the rise: the Indian Ministry of Health reported that 18% of households faced catastrophic health costs in 2011-12, as compared to 15% in 2004-5. *(National Health Policy 2015 Draft, 2014)* The vast majority of healthcare-related impoverishment takes place in rural areas, and occurs in the context of outpatient care. As per 2015 Government of India (GoI) report states, “incidence of catastrophic expenditure due to health care costs is growing and is now being estimated to be one of the major contributors to poverty. The drain on family incomes due to health care costs can neutralize the gains of income increases and every Government scheme aimed to reduce poverty.” *(Berman et al.)*

Analysis of one national survey shows that poor people tend to spend the largest portion of their out-of-pocket (OOP) budget on purchasing drugs, and the least on inpatient treatment. Seventy-two percent of OOP expenditures (74% in rural areas, 67% in urban) are drug-related, vs. 30-35% on inpatient and outpatient care combined. In the poorest states, the proportion of drug sales is even higher. Even though the health indicators of the country have lagged behind the impressive economic progress over the past two decades and there is a need for a comprehensive national health policy to help reconfigure the health system in the country, increase the allocation of budget for healthcare, There is a light at the end of the tunnel as the report of National Health Accounts estimates for India 2017-18 states that the out-of-pocket expenditure has come down from 64.3 percent of total health expenditure in the year 2013-14 to 48.8 percent in the year 2017-18. This was an outcome of the efforts of the Government of India under the Ayushman Bharat, the Pradhan Mantri Jan Arogya Yojana which has increased the trust levels of people on service provision by public health care facilities through health systems strengthening and improvement and has led to Reduction in out-of-pocket expenditure of the common people. *(2020-21 Health Report, n.d.)*

Source: Out of Pocket Expense as per National Health Accounts Estimates for India 2017-18 *(National Health Accounts 2017-18, n.d.)*

The other extremely important point touches on access to medicines. Private (out-of-pocket) expenditure in healthcare constitutes 80 percent of the total healthcare expenses in India. Despite India’s billing as the ‘pharmacy of the world,’ it’s population’s access to medicines is severely restricted as nearly 65 per cent of all health spending is in the form of OOP spending by households, two-thirds of
it on drugs and underfunding of public sector facilities and the rapid growth of private sector providers contributed to rising OOP costs on health care. A significant share, almost two-thirds of OOP expenses, are for purchasing outpatient care, especially medicines. *(Household Out-Of-Pocket Expenses on Health Services Push 55 million into Poverty in India: WHO Report, 2022)* This high expenditure on pharmaceuticals has led to the pharmaceutical sector rushing to encash this lucrative share in the market. This sector has witnessed an unprecedented number of mergers and acquisitions involving big Indian pharmaceutical companies (those with a considerable generic product line) by large multinational corporations (MNCs), who specialise in patented drugs. This is likely to take the price of medicines further northwards, and restrict the volume of generic medicines supply in the market.

The government has taken cognisance and recommended the use of tools like compulsory licensing to maintain supply of drugs in the market in case there is a fall in supply but it is a pity that these mergers did not have to pass through the Competition Commission of India’s scrutiny as provisions pertaining to merger review of the Competition Act 2002 of India, had not been notified then. *(Overseeing Pharma Mergers through Competition Lens, 2010)* The increased cartelization in the pharmaceutical industry causing anti-consumer environment had to be tackled and in the absence of the Competition Commission of India taking any step in the initial days, the Ministry of Health and Family Welfare, took steps. The most drastic amongst them being the capping of price of medicines and devices under the National List of Essential Medicines (NLEM) which was previously only an eyewash.

In India, the central government regulates prices of essential drugs under the Essential Commodities Act, 1955. The rationale behind price ceilings is to make drugs cheaper and easily accessible to everyone. This is important because a large section of the Indian population finds it difficult to bear the cost of medications, which forms a significant chunk of out-of-pocket expenditure on healthcare. The National Pharmaceutical Pricing Authority (NPPA) was set up in 1997 to fix or revise prices of pharmaceutical products, enforce the provisions of DPCO (Drug Price Control Order) and monitor the prices of controlled and decontrolled drugs. Currently, DPCO lists 851 drug formulations whose prices can be capped. This policy is applicable for a specified dosage. The ceiling price is the average price for all brands selling a particular drug with more than 1 per cent of market share. If the price of a drug is below the ceiling price, it can be raised only after a year. However, this policy is not applicable for patented drugs or fixed-dose combination (FDC) drugs. *(Motkuri & Mishra, 2020)* Also, to counter the anti-competitive practices of the pharmaceutical companies where by they colluded with health care providers to prescribe their medicines and devices, in exchange of considerations, thereby leading to huge burden and exploitation of patients, Ministry of Health and Family Welfare, had passed various orders from time to time to the hospitals and departments under it to procure generic medicines only. *(Procurement of Allopathic Drugs in CGHS, n.d.)* Apart from this the Medical Council of India, vide insertion in Clause 1.5 of Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002, made it mandatory for the doctors to prescribe generic names of the medicines in eligible handwriting. *("Indian Medical Council Act, 1956," n.d.)*
Collusive Practices in Pharmaceutical Industry

International Financial Institution (IFI) Guidelines define collusive practices as: “...an arrangement between two or more parties designed to achieve an improper purpose, including to influence improperly the actions of another party.” (Collusive Practices, n.d.)

As per the Organisation for Economic Cooperation and Development (OECD), Collusion refers to combinations, conspiracies or agreements among sellers to raise or fix prices and to reduce output in order to increase profits. (Collusion, n.d.) In simple terms, collusive practices are arrangements made among/between market players (in specific markets) to garner higher revenues than otherwise accrue to them under normal market situations, and which have adverse effect on other market players as well as consumers. Impacts on other players in the market (who remain outside the circuit of such arrangements) include barriers to entry, access to raw materials/supplies, impediments to distributions channels and lack of access to consumers. Increased costs reduced supply and limited choice of goods and services are some of the adverse impacts of such collusive agreements on consumers.

The Monopolies and Restrictive Trade Practices Act of 1969 in short MRTP act was outdated and was not in a position to deal with the emerging situation in the market. However, in the year 2002, the parliament enacted the Competition Act 2002, which was notified in 2003 and was amended in 2007. This act prohibits anti-competitive practices like Anti-competitive agreements whereby no enterprise or association of enterprises or person or association of persons shall enter into any agreement in respect of production, supply, distribution, storage, acquisition or control of goods or provision of services, which causes or is likely to cause an appreciable adverse effect on competition within India, (Section 3, Competition Act 2002). There is prohibition on abuse of dominant position in the market such that it causes barriers to competition in market, (Section 4, Competition Act 2002.) and on mergers, combination etc which will adversely impact fair competition in market and cause impact on other market players (Section 5, Competition Act 2002).

The Competition Commission of India has initiated enquires and action against many erring pharma companies, organizations etc for creating anti-competitive environment and causing appreciable adverse effect on competition in the market. For example, Competition Commission found All India Organisation of Chemists & Druggists (AIOCD), an all India grouping of chemists and druggists, guilty of indulging in unfair trade practices that influenced the prices of medicines and restricted supplies into the market and it slapped a penalty of Rs 47.41 lakh on All India Organisation of Chemists & Druggists (AIOCD), as well as the Commission has directed AIOCD members to “cease and desist from indulging in and following the practices which have been found anti-competitive” however this order was later set aside later on appeal by the AIOCD. (COMPAT Sets aside Penalty Imposed by CCI, n.d.)

In an order passed in the year 2014, the Competition Commission, imposed a penalty on the Chemist and Druggists Association, Goa (CDAG) as on enquiry it
was found that CDAG was continuing to exercise control on the supply chain through which drugs and medicines are made available in the market through the practice of requirement of LOC/ NOC prior to appointment of stockists by pharmaceutical companies without having any legal or statutory authority in this respect. Further the Commission also found that CDAG forced pharmaceutical companies to follow its mandate by threatening the other stockists in Goa to stop taking supplies or suspend receiving supplies from them till such time they stopped supplies to the unauthorised stockists such as M/s Xcel Healthcare. (Competition Commission of India Imposes Penalty, n.d.)

The Competition Commission of India (‘Commission’) has found the Chemists and Druggists Association of Baroda (‘CDAB’) to be in contravention of the provisions of the Competition Act, 2002 (‘Act’) in 2019. A complaint/information was filed with the Monopolies and Restrictive Trade Practices Commission (MRTPC) in 2009 alleging that the CDAB has indulged in restrictive trade practices. The allegations were that the CDAB, through its practices, is limiting and controlling the supply of drugs and medicines in the market by mandating ‘No Objection Certificate’ (‘NOC’) prior to appointment of stockists and payment of ‘Product Information Service’ (‘PIS’) charges prior to introduction of new products in the market by pharmaceutical companies. Besides, there were allegations that CDAB was fixing the trade margins for the wholesalers/retailers and imposed penalty on it. (Competition Commission of India Imposes Penalty, n.d.)

7. Conclusion

Now that the CCI is functioning and has started to investigate alleged violations of the Competition Act 2002, it would be necessary for the CCI to keep a close watch on the healthcare sector in the country. CUTS and Oxfam India are of the view that evidence gathered from the field about collusive practices among healthcare providers in the country, and its impact on the price and availability of healthcare goods (medicines) and services would enable greater scrutiny by civil society at the micro-level and also provide useful leads for the CCI to initiate investigations. Also a healthy population of any nation is its biggest investment and hence all countries and especially a developing nation like India who has a vast population with high load factor on the health care system which was very much evident during the 2nd wave of Covid-19, the last nail in the coffin can be collusions between health care system, pharmaceutical companies and service providers and hence it is the duty of the government through the CCI to keep a watch and prevent any anti-competitive practice.

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