

CHAPTER I INTRODUCTION

“The enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being.”

- *Preamble to the WHO Constitution*

It is undeniable that access to healthcare is one of the most basic needs, an inviolable right of every human. Healthcare is an intrinsic component of the development process. Limitations in healthcare may be immediately associated with a lack of adequate public or private health facilities or the inability to afford what is available, but the impact of the same lies in the lack of freedom to live healthy lives, free from preventable ailments and untimely death.¹

International human rights law recognizes the right to health in a number of legal instruments, significantly the Universal Declaration of Human Rights (UDHR) and the 1966 International Covenant on Economic, Social and Cultural Rights (ICESCR). The Declaration of Alma Ata has expressed the need for urgent action by all governments, all health and development workers and the world community to protect and promote health of all the people in the world. In India, the right to health is recognized as a derived fundamental right, under Article 21 of our Constitution², the cornerstone of our nation. The report of the Bhore Committee submitted in 1946 embodied a lofty vision of India’s health services, enunciating the principle that there should be access to health for all, free of charge³.

In theory, there are constitutional commitments to provide access to health to the nation’s population. The arguments justifying such a commitment are also watertight. Yet there is a stark difference in what is and what ought to be. The reality echoes what Rudolf Virchow had said in 1848, “that health is politics and politics is health, as if

¹ See generally, Jean Dreze, Amartya Sen, *India Development and Participation*, Oxford University Press, New Delhi, 2002, p. 5

² ND Jayal v. Union of India [2004 (9) SCC 362]

people matter”.⁴ Despite the plethora of promises made to the people of India assuring them access to medicines and health services, such promises have not yet been transformed into tangible actuality.

Access to healthcare is not a problem confined to India and may easily be ranked as a crisis of global dimensions. Over one-third of the world’s population lacks access to healthcare and pays a heavy price in terms of poor health and elevated mortality⁵. Lack of access to healthcare also increases poverty. One of the main factors driving families below the poverty line in India is financing their own healthcare⁶. There is a widely held assumption that healthcare for the poor is very inexpensive given their reliance on welfare driven government institutions. However, in reality, the poor are often compelled to avail of more expensive private services due to a range of factors and government hospitals also have many hidden costs.

In developing countries, a large proportion of the population has no access to necessary medicines. In the poorest parts of Africa and Asia, the picture is even worse, with over 50 percent of the population lacking access to even the most basic essential drugs.⁷ In India, according to one estimate, only some 35 percent of Indians can access essential medicines.⁸

The matter of healthcare, like most other development issues, is simply so enormous in magnitude that the government alone cannot be expected to provide the perfect panacea to resolve all issues in the area. The involvement of the people and relevant industries is essential to transform the paper pledges into reality.

There are two institutions of vital importance in ensuring access to medicines and healthcare. Firstly, there is the health delivery system, which is inclusive of doctors,

³ Debabar Banerji, *Politics of Rural Health in India*, Economic and Political Weekly, July 23rd, 2005, P.3253. Also see, KR Nayar, *Rural Health: Absence of Mission or Vision?*, Economic and Political Weekly, November 6th, 2004, p 4872.

⁴ Rosen G, *History of Public Health*, MD Publications, New York, 1958, p 7.

⁵ Nitya Nanda and Ritu Lodha, *Making Essential Medicine Affordable to the Poor*, Wisconsin International Law Journal, Vol. 20, No. 3, p. 581, 2002

⁶ See generally Report of the National Commission on Macroeconomics and Health, September 2005, p. 33

⁷ Ibid

⁸ Prabodh Malhotra and Hans Lofgren, India’s pharmaceutical industry: hype or high tech take-off?, *Australian Health Review*, Vol. 28, No. 3, p. 183

hospitals (both public and private), diagnostic labs, pharmacists and primary health centres, to mention only a few of its components. Also to be considered is the pharmaceutical industry, which manufactures and markets medicines and invents new medicines.

Access to medicines and healthcare has five aspects: availability of supply, price, quality, ability to pay and access to proper and affordable consultations. All these aspects are vitiated in our country by a number of factors, which range from poverty and poor infrastructure to corruption, market malpractices and lack of awareness. Market malpractices in general and in particular, anti-competitive conduct in the pharmaceutical industry and the health delivery system, have serious implications for access to healthcare by people. Examining legal and policy options to effectively curb such anti-competitive practices will be the focal point of this study.

Anti-competitive practices in the pharmaceutical sector and the health delivery system include, amongst others, price fixing, abuse of dominance, collusive agreements and tied selling. Even practices such as kickbacks to doctors and pharmacists may be deemed as anti-competitive as they result in depriving patients of best possible medicines and services at the lowest possible prices. The primary effect of anti-competitive practices on the health sector is that medicines and services are rendered costlier.

In the context of India's new patent regime and the increasingly deregulated environment, new concerns arise with respect to access to medicines and healthcare⁹. Will there be abuse of the monopoly rights of the patent-holder, causing an increase in prices? Will relaxation in price controls lead to rising prices? Will the inevitable increase in MNC presence, post-TRIPS, usher in the many anti-competitive practices? Will the current spurt in mergers and acquisitions create market structures, which may result in abuse of dominance? These are a few of the many questions arising in the wake of a series of changes in the pharmaceutical industry.

⁹ The differing implications of the process patent regime and product patent regime and the impact of the transition from one patent regime to the other is discussed in the second and third chapters.

One issue, which now renders it essential that there be careful monitoring of anti-competitive practices in the health sector, is that the Government is presently emphasising on promoting the private sector and such anti-competitive practices as outlined above are believed to be more prevalent in the private sector than in the public sector.

Many of the issues to be discussed in this report, including the anti-competitive practices prevalent in the health sector and the very need to efficaciously regulate and monitor the pharmaceutical industry and the health delivery system, are all underpinned by the basic conflict arising from private profit-driven institutions being major providers of health related products and services having enormous public good implications.

The emerging competition regime in India is likely to deal with some of these practices. However, competition law and policy will alone not be able to ensure adequate access to medicines and healthcare. Many problems need to be effectively addressed, at least to an extent, (for instance our endemic poverty and inadequate distribution mechanisms), if access to health is to become a reality. Nevertheless, effective control of anti-competitive practices in the health sector will go a long way in facilitating such access.

The methodology adopted for this study comprised of analysis of primary and secondary data. Primary data utilised for the report consisted of survey results, opinions culled from interviews, legislations, case law, the Current Index of Medical Specialities (CIMS) and Monthly Index of Medical Specialities (MIMS). A survey was conducted of five survey groups, namely, doctors, hospitals, pharmaceutical industries, pharmacists and consumer-oriented NGOs. In total, one hundred and thirty-three (133) doctors, one hundred and three (103) hospitals, fifty-four (54) pharmaceutical companies, one hundred and twenty-three (123) pharmacists and one hundred and eight (108) consumer-oriented NGOs were surveyed. The survey of all five sectors was carried out in four metro cities, namely, Delhi, Mumbai, Kolkata and Chennai, except in the case of pharmaceutical companies, where Chennai was substituted with Ahmedabad. Information generated through a survey conducted by CUTS earlier was also used wherever relevant, particularly the results of the survey of

consumers. Personal interviews were conducted with experts. An analysis of mergers and acquisitions related statistical data has been conducted and incorporated into the report. Secondary data were sourced from books, journals, newspapers, magazine and websites.

The structure of the report has been organized as follows: Chapter II provides a brief overview of the pharmaceutical industry and the health delivery system in India. Chapter III discusses existing and probable anti-competitive practices, at the local as well as cross border level, in the context of both the pharmaceutical industry and the health delivery system and the impact of such practices on the access to medicines and healthcare. Chapter IV presents an in-depth critical analysis of the existing legal and regulatory framework germane to dealing with the competition concerns in the health sector. Chapter V recommends certain measures and strategies to deal with anti-competitive practices in the pharmaceutical industry and the health delivery system, facilitating thereby access to medicines and healthcare. Chapter VI comprises of the conclusion to the report. The experience of different countries and lessons India could learn from such experiences, have been included throughout the report as and where deemed appropriate.