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To What Extent the Notion of Access to Medicine is Available under the Notion of Access to Health with Special Reference to India

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ABSTRACT

Health is essential for the survival of human beings in the world. There is a saying "health is wealth", which very well shows that health is the most vital asset of living beings than any other asset. When saying about health it implies good and adequate health free from diseases. Not only free from diseases but the highest standard of health with dignity. So in order to fulfill this, the public needs to get proper medical care especially medicines for curing diseases. When speaking about public it includes everyone, irrespective of caste, gender, age, rich or poor. So the medicines should be made available to everyone equally. But is it happening in practical. Millions of people around the world still do not have access to even essential medicines that are affordable and of good quality. According to the intuitive estimate of the World Health Organization (WHO) at least one-third of the world's population have no regular access to medicines[2]. Access to medicines also includes access to treatment. It is said that access to essential medicines is part of the human right to health[3].

There are many important entities which plays crucial role to ensure that this right is enjoyed by all. Government i.e. the State is at the top most as far as the responsibility is concerned. Laws have to be efficient and effective. Judiciary also plays a crucial role. Medical fraternity should be very much responsible and take up this profession as service rather than business oriented or with profit motive.

Keywords: *Health, access to medicine, Right to health, right to health, access to health.*

I. INTRODUCTION

WHO defines health as "a state of complete physical, mental and social well-being and not

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[2] World Health Organisation (2011), p. 8.

[3] Karin Wiedenmayer, "Access to Medicines", Swiss Centre for International Health, available at http://apps.who.int/medicinedocs/documents/s18422en/s18422en.pdf (accessed on 11.04.2018)

 [ISSN 2581-5369]

merely the absence of disease or infirmity". Being healthy doesn't mean fitness only. It has to encompass many other facets. To stay healthy availability of proper food, pure water, good environment, sanitation, waste management etc. is essential along with the availability of proper medicines and healthcare is also inevitable. To make this possible State bears a greater responsibility. In India the health services are provided both by the Central and State Governments. But the point is the available resources with governments are not enough to cover all citizens under health care services. Hence effective initiatives are required to be taken to ensure availability of medicines to the needy in the country so that public health is achieved in its fullest sense.

II. INTERNATIONAL FRAMEWORK ON ACCESS TO HEALTH AND ACCESS TO MEDICINES

Peters *et al.*[4] define access as 'the timely use of services according to needs'. As far as access to medicines are concerned important requirements include: availability (medicines should be made available to all), affordability (medicines should be made available at affordable prices), acceptability (it includes the characteristics of products and services and user's attitudes, expectations of products and services) and accessibility (it includes the supply location of medicines, the user location. Medicines should be accessible to the public). These factors are essential that need to be followed.

Access to essential medicines as part of the right to the highest attainable standard of health ("the right to health") is well-founded in international law. The right to health first emerged as a social right in the **World Health Organization** (WHO) Constitution (1946). The preamble of the World Health Organization (WHO) Constitution defines health broadly as "a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity." [5] The Constitution defines the right to health as "the enjoyment of the highest attainable standard of health," and enumerates some principles of this right as healthy child development; equitable dissemination of medical knowledge and its benefits; and government-provided social measures to ensure adequate health. So WHO has laid down a higher standard for right to health and includes access to medicines. Article 25 of the **United Nations' Universal Declaration of Human Rights 1948** states that *"Everyone has the right*

[4] Peters DH, Garg A, Bloom G, et al. "Poverty and access to health care in developing countries", Annals of the New York Academy of Sciences, 2008, vol. 1136, pg. 161-71.

[5] The Constitution was adopted by the International Health Conference held in New York from 19 June to 22 July 1946, signed on 22 July 1946 by the representatives of 61 States (Off. Rec. Wld Hlth Org., 2, 100), and entered into force on 7 April 1948.

 [ISSN 2581-5369]

to a standard of living adequate for the health and well-being of himself and of his family, including food, clothing, housing and medical care and necessary social services." The Universal Declaration makes additional accommodations for security in case of physical debilitation or disability, and makes special mention of care given to those in motherhood or childhood. UDHR have specifically mentioned medical care. The **International Covenant on Economic, Social, and Cultural Rights (ICESCR) of 1966** defines right to health in Article 12 and details the progressive realization of the right to health through four concrete steps, which includes[6]:

- The reduction of the stillbirth-rate and of infant mortality and for the healthy development of the child;
- The improvement of all aspects of environmental and industrial hygiene;
- The prevention, treatment and control of epidemic, endemic, occupational and other diseases;
- The creation of conditions which would assure to all medical service and medical attention in the event of sickness.

The **International Convention on the Elimination of all forms of Racial Discrimination, 1969** has provided for the protection of right to public health, medical care, social security and social services.[7]

So the International framework as we can see has recognized access to health and access to medicines.

III. INDIAN LAW ON RIGHT TO HEALTH

In India there is no explicit provision dealing with right to health under the Indian Constitution or elsewhere. Since we are member to the United Nations, it has ratified the international conventions which provides for health care rights of individuals. The concept of democratic socialism which can found place in the preamble of the constitution aims to improve the condition of health care of the people.[8] **Article 21** of the Constitution of India guarantees a fundamental right to life & personal liberty. The expression 'life in this article means a life with human dignity & not mere survival or animal existence.[9] It has a much wider meaning which includes right to livelihood, better standard of life, hygienic condition and safe condition in workplace. The expansion of Article 21 is through judicial interpretation has been discussed

[6] Article 12 of International Covenant on Economic, Social and Cultural Rights, 1966.
[7] Article 5 (e) (iv), International Convention on the Elimination of all forms of Racial Discrimination, 1969.
[8] *'Social and economic justice'* mentioned under Preamble of the Constitution.
[9] *Maneka Gandhi* v. *UOI,* 1978 AIR 597, 1978 SCR (2) 621.

 [ISSN 2581-5369]

briefly later in this article. **Directive Principles of State Policy** (DPSP) have provisions dealing with public health. Articles 38 impose liability on state to secure social order for the promotion of welfare of the people[10] but without public health we can't achieve it. Article 39(e) is aimed at the protection of health of the working class. Article 41 imposes duty on state to provide public assistance basically for those who are sick & disable. Under Article 42 it's a primary responsibility of the state to protect the health of infant & mother by maternity benefit. Article 47 discusses the duty of the state to raise the level of nutrition & the standard of living of its people.

Since DPSP are directives on the state and non-justiciable, to claim right to health, Article 21 is relied upon by the citizens. Judiciary has from time to time interpreted Article 21 so as to include right to health within its ambit. In *Vincent Panikulangara* v. *UOI*[11] the Supreme Court emphasized that a healthy body is the very foundation of all human activities. Article 47, a Directive Principle of State Policy in this regard lays stress note on improvement of public health and prohibition of drugs injurious to health as one of primary duties of the state. In *Rakesh Chandra Narayan* v. *State of Bihar*[12], a letter petition in regard to Mental Hospital at Ranchi was considered as a Public Interest Litigation under Article 32 of the Constitution. The Bench consisting of Misra Rangnath and Venkatachalliah (J) held that the Government has an obligation to ensure that medical attention is reaching out to all the citizens in the country. The case focused on the deplorable condition of the mental hospital in Ranchi. Another important case relating to medical care is ***Parmananda Katara* v. *Union of India*** [13] **where the Supreme Court** has very specifically clarified that preservation of life is of paramount importance. The Apex Court stated that 'once life is lost, *status quo ante* cannot be restored.' It was held in this case that it is the professional obligation of all doctors (government or private) to extent medical aid to the injured immediately to preserve life without legal formalities to be complied with the police. Article21 casts the obligation on the state to preserve life. It is the obligation of those who are in charge of the health of the community to preserve life so that the innocent may be protected and the guilty may be punished. No law or state action can intervene to delay and discharge this paramount obligation of the members of the medical profession. No law or State action can intervene to avoid/delay the discharge of the paramount obligation cast upon members of the medical profession. The obligation being total, absolute and paramount,

[10] Article 38 of the Constitution of India.
[11] 1987 AIR 990.
[12] 1989 AIR 348.
[13] 1989 AIR 2039.

 [ISSN 2581-5369]

laws of procedure whether in statute or otherwise which would interfere with the discharge of this obligation cannot be sustained and must, therefore, give way. The court also observed:

> *"Art. 21 of the Constitution cast the obligation on the State to preserve life. The patient whether he be an innocent person or a criminal liable to punishment under the laws of the society, it is the obligation of those who are in charge of the health of the community to preserve life so that the innocent may be protected and the guilty may be punished. Social laws do not contemplate death by negligence to tantamount to legal punishment…. Every doctor whether at a Government hospital or otherwise has the professional obligation to extend his services with due expertise for protecting life."*

In *CESC Ltd*. v. *Subash Chandra Bose*[14] the Supreme Court relied on international instruments and concluded that right to health is a fundamental right. In *Consumer Education and Research Center* v. *UOI*[15], the Court explicitly held that the right to health was an integral factor of a meaningful right to life. The court held that the right to health and medical care is a fundamental right under Article 21. The Supreme Court, in *Paschim Banga Khet Mazdoor Samity & Ors* v. *State of West Bengal & Ors*,[16] while widening the scope of art 21 and the government's responsibility to provide medical aid to every person in the country held that in a welfare state, the primary duty of the government is to secure the welfare of the people. Providing adequate medical facilities for the people is an obligation undertaken by the government in a welfare state. Recently in *Navtej Singh Johar* v. *UOI & Ors.*[17], a 5-judge bench of the SC decriminalized homosexual intercourse, Justice Chandrachud, in his concurring opinion held: *"Article 21 does not impose upon the State only negative obligations not to act in such a way as to interfere with the right to health. This Court also has the power to impose positive obligations upon the State to take measures to provide adequate resources or access to treatment facilities to secure effective enjoyment of the right to health."*

Thus by interpreting Article 21 the Court has recognized right to health thereby recognizing access to medicines. But even this is the situation how effectively and efficiently our government has taken initiative to adequately protect the health of the people and make available medicines are insufficient or inadequate.

The subject gains much significance in this COVID – 19 scenario were the government, both Central and State governments are in a situation to respond to the high end needs of the society.

[14] AIR 1992 SC 573,585
[15] AIR 1995 SC 636
[16] (1996) 4 SCC 37.
[17] W.P. (Crl.) No. 76 of 2016 D.No. 14961/2016.

 [ISSN 2581-5369]

The Courts are witnessing and thus addressing the deplorable health conditions in hospitals throughout the country. They are of the opinion that while making medical facilities available to the people the government cannot make any lame excuses of financial difficulties or inadequate resources since it is the State's constitutional obligation to make it available to the people in need.[18]

IV. PATENTS AND ACCESS TO MEDICINES SPECIAL REFERENCE TO INDIA

How Intellectual Property is related to access to medicines and thus right to health has been into discussions enormously. Important agreement on Intellectual Property, the TRIPS Agreement obliges signatory countries to give patent protection to drugs, along with other inventions for a period of 20 years. Thus pharmaceutical products are given patent protection if they have complied with the requisite standards of patent law. Patent to pharmaceuticals have been subjected to criticism in various times as it is a sensitive area concerning human health and their survival.

WTO has come under fierce criticism because of the effects that increased levels of patent protection will have on medicine prices. Patent protection seems important to the pharmaceutical industry because their contention is that when comparing with any other inventions; Pharmaceutical industry spends more in Research and Development. They say that development of new drug is a costly process and it is relatively easy to copy an existing drug.[19] The patent system thus allows firms to charge prices that are higher than the marginal price of production and distribution. It is only after the patent protection for the product expires that competition among generic versions can bring the price closer to the marginal cost.[20] Here the problem will be to the public, especially those in lower economic strata who can't afford the prices of the patented medicines. But to avoid this problem of hindering access to medicines, there are provisions incorporated under the Indian law which was incorporated as part of the flexibilities provided in the TRIPS Agreement.

Article 8 of the TRIPS Agreement provides that states can adopt measures necessary to protect public health and to promote the public interest in sectors of vital importance to their socioeconomic and technological development. Article 30[21] also permits state to limit the

[18] Rahul Bajaj, "Can the Judiciary invoke right to health to demand a more vigorous response to COVID-19", The Wire, 31 March 2020, refer https://thewire.in/law/can-the-judiciary-invoke-right-to-health-to-demand-a-more-vigorous-response-to-covid-19

[19] Harvey E. Bale, Jr., "The conflict between parallel trade and product access and innovation: the case of pharmaceuticals", Journal of International Economic Law I, 1998, p. 637.

[20] John H. Barton, "Differentiated pricing of Patented Products", Commission on Macroeconomics and Health Working Paper Series no. WG 4:2, 2001.

[21] Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such

exclusive privilege granted through patent rights. These provisions can be used by member states to pursue public health goals. Article 31 permits States to issue compulsory licenses in respect of the generic manufacture of patented goods for a particular purpose without the consent of the patent-holder. Even though TRIPS have provided with several safeguards and flexibilities how far it is effectively used by the Indian law is a question that needs to be answered.

While discussing on access to health, the Fourth WTO Ministerial Conference, held in 2001 in Doha, Qatar, adopted a Declaration on TRIPS and Public Health ("Doha Declaration") which affirmed the sovereign right of governments to take measures to protect public health. Public health advocates welcomed the Doha Declaration as an important achievement because it gave primacy to public health over private intellectual property, and clarified WTO Members' rights to use TRIPS safeguards. These measures include **compulsory licensing** to allow the production or importation of generic medicines without the consent of the patent holder, and **parallel importation** to allow governments to seek the cheapest available brand-name medicine on the global market. Although the Doha Declaration broke new ground in guaranteeing Members' access to medical products, it did not solve all of the problems associated with intellectual property protection and public health.

Intense lobbying from the multinational pharmaceutical industry and some Western governments, for instance, has frustrated the use of these safeguards. Experience from South Africa, Thailand, Kenya and Guatemala shows the enormous pressures countries face in implementing the TRIPS Agreement in a manner that protects public health and underscores the vital role played by civil society in defending the right to access affordable medicines.

By granting patent what we can see is that it has the potential to improve access by providing incentives for the development of new drugs, as well as to restrict access because of the higher prices of patented drugs. Price seems to be a major issue for hindering access even though it is not the only issue.

Right to health includes access to essential drugs. General comment 14 of CESCR: The Right to the Highest attainable standard of Health links the identification of essential drugs to the WHO's list of essential medicines, which has been updated from time to time since its initial adoption in 1977. Only about 5 per cent of drugs on the current list are protected by patent[22]. How can this be, when numerous patented medicines are the only treatments

exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.

[22] See Amir Attaran, 'How Do Patents And Economic Policies Affect Access To Essential Medicines In

available, or are the most effective treatments, for certain deadly diseases? One important criterion for inclusion on the WHO list is cost effectiveness. Given that many States cannot afford patented medicines, they are not 'cost effective' so they are excluded from the list[23]. The exclusion of patented medicines is caused by their high prices rather than any lack of comparable (or superior) effectiveness compared to the cheaper medicines on the list.

TRIPS and the patent system had seemed to be in conflict with access to medicines and access to health. But what need to be noted is that States had to take advantage of available TRIPS flexibilities if they are unable to independently facilitate access to patented goods. That is, States had to make full use of compulsory licensing, importation of generic goods under the 2003 waiver, parallel importation, the limited exceptions permitted under Article 30 TRIPS, and remaining transition periods. States should also properly exercise their discretion over the standards for patentability to allow for opposition and revocation procedures and to combat anti-competitive practices[24].

When taking into consideration the Indian law on compulsory licensing under **Section 84**, the period for filing application is 3 years from the date of grant on all the three grounds. TRIPS haven't mentioned such a time period but Paris Convention, 1883 have provided for the same[25] which is limited to non -working only. But India has gone beyond that. and when looking into **Section 3(d)** of the Patents Act, 1970, which has been incorporated to prevent ever-greening of patents and thereby facilitating access to medicines intents to lay down a higher standard by adding proving of "enhanced efficacy" which is not there in TRIPS. This negates the objective of incorporating the provision that is facilitating access because pharma companies can come with newer versions of medicines showing enhanced efficacy. So in this way what we can infer is that Indian law has not properly utilized the available flexibilities provided in TRIPS which can thereby facilitate access.

V. CONCLUSION

Thus it can be concluded that in India notion of access to medicines under access to health cannot be seen in its full practical sense. Through judicial decisions by interpreting article 21,

Developing Countries?' (May/June 2004) *Health Affairs* 155

[23] See World Health Organization, *The World Medicines Situation* (WHO, 2004) Chapter 7, available at http://apps.who.int/medicinedocs/en/d/Js6160e/9.html (accessed 11.04.2018.)

[24] Sarah Joseph, :TRIPS and Right to Health", Oxford University Press, 2011, available at www.oxfordscholarship.com/view/10.1093/acprof:oso/9780199565894.001.0001/acprof-9780199565894-chapter-8 (accessed on 11.04.2018)

[25] Article 5 (4) A compulsory license may not be applied for on the ground of failure to work or insufficient working before the expiration of a period of four years from the date of filing of the patent application or three years from the date of the grant of the patent, whichever period expires last […].

right to health has been recognized but when coming to its practical application we cannot find its benefit. Even today a large population in India doesn't have access to essential medicines. Affordability is one major issue as far as access in India is concerned. Making high reach of generic medicines is also not witnessed in the country. It is the pure lobbying of pharmaceutical industries and the multi- national companies who are behind this.

In this pandemic also this gains relevance. Some companies have agreed to pledge COVID-19 drugs for developing countries. But these are not been noticed by the large or it is avoided intentionally. Patent wavering of COVID-19 drugs has been into discussion but came out in vain. This has to be tackled effectively. Provisions of Compulsory licensing even though inserted with a great objective, is not put into its actual use effectively. Using the provision of compulsory licensing only one drug has been given the license in 2012 to the Indian generic drug manufacturer Natco Pharma Ltd. for Sorafenib Tosylate (a cancer drug patented by Bayer). This shows the extent to which our laws get enforced. So in India access to medicine can just be said as a 'notion' existing without any life.

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