

**PUBLIC-PRIVATE PARTNERSHIP AND IPR IN INDIAN
PHARMACEUTICAL SECTOR**

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Abstract:

Intellectual property rights (IPR) have become important in the face of changing trade environment which is characterized by the following features namely global competition, high innovation risks, short product cycle, need for rapid changes in technology, high investments in research and development (R&D), production and marketing and need for highly skilled human resources. Geographical barriers to trade among nations are collapsing due to globalization, a system of multilateral trade and a new emerging economic order. It is therefore quite obvious that the complexities of global trade would be on the increase as more and more variables are introduced leading to uncertainties. This paper focuses on Intellectual Property Rights and Pharmaceuticals, Public-Private Partnership in Indian pharmaceuticals.

Key words: Intellectual Property Rights, PPP, Pharmaceuticals, Technology, etc.

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Introduction:

Many products and technologies are simultaneously marketed and utilized in many countries. With the opening up of trade in goods and services intellectual property rights (IPR) have become more susceptible to infringement leading to inadequate return to the creators of knowledge. Developers of such products and technologies would like to ensure R&D costs and other costs associated with introduction of new products in the market are recovered and enough profits are generated for investing in R&D to keep up the R&D efforts.

One expects that a large number of IP rights would be generated and protected all over the world including India in all areas of science and technology, software and business methods. Public private partnerships or PPPs are seen to have a significant role in bringing in much needed investments as well as efficiencies in utilisation and management of The World Trade Organization's agreement on Trade-Related Aspects of Intellectual Property Rights set global minimum standards for the protection of intellectual property, substantially increasing and expanding intellectual property rights, and generated clear gains for the pharmaceutical industry and the developed world. India too showed signs of resistance to quick enforcement of International Intellectual Property Right (IPR) protection laws as demanded by the developed countries.

The intellectual property (IP) system, and in particular the patent system, can play a pivotal role in relation to health-related development objectives as an incentive for innovation in the pharmaceutical field and as a policy tool to facilitate technology diffusion and access to essential drugs. Conversely, poorly structured IP systems, with an inappropriate balance between innovation and access, can hamper the ability of governments to deliver one of their primary development objectives, safeguarding the health of their populations.

Public-Private Partnership in Indian Pharmaceutical Sector:

PPP in health is an approach to addressing public health problems through the combined efforts of public, private and development organisations complimenting each other by contributing or sharing their core competency. The public-private partnership is an initiative to

improve efficiency, effectiveness and equity in the provision of healthcare services. This essay comments on the lessons that should be learned from some examples of such partnerships in various Indian states. The private sector is the most important source of healthcare services in India, providing close to 80 per cent of all services, according to the government's own reckoning¹. A related fact is that nearly 75 per cent of health-related expenses are out of pocket and occur at the point of service delivery.

Over the last few years there have been many initiatives to improve the efficiency, effectiveness and equity in provision of healthcare services in the country. Public-private partnership is one such initiative. Before considering emerging public-private partnerships in health in India, it may be worth recalling that healthcare has historically (even in developed nations) been a private sector activity. The emphasis on the government's responsibility for providing or supporting healthcare services for the entire population is recent. The National Health Service in the United Kingdom, often seen as the model for delivering universal and comprehensive healthcare services, was established only in 1948, after World War II. Starting from the Bhore Committee report in 1946 there has been an increasing emphasis on the state providing healthcare services through a three-tiered approach in India. However, despite these efforts and despite many healthcare and family welfare plans and programmes made since then, health outcomes in India have remained closer to those in sub-Saharan Africa than in industrialised nations among which India would like to be counted. Public-private partnerships aim to harness the large pool of private sector healthcare resources and draw them into the process of nation building.

According to the traditional view, there is a natural division of labour between the public sector, which is responsible for the production of public goods, and the private sector, which does the same for private goods. The former commodities that cannot be given a market price are therefore best funded out of collective tax revenues, whereas the latter are the commodities that can be allocated using prices. The resultant need for increased taxation to pay for these public commodities has proved both politically unpopular and unmanageable, where the revenues cannot be raised. The result has often been a decline in the level and quality of such 'public' goods and services. The research and development in biotechnology needs certain rules to be clearly fixed in order to reach its optimal level in a country like India. The first rule that needs to

be fixed for the private as well as the public research to have a reasonable incentive to invest in research leading to economic application is the rule of intellectual property protection².

A key difference in the public-private partnership approach in India today and earlier such initiatives around the world is that those were implemented in times of economic crisis when state funding for the health sector needed to be reduced. India, on the other hand, is experiencing unprecedented economic growth and there has been an explicit commitment to increasing state funding on health from 0.9 per cent to 2-3 per cent of the gross domestic product.³ Thus the primary reason to encourage private participation does not appear to be a lack of funds but a lack of managerial and technical ability⁴. The Indian Government recognised the usefulness of public private partnerships (PPPs) as a tool to promote innovation and entrepreneurship, there has been lot happening in the pharmaceutical industry. The Public Private Partnership summit 2008 provided a platform for discussions on the scope and future of PPPs and stressed on the need for PPP in life sciences as it will allow companies to leverage the knowledge and capabilities within the institutes to rekindle their product basket. In all it will be a win-win situation for both the parties as PPP will lead to the benefit of commercialization of novel inventions that have potential to generate additional revenues for both the researchers and the institute⁵.

Public-private partnerships have been explored as a mechanism through which to mobilize additional resources and support for health activities, particularly in under-resourced developing countries. Over 80 such partnerships exist, many focusing on combating neglected diseases or engaged in developing new drugs or vaccines⁶. The UN and its agencies have been at the forefront of engaging with the private sector in an attempt to foster collaboration that would deliver more resources for health in poorer countries⁷. The World Health Organization (WHO) has identified partnerships with civil society organizations, philanthropic foundations and the for-profit private sector as key to the future of global health⁸. This burgeoning collaboration with the private sector is in accordance with the United Nations⁹ Global Compact which seeks to increase and distribute the benefits of global economic development through voluntary corporate policies and actions in the areas of human rights, labour, the environment, and good governance.¹⁰

Public-private partnerships come in diverse forms and can mean different things to different people. While the terms "public" (state-financed and controlled) and "private" (non-state actors operating solely for profit or on a not-for-profit basis) are less controversial, that of "partnership" is loaded with ambiguities and has no single acceptable definition. It has been used to describe a variety of collaborations between different actors. Literally, it implies the commitment to a common goal through the joint provision of resources and expertise and the sharing of risks¹¹. In the health sector, public-private partnership commonly refers to any partnership in global health involving government and/or inter-governmental institutions and industry¹². To some people, collaborations between government institutions, particularly ministries of health and non-governmental organisations, are good examples of public-private partnership. For purposes of the analysis in this paper, the WHO's definition which sees public-private partnership as the "means to bring together a set of actors for the common goal of improving the health of a population through mutually agreed roles and principles" appears more appropriate¹³.

CONCLUSION

Underlying the bulk of global partnerships for health is the desire to bridge the inequity gap in healthcare access between rich and poor countries, especially access to essential drugs, and to develop new vaccines for diseases of prime importance to poorer nations. In particular, partnerships involving the UN agencies consider equity a primary goal as the organisation appears to have rediscovered its core equity values in recent years. But to what extent do these partnerships seek to and actually deliver on equity? Evidence of how public-private partnerships in the health sector have affected global health equity is scarce. In addition, scepticism about the profit motives of private corporations involved in these partnerships, especially pharmaceutical companies, often leads people to overlook any of their potential equity benefits. Indeed, many have criticised what they perceive to be an "open invitation" to private corporations to play a greater role in healthcare delivery, citing the risk of exacerbating current inequities in health as a major concern. The growing inequities in health and access to healthcare worldwide require serious global attention and strong leadership from the WHO and national governments.

Partnership with the private sector brings to the public health sector private financing and private sector know-how. In several instances, it has contributed to improving access to essential medicines in poorer countries and helped to mobilise additional resources and support for healthcare in the face of declining investments and rising demand for services. However, in terms of equity, public-private partnership is like a double-edged sword - it can promote as well as undermine fairness in global health. Private companies are established to generate profit and will not invest or participate in partnerships where the opportunity to make profit does not exist. The public sector stands the risk of subsidizing the commercial sector with public funds if it does not go into these partnerships with well defined goals and achievable targets. It is incumbent on all governments and inter-governmental agencies engaging in partnership with the private sector to set out clear goals for improving global health equity and ensure that these goals are achieved. This should go beyond narrowly promoting equity in access to essential medicines and target improving overall equity in health by paying special attention to the determinants of ill health, the establishment of effective health systems, and improvement of access and quality of care for those worst-off¹⁴.

The public-private environment can greatly influence the growth of the biotechnology sector in India to understand the mechanisms of interaction between the public research institutions and the companies with biotech activities. The public-private involvement plays a critical role in the development of the biotechnology sector. The areas include human resource development, public research and infrastructure development. The main government agencies are responsible for financing and supporting research in biotechnology. The share of each budget actually dedicated to biotechnology research funding is not available.

- *Public-Private partnerships in health care at very early stages*
- *Will need significant institutional development work in terms of financial analysis capabilities, monitoring and evaluations systems*
- *Appropriate regulations to check the unintended outcomes of private sector growth in health*

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