



Pharmaceutical growth versus health equity in India: when markets fail

Kausiki Mukhopadhyay¹ · Pallab Paul¹

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Abstract

Aim To reveal inequity in health in India.

Subject and methods The global paradigm of the knowledge economy propounds that growth and equity will occur if there is a free-market economy without state intervention and if patents are provided as incentives for innovation. In this paper, we explore the veracity of this thesis by investigating growth in the pharmaceutical and biotech sectors in India, and by looking at equity issues through the lens of gender health and health costs for poor consumers. We used data from current publications to support this thesis.

Results We found that growth has been characterized by multiple handicaps and oligopoly, with the nature of expansion not having relevance for the disease profiles in India. The scenario of gender health and health costs of the poor is grim due to state retrenchment and neglect of the provision of public good, such as in health matters.

Conclusion One can conclude that equity has not occurred under a growing pharmaceutical sector. This finding has huge implications for public policy in India and other emerging nations.

Keywords Ethics · Equity · Growth · Health · India · Patents

Introduction

As globalization increases, developing countries have been adopting the knowledge economy model (Kasemsap 2017; Paul and Mukhopadhyay 2010) with its flagship feature product patents based on intellectual property rights (IPR), and prescription of state retrenchment from public services. The Government of India (GOI) adopted this developed world model in the early 1990s and has been guiding its public policies on science and technology (Petrescu 2009) and public health improvement based on the model's prescriptions ever since. The sustainability (Bennett et al. 2017; Hill et al. 2014) of this model of governance in generating equity, and its underlying ethics, are the primary focus of this paper.

Public policies on science and technology are basically focused on the adoption of product patents based on the regime of trade-related intellectual property rights (TRIPS). Helfer and Austin (2011) provide a full review of the extant human rights and intellectual property regimes, institutions,

and laws, and the rationale for the disjuncture between the two in a historical context, as well as demonstrating the growing tension between the requirements of the two opposing philosophies. This mismatch is heightened by the fact that corporations now claim protection of human rights in the name of their right to property, in order to protect their patents. Anomaly (2011) highlights the critical theoretical foundations required to understand the rationale behind the necessity for considering public health as a public good. Sridhar (2008) provides the outline of debates surrounding provision of essential medicines and the need to prioritize health concerns in the global governance system. Morbidity and mortality have been severely increasing across developing countries due to lack of access to essential medicines. Corporations have been dismissing such concerns by attributing them to structural barriers within individual economies, such as poverty, lack of proper healthcare systems, and so on, thereby absolving themselves of their global citizenship responsibilities. Collste (2011a, b) provides a theory and a justification of rights to the issue of TRIPS and the barriers it creates to accessing medicine for the poor.

The knowledge economy model has put severe pressure on the 'right to development' (Arts and Tamo 2016; Gupta and Arts 2017; Rajagopal 2013) and the 'right to life' (Bernstein 2014; Helfer and Austin 2011; Turcotte

✉ Pallab Paul
ppaul@du.edu

¹ Daniels College of Business, University of Denver, 2101 S. University Blvd, Room 497, Denver, CO 80208, USA

2018) because of prescribed state retrenchment in favor of the release of a free-market economy. Though both states and markets are ‘master institutions’, states enjoy de jure and de facto international recognition, while markets have only de facto validity in the global arena. Markets can therefore only thrive under the legitimacy umbrella of sovereign states and gain validity by being embedded in multilateral processes of states (Buzan 2004; Cormier 2016; Pattberg and Widerberg 2015). Markets can exert coercive disciplinary pressure on states, but in the final analysis it is the states that have the right to enact legal actions having the genuine ‘power’ of being backed by penalties or sanctions. States are generally expected to enact laws based on the moral wellsprings of the multi-stakeholder social arena, but as demonstrated in the history of the TRIPS regime (Löfgren 2018; Sell 2003), particularly in the context of hegemonic, yet non-altruistic decision-making by the US (Helfer and Austin 2011), states have typically failed to do so. Despite their authority, states have started to willingly relinquish their power to markets, with far-reaching detrimental consequences in the arena of provision of public goods.

In tune with the thrust towards the knowledge economy, there has been growth in the patent-oriented pharmaceutical and biotech industries. However, this expansion has been defined by handicaps for local pharmaceutical businesses, buy-outs by foreign companies, and the emergence of an oligopolistic sector, made possible due to a lack of government intervention in free-market economies. Oligopoly combined with monopoly patents (patents are granted for 20 years) has led to soaring prices for medicines and inaccessibility for poor consumers. The mantra of growth has subdued claims of equity. The GOI has been putting the emphasis on expansion (10% for most of the past decade) more than equity. The result of non-egalitarian growth is that India has poverty levels worse than sub-Saharan Africa (Babones 2018; Burke 2010; Kanti 2018). Lack of inclusive development can severely affect disadvantaged consumers (Beaty 2017; Blankson et al. 2017; Dadzie et al. 2013). We thus explore the consequences of such growth via two criteria—gender health in India and health costs of the poor.

We begin this paper by first defining the key term ‘knowledge economy’. We then outline the growth that has taken place in the pharmaceutical sector, pointing out that it has been largely irrelevant for the people of India, since most drugs created are for developed country diseases and are intended primarily for export. Next, we explore the state of women’s health in India. The knowledge economy promises growth and equity. Health equity is a critical measure of such fair distribution and is also impacted by affordability. Hence, we next look into the health costs of the poor in India. The picture painted by the public data is quite grim and shows that growth has not led to equity.

Therefore, there is room for public policy enactment. Health equity is a major issue just about anywhere in the world today. Even in an advanced country like the USA, older citizens are concerned about the likelihood of not being able to access healthcare in the future, which warrants a modification of healthcare policy (Mercier and MC Shelley 1997). In the Indian context, one possible solution would be for the government to focus more on equity, ensure better access to medicines, and improve healthcare infrastructure for the disadvantaged sections of society. Our study underscores the need for such a public policy in India in the health sector, and this is where the contribution of this research lies.

Knowledge economy

Before expanding on the thesis of the impact of the knowledge economy, it is critical to gain a background understanding of the assumptions behind this paradigm. We begin with the rationale of state retrenchment and finish with the logic of patents.

The knowledge economy model is propounded by neoliberalists who favor the operation of market economy over hierarchical state coordination for the provision of public services. This is because they consider the state to be inherently inefficient and corrupt, and ultimately a defective institution that is prone to non-performance and failure to maximize social returns. The state is considered a monopolistic institution that caters to majoritarian interests that deny individual freedom. In contrast, the free market provides for personal choice through unfettered competition and aligns private and social costs (Coleman 2013). The neoliberals overlook the fact that the state is an embodiment of the collective will of the citizenship with a commitment to shared ‘public’ interests. Instead, they prescribe complete retrenchment of the state from the provision of public services such as healthcare. They view privatization and deregulation to be the emerging norm and advocate that the state should do everything to ensure the emergence of a free-market economy. State legitimacy would then subsist as a form of sovereignty limited to guaranteeing economic activity (Lemke 2001; Schiavo 2015).

For neoliberals, an auto-regulated, asocial, free-market economy, unfettered by regulation and based on principles of demand and supply and their intersecting ‘evaluative’ point of pricing would provide for adequate and efficient services through proper allocation of factors of production. In doing so, neoliberals ignore all forms of market failure, such as the inability to provide for the collective/public good in areas such as healthcare.

Neoliberals ‘extend the market’ into the political arena, thereby creating a ‘marketization of the state’ (Olssen 2006; Sandu et al. 2014). The state, however, instead of being ‘independent of and outside the market’, in a position to define

and monitor market freedom, is itself now ‘subject to market laws’ as its organizing and regulative principle (Olssen et al. 2004). ‘Economic and market exchange relations then govern all areas of human interaction’ (Olssen et al. 2004), and the public sector becomes economized to ‘reflect market principles and mechanisms’. The job of government is then to universalize competitive principles in order to ensure efficiency and create all the political, legal, and institutional infrastructure that will help the market thrive (Olssen 2006). Collective or public responsibilities of achieving social welfare, particularly for those who are structurally disadvantaged, like women and the poor, are put on a back burner. Individuals are regarded as autonomous subjects functioning on subjective voluntary calculations and hence, their choice in terms of ability to purchase a product is a decisive ‘democratic vote’ about their preferences. Such preferences are based on the rationality of profit and loss, or cost and benefit, and the responsibility for personal choices is fully attributable to them. In short, all structural barriers of power are discounted and the individual is made entirely answerable for his or her actions.

Neoliberals are highly concerned with efficiency, defined as a measure of the ratio between outputs or outcomes, and inputs. Inefficiency would mean that state services have more inputs than outcomes. State retrenchment may mean more economy in terms of reduced inputs but not necessarily more efficiency or effectiveness. This is because the state provision of ‘inputs’ or social services aimed at providing healthcare for the public, reducing poverty handicaps of the general populace, and so on, are all precursors for the proper functioning of a market economy. Without a concerted effort to create a level playing field in a world of inequities, efficiency cannot thrive. Positive outcomes of a well-functioning knowledge economy are impossible when the world is skewed in favor of the privileged only. State services should therefore be seen as civic investment in the welfare of communities as a whole.

Neoliberals expect the gap in governance created by state retrenchment to be filled by corporations assuming the mantle of justice through adoption of best practices of corporate social responsibility (Johnstone-Louis 2017; Paul and Mukhopadhyay 2010). The success of such measures of governance in the case of health equity would be availability of free or low-cost medicines for the poor, specifically drugs targeting diseases common among them. Beyond medicines, corporate hospitals should have provisions for free or low-cost treatment of the poor. Such hospitals and clinics should be evenly distributed across urban and rural sectors to make accessibility easier for poor rural populations. However, all such demands that have been traditionally met by the state require corporations to overcome irrational greed for profit and cost–benefit analysis in order to perform redistributive justice. That is a very tall order, and we argue that corporations have typically failed to provide health equity. Vast scale inequality thrives in India despite free-market reforms.

Let us now look at the logic of patents. Knowledge economy presupposes a uniform distribution of knowledge in the international system. However, this model is actually the preserve of nations that are already developed and capable of producing value-added, technologically advanced finished goods (Mukhopadhyay 2014; Paul and Mukhopadhyay 2010). Finished goods embody advanced levels of skills and hence represent highly developed cutting-edge knowledge processes. There have been efforts to safeguard such innovation through patents, as inscribed in the international TRIPS treaty. As Sell (2003) argues, advanced states in cahoots with their corporations instituted a regime of patents due to heavy protectionist lobbying of their corporate sector, wanting to ensure that any competition undermining their advantage was blocked (Cohen 2008; Cutler and Dietz 2017; Whytock 2016). As a consequence, developing states have been left with very little economic policy leverage for distributional issues (Khan and Patomaki 2010).

The key argument for protection through patents has been made by the powerful US Pharmaceutical Research and Manufacturers of America trade group (PhRMA). They argued that reverse engineering of drugs done by generic companies in developing economies was basically stealing innovations which someone else had created. The protection provided to such generic drugs through ‘process’ patents by developing countries was a disincentive to innovation. Hence, all innovations should be ‘product patents’. Critics point out that this kind of argument lacks validity. According to Noah (2011), PhRMA does not really innovate. It simply buys out innovations created within universities and uses its marketing muscle to sell the drugs. It then declares its marketing costs as part of R&D, and therefore an innovation cost. More critically, consumers end up not just paying twice for the drugs, but also at a price that is hugely inflated or abnormal. Consumers first pay for the taxes that go to help universities develop their biotech programs. They then again pay a high price for the innovated drugs.

The United States as the world’s hegemonic nation state convinced all other major developed countries to agree on the position that ‘standardized’ product patents are critical for growth and, hence that their protection is vital for stability and ‘fairness’ in the international trading system. It also actively used sticks and carrots of non-access or access to its huge consumer market for developing country goods, particularly agricultural products, in order to force other countries to agree to this position. The result was the establishment of TRIPS in the World Trade Organization (WTO) which signified the emergence of ‘private power leading to public law’ (Johns and Wellhausen 2016; Sell 2003).

Legal patents help to garner increasing rates of return or provide accumulation of wealth for corporations (Herstatt et al. 2008; Narula and Kodiyat 2016; Watkins et al. 2015). The assumption is that this incentivizes corporations to engage

in increasing foreign direct investment (FDI), which in turn leads to higher levels of growth for developing economies. Patents are supposed to provide incentives for individual motivation, too. In a knowledge economy, the focus is on developing human capital by transferring labor from subsistence activities to modern sectors, such as the pharmaceutical and biotechnology industries.

The emergent consensus outlined above regarding human capital, knowledge, and growth among developed countries in the WTO is not shared by developing and emerging countries. Although subject to the TRIPS treaty, developing nations were actually mainly ‘coerced’ into it and therefore feel that their joining was not through a legitimate process of consensus building. As a result, there has been a continuous battle to integrate human rights and development into the TRIPS agreement (Chorev and Shadlen 2015; Gleeson et al. 2015; Sell 2003, 2007; Sell and Prakash 2004; The Corner House 2004). The main focus of this struggle has been the problem of lack of access to medicines by the poor due to patent barriers.

From the perspective of vociferous proponents of a genuine ‘fair trade’ system, the enactment of TRIPS in the under-developed world has had severe consequences on equity. TRIPS advocates, on the other hand—mainstream neoliberal economists who actively support the knowledge economy and IPR—often neglect the negative impacts, because the main concern is not about ‘universal’ human rights of all groups and distributional equity across society, but about ‘individual’ interests and wealth accumulation. Implementation of the TRIPS regime has certainly impacted public policies geared towards distributional equity. With the increasing normative thrust towards privatization and free-market-led auto-growth, emerging country governments have taken a back seat. A lack of proactive protection against market distortions endangers the survival of the poor, particularly of poor women.

Growth in pharmaceutical and biotechnology sectors

Due to adoption of the knowledge economy model, the GOI has been emphasizing the growth of the pharmaceutical and biotech sectors. However, there are some significant constraints to contend with in India. To tackle these restrictions, Indian corporations have come up with their own expansion strategies. This section will therefore look at these handicaps and advancement strategies before looking at concrete development figures.

Biotech industries in India are hamstrung by several major problems. The first they face is a lack of private investment and venture capital for the biotech novel drug development sector because it requires substantial risk-capital outlays for long periods of time, coupled with a high

uncertainty of return. In 2006, private and venture capital investment in India was about US\$ 7.5 billion, of which less than 7% went to healthcare and the life science industry. Hence biotech industries comprised of medicines, vaccines, and diagnostic and gene therapy are still impaired by the difficulties they face in commercializing technology (Arora 2010; Mukhopadhyay 2014).

According to the Department of Industrial Policy and Promotion, the pharmaceutical sector attracted FDI worth US\$ 1.67 billion between April 2000 and March 2010, with an annual average of US\$ 0.167 billion. In comparison, FDI inflow for all sectors during the same 10-year period was US\$197.935 billion at an annual average of US\$19.79 billion. The pharmaceutical share was thus only 0.84% of the total inflow of FDI. FDI into India during the 10-year period for all sectors was US\$ 132.837 billion at an annual average of US\$ 13.28 billion. Mauritius, Singapore, the USA, the UK, the Netherlands, Japan, Cyprus, Germany, France, and the UAE all contributed to FDI inflow during 2009–2011, but there was no investment in the drug and pharmaceutical sector. ‘However, there was a 2% inflow into chemicals (other than fertilizers)’ (Express Pharma 2012). Overall, counter to knowledge economy predictions, imposing a product patent system has not attracted a significant stream of FDI to India. For example, according to the UN Conference on Trade and Development, FDI flows to India dropped 29% to US\$ 26 billion in 2012 (United Nations Conference 2012).

The second problem faced by the biotech sector is that most of the companies are small and medium-sized, and as such cannot access the benefits provided by the GOI through its Special Economic Zone programs due to issues of scale and investment threshold. Most of these companies set up by returning Indian scientists from the USA face bureaucratic barriers in accessing financial assistance from the GOI. They have less well developed infrastructures and formal marketing methods at their disposal, and hence rely heavily on personal networks and word of mouth. Since they also face stiff competition from large biotech companies, both domestic and foreign, they have tried to circumvent such problems by tying up with homegrown universities, in the fashion of US pharmaceutical company growth styles (Arora 2010; Mukhopadhyay 2014).

A third problem faced by biotech companies arises from their desire to leverage biosimilars, or generics of biologics. Most research is currently focused on biosimilars as the market for them is pegged at well over US\$ 100 billion. In the US alone, eight major biologic products such as Enbrel (Amgen/JandJ) and Lovenox (Sanofi-Aventis) went off-patent in the period between 2009 and 2013. The total revenue from these drugs was over US\$ 15 billion. In the next decade, 48 biologics worth an estimated US\$ 73 billion are going to become off-patent. Thus, biosimilars will become new streams of revenue for biotech companies (Express Pharma 2012).

However, creating biologics is a difficult process, and hard to reproduce. Unlike synthetic generics where a “one-size-fits all” approach can be adopted, biosimilars are more targeted, and any change in the manufacturing process could have unpredictable effects on the human body (Kale and Huzair 2017; Kamath 2011). This means that only highly skilled biotech companies can thrive in the market and are likely to draw more collaborative capital. Moreover, while basic research is available internationally through scientific publications, the translations of such biotech research into low-cost production processes are guarded by developed country firms, as this forms the basis of their comparative advantage (Bagchi-Sen and Smith 2008; Isaksen 2016). This hampers the development of the biotech sector as a whole.

The pharmaceutical sector has typically focused on the development of small molecules of chemical entities for drugs. The biotech sector, on the other hand, is concerned with the discovery of large molecules/biologics based on living cells from humans, animals, and microorganisms for creating sugars, proteins, nucleic acids, or other complex combinations that can be used for therapeutic purposes. Given the highly enhanced degree of complexity involved in biotech drug and vaccine discovery for three primary diseases—cancer, rheumatoid arthritis and diabetes—emerging market biotech companies often face accusations from the developed world of producing poor-quality biosimilars. The Indian regulatory environment itself is described by some as being of a poor or low standard, and hence generic versions of biologics are called biogenerics, rather than biosimilars (Slideshare 2014). In 2012, the USA banned the entry of biosimilars (Arts and Tamo 2016; Rajagopal 2012). Since the USA constitutes the world’s largest drug market, this has left Indian companies with only marginal profits in the European and other emerging markets. On top of that, stiff competition has meant that only large, successful Indian companies with significant capital outlay have the possibility of penetrating such markets. For example, in early 2008, Biocon, the largest Indian biotech company, ranked 16th out of the top 20 global companies (Arora 2010), acquired a 70% stake in the German pharma company Axicorp. Axicorp specializes in the marketing and distribution of generics and has helped in marketing Biocon’s injectable insulin (Slideshare 2014).

Fourthly, biotech companies face a lack of significant innovation. According to Arora (2010), the majority of Indian small and medium-sized biotech firms do not have the capability to be prospectors or innovators and first-movers with a focus on R&D, and hence are not able to create value. Rather they tend to be analyzers, that is, they are inclined to emphasize low-cost production and efficiency in a secure niche market during stable times. When markets are turbulent, they adopt a wait-and-monitor approach in order to see which competitor innovations appear to have strong potential so that they can

adopt them. This has meant that in comparison to global multinational companies (MNCs), Indian companies’ investment in R&D is very low. For example, while 13 major Indian companies together spent US\$ 454 million in 2007–08, Pfizer, the largest MNC, spent US\$ 8.1 billion in 2007 alone (Abrol et al. 2017; Chaudhuri 2010; Haeussler and Rake 2017). Moreover, only 10% of Indian R&D funds are aimed at diseases primarily affecting developing countries, including India.

Companies that stand tall in innovation in the Indian market, such as Strides Astrolabs, responsible for creating breakthrough biotech products related to hormones and anti-carcinogenic drugs (Khan 2008), are those that have significant capital outlay. Companies engaging in clinical research including Nicholas Piramal, Reliance Life Sciences, Lambda Labs (a division of INTAS pharmaceuticals) and Lotus Labs (an offshoot of EROS Pharma) are all major Indian companies (Bagchi-Sen and Smith 2008). Nevertheless, not all major companies are always successful. For example, Panacea Biotech claims that it is in the process of graduating from pediatric to adolescent and adult vaccines for diseases such as rotavirus, HIV, dengue fever, Japanese encephalitis, pneumococcal infections, and hepatitis. However, the WHO recently barred its ‘pre-qualified’ triple combination vaccines that the company had supplied to the organization because an on-site audit team spotted deficiencies in the Punjab plant’s quality management system. The consequent financial impact on the company is likely to prevent progress in innovations (Amirapu 2011).

Indian companies have overcome the above-mentioned handicaps by cooperating with biotech MNCs for innovative drug discovery (Mukhopadhyay 2014; Srivastava et al. 2010). Collaboration often takes the form of the USA outsourcing its R&D. In the USA, usage of generic medications have been increasing, and Indian companies have started to aggressively tap into the generic medicine market by taking advantage of a number of blockbuster drugs going off-patent, such as GlaxoSmithKline’s (GSK’s) cholesterol drug Lipitor (Beasley 2018). This has enhanced the credibility of Indian companies.

These newly emerging partnerships have led to the creation of Contract Research Organizations (CROs) for drug manufacturing, discovery and clinical research (Arora 2010). For example, the Indian biotech firm Avestagen Laboratories now performs R&D for many European pharmaceutical companies. Syngene, promoted by Biocon, has tied up with Bristol Myers Squibb (BMS) to operate an R&D center comprising around 400 scientists. Syngene also collaborates with Astra-Zeneca for drug discovery. Orchid Chemicals has partnered with Bextel for drug discovery in metabolic diseases. Biocon cooperates with BMS, Pfizer, and Astra-Zeneca for contract researching of new bulk drugs. Divi Laboratories is involved with Merck, Abbott, and GSK for manufacturing patented

drugs, custom synthesis and scale-ups. Sashun Chemicals has R&D service agreements with Aventis, Eli Lilly, GSK, and Teva for contract research and custom synthesis services. Astra Zeneca and Torrent share collaborative R&D for discovering a drug for treatment of hypertension. Bexel Lab has joined forces with Orchid Pharmaceutical for development of anti-diabetic molecules. Lupin has entered into a development and licensing agreement with Cornerstone Bio Pharma Inc. for an anti-infective product. Jubilant Organosys has a contract for R&D services with Eli Lilly for diabetes and oncology. Given such extensive tie-ups, the market for CROs is expected to grow at 20–25% a year (Khan and Nasim 2016; Rai 2008; Shabaninejad et al. 2014; Venkataraman et al. 2015).

Indian companies also participate in collaborative in-licensing models that enable the local manufacture of extant drugs owned by MNCs and the sharing of profit with them. For example, Glenmark has in-licensed Crofelmor, Napo's proprietary anti-diarrheal compound. Wockhardt has in-licensed Syrio Pharma SpA's dermatology products, and Nicholas Piramal has entered into an agreement with Roche for launching products for the treatment of cancer, epilepsy, and HIV/AIDS (Rai 2008). Bharat Biotech and Serum Institute have licensed technology from institutions in the USA, Canada, and Netherlands (Express Pharma 2012).

Collaboration between India and other countries can also take the form of writing research papers. India's research output (its growth rate, publication share, and world ranking) has been steadily growing in recent years. In 1998, India ranked number 14 and by 2007 it was number nine, with publications rising sharply from 1.77% of the global share in 1998 to 2.37% in 2007. Fifteen foreign journals, including the renowned *Nature* and *Science*, together contributed to 22.52% of India's total output during this time period. In all this research, the USA was the largest collaborative partner, accounting for a 43.55% publication share (Bala and Gupta 2010).

The general view in the Indian pharmaceutical industry is that to overcome handicaps, more investment from the government is needed in order to ramp up fundamental research capabilities to enable the development of novel products and new drug delivery systems. Domestic biotech companies are already benefitting through schemes including the Small Business Innovation Research Initiative, the Biotech Industry Partnership Program, the Biotechnology Industry Research Assistance Program, the Industrial Infrastructure Upgradation Scheme, the Industrial Park Scheme and the Scheme for Investment Promotion of the Ministry of Commerce and Industry, the National Agricultural Research system of the Indian Council of Agricultural Research, the Talent Research Scheme, and the Extra Mural Project of the Indian Council of Medical Research (Express Pharma 2012). Despite such growth strategies, 75% of the patents in India are still currently assigned to foreign MNCs (Arora 2010).

The fifth challenge is that Indian drug companies are handicapped by regulatory demands. For example, in order to launch drugs in the US, Indian companies have to conduct a substantial portion of their clinical trials there. This is highly cost-prohibitive. Under such circumstances, Indian companies tend to develop new molecules up to a certain stage and license them out to MNC partners and use their help for commercialization. This is contrary to the TRIPS prognosis regarding the inward transfer of technology to developing countries. Moreover, such activities mean that molecules that are licensed out are those that the global MNCs are keen to develop into drugs that cater to their main markets in the developed countries. For example, in 2004, Biocon entered into a strategic partnership with the US pharma company Nobex Corporation for the co-development and commercialization of oral insulin for diabetes treatment on a global scale (Jamali and Karam 2016; Khan 2008). However, the licensed molecules sometimes may not be further developed by the MNC if it competes with existing or planned products of their own. Licensing may then result in the perverse situation of non-drug development and curtailing of knowledge growth and an antithesis to knowledge economy predictions.

To overcome the handicap of regulatory demands and ensure advancement of lead molecules, some Indian drug companies such as Dr. Reddy's have started to explore alternative business models, such as joint development and sharing of costs with smaller specialized research companies, including Rheoscience and Clin Tec. Both MNCs and Indian companies are increasingly tying up with specialized clinical research companies such as Vimta Labs, Synchron, and Reliance Clinical Research.

Indian companies have also been able to overcome the drawbacks of regulatory demands due to an emerging trend among the MNCs. There has been a growing reverse tendency to license out lead molecules due to the ever-higher expense of clinical trials in developed countries. The need to make savings is increasingly pushing MNCs to conduct clinical trials in India. Recent studies show that Phase I trials cost half that of those conducted in the USA, and that Phase II and III cost less than 60%. Clinical trials are expected to represent 65% of the growing CRO market in India. Pfizer itself has invested US\$ 13 million in India for Type I clinical trials (Garg et al. 2011; Marwah et al. 2016). Up to June 30, 2010, 1078 trials had been registered, 666 of which were drug trials and 157 biological. Most of them were in the fields of developed country diseases such as various types of cancers, 'disorders of the central nervous system ... diseases of the circulatory system ... and endocrine nutritional and metabolic diseases including diabetes, obesity and cardio-vascular disorders,' (Shenoi 2011). Developing country diseases such as malaria and TB simply do not get researched. This is despite the fact that communicable diseases, maternal and perinatal conditions, and nutritional

deficiencies contribute to 36% of deaths and 42% of disability-adjusted life years in India (Balarajan et al. 2011; Wirtz et al. 2017).

Beyond the above-mentioned strategies, joint ventures have been another modality of growth for Indian companies. For example, in 2009, Biocon entered into partnership with Mylan to produce several biosimilars, such as Herceptin, a breast cancer drug. This drug produced by Roche is soon to go off patent (Rajagopal 2012). However, Mylan has exclusive marketing rights in the USA and Europe with a special profit-sharing agreement with Biocon. Biocon intends to launch such biosimilars into the established Indian market (Slideshare 2014). Similarly, GSK has recently entered into a 50/50 joint venture with Biological E. (B.E.), a leading Indian manufacturer of vaccines. The purpose was early stage R&D of a six-in-one combination pediatric vaccine that would help protect children in developing countries including India from polio and other infectious diseases. The vaccine was designed to combine GSK's polio with B.E.'s pentavalent vaccine for diphtheria, tetanus, whooping cough (whole-cell pertussis), hepatitis B, and Haemophilus influenzae, and would involve fewer injections for children, thereby improving compliance with the immunization schedule (GSK 2013). Boehringer Ingelheim has partnered with Kemwell for manufacturing drugs at low cost (Express Pharma 2012). Claris Life Sciences Ltd. has sold a majority (80%) stake of its infusion business in India and other emerging markets by forming a three-party joint venture with Japan's Otsuka Pharmaceuticals Factory Inc. and Mitsui Company Ltd. Claris will move its anti-infectives, common solutions, plasma volume expanders, and parental nutrition therapies businesses to the joint venture. The emerging company (Claris-Otsuka) will bring Otsuka's specialty products to India (Reuters 2012). Overall, north–south collaboration of biotech firms ranges between 60 and 75% in India (Geary 2017; Melon et al. 2009).

Joint ventures and collaboration are not the only routes to growth in the biotech sector. Some companies such as Dr. Reddy have made solo strides in the field of biosimilars. In 2007, Dr. Reddy launched rituximab, a biosimilar of Roche's US\$ 6 billion cancer drug Rituxan. The company is selling the drug in emerging markets at a 30–50% discount to the innovator brand. Similarly, its darbepoetin, a drug for severe anemia, was the first biosimilar of Amgen's US\$ 2 billion Aranesp (Kamath 2011). To be strongly innovative, it set up a lab for discovery and design of novel therapeutics in Atlanta, USA, in 2000. The purpose was to tap into the diaspora of scientists who can not only provide a knowledge base, but also facilitate entry into the US technology networks (Kale et al. 2008).

The Indian biotech sector has also been characterized by brownfield merger and acquisition investments (Banerji 2009; Papaioannou et al. 2016). Such undertakings squeeze the biotech domain into a more oligopolistic market, reduce

competitive growth, and thus raise the price of drugs (Kumar 2018). For example, Ranbaxy was taken over by Daiichi Sankyo of Japan in 2008. Ranbaxy had been the fifth largest generic company in the USA, with 81 generic products approved by the FDA. With acquisition, the availability of such drugs for the Indian market became uncertain. Shantha Biotechnics was taken over in 2008 by Sanofi Aventis of France (Kamiike and Sato 2011; Mohammad and Kamaiah 2016). The availability for the domestic market of the company's extremely cheap hepatitis B vaccine, which cost US\$ 0.50 as compared to SmithKline Beecham's US\$ 10 became uncertain. Another example is the Indian company Matrix, one of the world's leading producers of active pharmaceutical ingredients, which was taken over by the US global healthcare company Mylan in 2006 (Rai 2008). Such buyouts make access to generic drugs problematic. Dabur India Ltd. was taken over by German company Fresenius Kabi in 2008 with a 73% stake. Orchid Chemicals was taken over by Hospira in 2014, and Piramal Healthcare was bought up by Abbott Laboratories (Krishna et al. 2017; Reddy and Kadri 2013; Zhuang 2017).

Despite several major handicaps and all the mergers and acquisitions, the Indian pharmaceutical sector has been growing steadily. According to Rai (2008), the Indian pharmaceutical industry ranks fourth in terms of volume and 13th in terms of financial worth worldwide. It accounts for 8% of global production and 2% of international markets in pharmaceuticals. Currently, in value terms, Indian companies produce 20–22% of the world's generic drugs, 60,000 finished medicines and nearly 400 bulk drugs used in formulations or active pharmaceutical ingredients. Since labor costs in India are 1/7th that of the USA and Western Europe, manufacturing expenditure is 30–40%, making the industry the provider of the cheapest drugs in the world (Rai 2008). At the same time, Indian pharmaceuticals is one of the world's most developed industries (Reddy and Kadri 2013), and India is the global leader in exporting generic medicines, worth US\$ 11 billion.

The Indian biotech market is dominated by biopharmaceuticals. In 2010–11, the Indian biotech sector netted revenue worth US\$ 2300 million (Rajagopal 2012). At a compound annual rate of 15–20%, global biopharma growth is expected to reach a value of anywhere between US\$ 50–74 billion by 2020. Industry estimates indicated that biologics worth US\$ 59 billion would go off patent between 2008 and 2015. This was expected to spur growth in an established biosimilar market like India (Kamath 2011). On top of that, the Indian government passed an initiative in early 2013 to allow for 100% FDI without the threat of compulsory licensing, as envisaged in the TRIPS treaty for provision of medicines for the poor in case of a national health emergency. This deliberate sidelining of investment was designed to foster growth.

Women's health in India

A key measure of whether a thriving pharmaceutical sector has led to improvement is to look at gender welfare. Under the norms of the Universal Declaration of Human Rights, the Indian government has the primary responsibility of ensuring access to health. Medical care in the event of sickness, and the prevention, treatment, and control of diseases are essential rights for attaining the highest possible standard of health (Coleman 2017; Droppert and Bennett 2015; Gopinathan et al. 2014; Khosla and Hunt 2012). These features depend upon access to medicines. Without such health rights, poor women's lives are defined by gross inequity, ill health, pain, fear, and loss of dignity and life. In light of the government's responsibility to protect these rights, it is critical to note that, despite a thriving biotech sector, the government has yet to deliver good health for the women of India. State retrenchment has not helped the gender health situation, either.

To understand the complexities of Indian gender health, it is critical to look at several gender development indicators. The Hausmann et al. (2011) adolescent fertility rate (births per 100,000 women aged 15–19) was 45 in 2011 (Langer et al. 2015). Since contraception is the way to prevent pregnancy, it is also important to look at contraceptive prevalence, which was 56% among women aged 15–49 in 2011. Institutional births or births attended by skilled staff accounted for 47% of all births in 2011. The rate for pregnant women receiving antenatal care was 75% in 2011. The maternal mortality rate (MMR) was 230 per 100,000 live births and the infant mortality rate (IMR) was 50 per 1000 live births in 2011. According to Balarajan et al. (2011), India accounts for one-fifth of maternal deaths and one-quarter of child deaths in the world. Among the poorest quintiles, the IMR was 82 per 1000 live births, compared to 34 for the richest quintile in 2005–06. Among the poorest of the poor, the Scheduled Tribes (STs), institutional delivery was 17.1% in 1998–99, with a minimal improvement of 17.9% in 2005–06. These statistics give India a Gender Development Index rank of 113 out of 117 countries in the global arena.

Along with mother's health, it is critical to look at children's health, which of course subsumes female children's health. First, the Indian government has failed to provide good immunization coverage to its poor population. As Baru et al. (2010) point out, full immunization in rural areas was 38.6% in 2005–06; among the lowest quintile it was 24.4%, among the oppressed Scheduled Castes (SCs) and STs it was 39.7 and 31.3% respectively (Chakraborty and Chakraborti 2015; Dwivedi and Pradhan 2017). In 2005–06, the all-India average for full immunization was 44%, representing only an 8% improvement from 1992 to 1993. According to Corsi et al. (2009), immunization rates in India increased between

1992 and 2006, but age-appropriate coverage is still under 50% nationally, and girls are significantly less well protected than boys (Francis et al. 2017).

According to the World Bank, the prevalence of under-5 child malnutrition was 43.5% between 2005 and 2011, and in 2011, the under-5 mortality rate per 1000 live births was 61 (World Bank 2013). Swaminathan (2011) points out that widespread malnutrition and endemic hunger persist in India (Kesavan 2015). About half of the world's undernourished children can be found here, as there has been a general decline in per capita calorie consumption. Currently, 42.5% of under 5's are underweight and 40% of infants below 3 years are undernourished. Chronic under-nutrition makes it difficult for women and children to overcome poor people's diseases such as TB, HIV/AIDS, and leprosy. Lack of access to medicines further compounds the problem.

Kumar and Khan (2010) argue that, in the case of poor women, the high burden of fertility, despite declining trends, exacerbates overall health problems. Despite the 2005–06 National Family Health Survey (NFHS) figures showing the current fertility rate was 2.7 compared to 1992–93 figures of 2.9, and notwithstanding universal knowledge about family planning, only 49% of married women aged 15–49 used modern contraceptives (Naderi et al. 2014). Numerous pregnancies, closely spaced births, and unwanted pregnancies terminated by unsafe abortions—all have a negative impact on women's health. In 2003, India reported approximately 400 deaths per 100,000 births. This situation occurred because there was a lower use of health facilities. Supervised delivery is better than home deliveries because complications can be taken care of by doctors. In 2005–06, 32.9% of SCs, 17.7% of STs, 37.7% of Other Backward Classes (OBCs), 33% of Muslims, and 53.4% of Christian women delivered in a health facility. Only 29% of deliveries in rural areas took place in healthcare facilities. Without effective primary healthcare, reproductive health issues are also aggravated—in particular for poor women.

According to Kumar and Khan (2010), over 100,000 Indian women die every year due to pregnancy-related factors. On top of such pressures, rural pregnant women are also burdened with issues such as excessive fatigue (48.7%), difficulty with vision during daylight (7.2%), night blindness (10.8%), convulsions that are not from fever (11.3%), swelling of the legs, body, or face (24.1%), and vaginal bleeding (4.1%). Anemia is the leading cause of fatigue, and 50–90% of all pregnant women suffer from it. Severe anemia accounts for 20% of all maternal deaths in India, as it increases the chance of dying from a hemorrhage during labor. Since most maternal deaths happen within 48 h after delivery, it is critical to note that according to the NFHS 2005–6 survey, 66.1% of rural women received no postnatal care after delivery. Overall, 62.9% of SCs, 68.6% of STs, 59.8% of OBCs, 64.1% of

Muslim, and 39.4% of Christian women did not receive any postnatal care. Also, 80.7% of the lowest quintile and 72.3% of the second lowest quintile of poor people did not receive at least one postnatal checkup. On top of that, 23.5% of women in the public sector, 15.4% of women going through NGO or trust hospital/clinics, and 15.4% of women in the private health sector did not receive any postnatal care.

Women's and children's health is severely affected by malnutrition. While undernourishment in India is found among all segments of the population, poor nutrition among women germinates in childhood and continues throughout their lifetimes due to gender discrimination. This is exacerbated in lower caste and economically weak families. According to NFHS 2005–6 statistics, the percentage of stunted women and children below the -3 standard deviation according to the International Reference Population median was 23.4%, while those with a below -2 standard deviation accounted for 48%. The figures for wasting were 6.1% and 19.1% for women and children respectively, and 16.4% and 43.1% respectively for underweight. Due to discrimination, early childhood mortality for girls in rural areas (63.9%) was higher than for boys (60.7%). Incomplete development of the fetus due to discrimination also increases the hazard of obstructed delivery during childbirths (Kumar and Khan 2010).

De et al. (2011) claims that nutritional deprivation leads to altered gene expression, and as a result the child's future health may be influenced during the intra-uterine experience. The risk of developing non-communicable diseases such as diabetes and hypertension increases in adult life depending on deprivations during fetal development (Patra and Vise 2016). However, micronutrient deficiencies, including iron, also remains a major problem among women of childbearing age in India, as is evident from the fact that more than 50% of women and 74% of children between the ages of 6–34 months are anemic. This situation gives rise to high risks of low birth weight, anemia, and postpartum hemorrhage, all of which contribute to maternal and neonatal mortality.

According to Upadhyay et al. (2011), 15% of all maternal deaths can be attributed to anemia. Vyas et al. (2009) noted that the prevalence of anemia among girls aged 15–19 years, a group which accounts for 17% of total fertility in India, is 56%. Provision of iron and folic acid to pregnant women is an integral part of the Reproductive and Child Health Program in India. Although 65% of mothers receive such supplements, only 23% consume them for at least 90 days, very likely due to the frequent gastro-intestinal side-effects of iron supplements. Hence the authors recommend the development of low-cost, culturally palatable leaf concentrates that contain micronutrients and provide better bio-availability.

Using data from the National Nutrition Monitoring Bureau's 1998/99 and 2005/6 data, Rao et al. (2010) found that the nutritional intake of all foods (except for vegetables,

roots, and tubers) was lower than the suggested level among rural and tribal women. Hence there was hidden hunger due to micronutrient deficiency during pregnancy and lactation. The prevalence of goiter was relatively higher among tribal women (4.9%) than their rural counterparts, who had 0.8% prevalence (Nair 2015). Tribal women were also particularly vulnerable to undernutrition and therefore suffered more from chronic energy deficiency (56%) compared to their rural counterparts (36%).

Saravanan et al. (2011) pointed out that in India, one-third of women in the reproductive age group (15–49) were acutely undernourished and 58% of pregnant women had anemia (Kok et al. 2015; Kok et al. 2014). With regard to delivery, 61% of births took place at home, and trained birth assistants (TBAs) were present in 37% of cases. TBAs first appeared during the 1970s and 80s when the World Health Organization (WHO) promoted their training to reduce maternal mortality rates. The dependence on TBAs for assistance during delivery is higher in rural areas (42%) as compared to urban areas (20%). Among the poor, 53% relied on TBAs as opposed to 9% of affluent households. However, since the 1990s, TBA training has been increasingly seen as irrelevant and ineffective since there was no MMR reduction, and many donor agencies have withdrawn their funding.

The above-mentioned gender health issues are exacerbated by violence against women. According to NFHS 2006, 22.5% of women aged 15–19 years had experienced physical or sexual violence as compared to 39% in the 40–49 year old age group. Both types of violence were higher for ever married women than for never married women. Almost 40% of ever married women had experienced physical or sexual violence, as against 16.9% of never married women. Compared to urban areas, the extent of domestic violence was higher in rural areas. About 38% of women in rural areas had faced either physical or sexual violence, as compared to about 29% women in urban areas. Physical and sexual violence from husbands are the most under-reported forms. Violence significantly contributes to HIV/AIDS problems. Women often do not have the power to negotiate safe sex and the falling prevalence of contraceptive use is a key indicator of the growing problem of HIV/AIDS (Azra Batool et al. 2018; Dwivedi et al. 2015; Nayak and Mahanta 2010).

The gender health situation at the Indian state level is not encouraging if one considers an economically fast-growing, rich sub-state like Maharashtra, which has the largest concentration of biotech companies. Jain (2010) pointed out that in 1996, Maharashtra's health expenditure as a percentage of total expenditure was 4.56%, but that by 2005 had declined to 3.51%. Between 1999 and 2003, female life expectancy at birth was 67.6 years; the female IMR per 1000 live births was 37 in 2005.

Given the status of Maharashtra as one of the fast-growing of the 29 states and seven union territories in India, it is

interesting to look at its ranking on several key health indicators. According to Mishra et al. (2008), Maharashtra ranked tenth in IMR among all of India's 36 entities, based on mid-2000s data. It rated ninth for full immunization of children, 32nd for prevalence of childhood pneumonia, 15th for death rates, fourth in terms of life expectancy, 12th for reproductive healthcare, 13th in terms of women who needed to visit health facilities but did not, and 30th/14th for RTI/STI (reproductive or sexually transmitted) infections for females/males respectively. Among 29 states, Maharashtra ranked 14th for body mass index of women below normal, and tenth for underweight children under the age of 3 years. For treatment in rural public facility OPDs/IPDs (outpatient/inpatient departments), Maharashtra ranked 15th/16th among 21 major states, and people's loss of income from visiting OPD/IPD ranking was 12th/6th. Furthermore, among the 21 major states, Maharashtra's rankings for antenatal care in a public facility, childbirth expenditure, and antenatal care expenditure were 14th, tenth and 15th respectively. Two of Maharashtra's fastest-growing districts also showed a negative trend in terms of human development. For example, compared to the Maharashtra's district average of 34, Pune's IMR was 42 and Nasik's was 50.

According to Mishra et al. (2008), all women with anemia accounted for 51.1% and pregnant women with anemia accounted for 56.4% of the population in rural areas in Maharashtra in 2005 (Goyal and Sekher 2015; Saha 2016). Children with all kinds of anemia accounted for 76.8%. Among girls in the 1–4 age group, anemia was the third most important cause of death, while among boys it was the eighth most important cause of death. According to Sonowal (2010), more than 60% of children aged 1–5 in Maharashtra were underweight and stunted in their development (Begum et al. 2017; Seshadri and Ramakrishna 2018).

Overall, poor gender health scenarios show that in India there has been a severe disjuncture between growth and welfare. There is a thriving pharmaceutical sector, but women still continue to suffer from lack of proper access to healthcare and medicines. For the most part, withdrawal of the government from the provision of public services has not led to better health outcomes for women. The situation is further worsened by the increasing privatization of healthcare and growing healthcare costs, as explored in the next section.

Health costs of the poor

Access to medicines is a universal human right, and states are primarily responsible for provision of that right. Currently, under the dictates of neo-liberal structural adjustment programs that demand privatization and liberalization of the health sector, there has been increasing withdrawal of the government from public sector welfare activities. In 2008–09,

India's total expenditure on health was 4.1% of gross domestic product (GDP), with overall public expenditure accounting for 1.10% of GDP (Balarajan et al. 2011; Ginsburg et al. 2017). This retrenchment was supposed to have curtailed corruption and make health delivery more efficient. However, health access under such steps has increasingly declined. As public expenditure drops, public facilities have taken a turn for the worse. For example, public hospitals are characterized by interminable waits in dirty surroundings. Since the public sector cannot provide many medicines and tests, patients have to go to expensive private shops and laboratories. Doctors may have to see an average of more than 100 patients in a single outpatient session. Incidentally, many patients are advised to meet doctors privately, legally or illegally, if they want more personalized care. In government hospitals, 30% of patients reported they had to pay bribes to jump queues for treatment and even to get better food, according to a recent survey conducted by Transparency International (Patel et al. 2015; Sengupta and Nundy 2005).

Given such issues, expenditure of the poor has increased, particularly costs for medicines, thereby increasing the burden of poverty. For example, estimated at 71.1% in 2008–09, India has one of the highest household out-of-pocket-expenditure (OOPE) rates in the world. This is largely due to rising drug prices. In the 1970s, 90% of drugs were under price control, whereas currently only 10% are. Moreover, according to Balarajan et al. (2011), whereas the cost of medicines on the essential drug list rose by 15%, the cost for non-price-controlled drugs or those not on the essential drug list rose by 137% between 1996 and 2006.

Also, contrary to the predictions of the knowledge economy, privatization and liberalization have not brought about better healthcare conditions. Corruption and inefficiency thrive in the private sector as much as they do in the public sector. Most importantly, the market fails to allocate resources for the diseases of the poor, and patents lead to monopolistic pricing of drugs. State retrenchment has meant that the GOI has become increasingly less active in controlling pricing and procuring medicines for the poor. For example, India has the third largest HIV/AIDS population in the world, but the government refuses to acknowledge the situation as a national emergency. As a result, it fails to use compulsory licensing to break patents and secure antiretroviral (ARV) drugs for the affected populations. While first-line ARVs are cheap because the Indian pharmaceutical sector developed them during the time period when India had process patents, second- and third-line ARVs are protected by product patents and therefore extremely expensive.

According to Boyer (2010), the Indian subcontinent only accounted for 1.2% of global pharmaceutical sales in 2005, even though poverty contributed to 50% of health-related conditions. The situation was worsened because of the low purchasing power of the domestic population and the virtual

absence of any health insurance (Chaudhuri 2010). This still holds true today, despite recent efforts made by the government under the Rashtriya Swasthya Bima Yojana health insurance scheme for below poverty line (BPL) households (Duran et al. 2014; Gusmano et al. 2017; Tediosi et al. 2015).

The drive for patents for new discoveries means a likely rise in the prices of any drugs and vaccines that are discovered (Jain 2011). Also, biotech-related drug research through patents is hampered by the fact that ownership of genes by one party may discourage investment in research on the same gene by another party. Hence, problematic genetic disorders that severely affect Indian women, such as anemia-related diseases like sickle-cell anemia or thalassemia, may either never get researched, or even if they do and a product is brought to the pipeline, it may never really be available to the poor. Non-accessibility may not simply be due to the high price of the drug, it may also be because public and private labs are unable to offer diagnostic tests due to costly license or royalty fees (Jain 2011).

According to WHO estimates, 39% of people in India currently live without access to essential medicines (Satyanarayana and Srivastava 2007). Satyanarayana and Srivastava (2007) contend that the R&D support for development of vaccines and drugs for neglected tropical diseases is still sub-critical. Out of 1223 new drugs approved between 1975 and 1997, approximately 1%—or 13 drugs—specifically treated tropical diseases or those specifically affecting the poor. New essential drugs are coming into the market, but they are under patent protection and likely to remain out of reach for poor people because of high prices. The market for essential drugs in India is miniscule. In 2005, the global pharmaceutical market in terms of ex-manufacturer prices was only US\$ 7.2 billion. In terms of global sales, this figure represented a mere 1.2%. While the biotech sector thrives, the majority of common people do not benefit from these successes as they are poor; help from the badly run, government-sponsored public sector healthcare is also not forthcoming.

The poverty-stricken Indian public continues to be burdened by private healthcare costs which they either cannot afford, or can only ill-afford, resulting in morbidities being untreated. In 2004, public health expenditure as part of GDP was 0.9%, per capita health expenditure was US\$ 31, and OOPE as a percentage of private health expenditure was 93.8% (Jain 2010). Baru et al. (2010) claimed that in 2004–06, government spending accounted for around 19–20% of all health-related expenditure in the country, while per capita health expenditure was around US\$ 35. As per National Health Accounts of India, in 2005, the government expenditure as a percentage of total expenditure on health was 17.9%, while private expenditure was 82.1%. Drugs and medicines account for nearly 70% of private health expenditure (Srivastava et al. 2010).

Kumar et al. (2011) pointed out that despite the steep increase in economic growth, per person income and tax collections, there has not been a corresponding rise in health welfare expenditure. For example, between the periods 1993–94 and 2004–05 compared to a 67% increase in real income and an 82% increase in tax collections, real per person public health expenditure at 1993–94 prices only increased from Indian Rupees (INR) 84 to INR 125 (US\$ 2–3), an increase of 48%. According to NFHS 2005, government expenditure accounted for 22% of total health spending. This represented a decline from 22.6% in 2001–02. Hence private spending, which in 2001–02 was 77.4%, went up to 78% in 2004–05 (Deshmukh et al. 2016).

Rao et al. (2011) demonstrated that 80% of outpatient visits and 60% of hospital admissions were in the private sector. As a result, 71% of health spending was OOPE. Every year this forces 4% of the population into poverty. These facts reveal the worsening conditions of the rural poor who spend a greater proportion of their income on healthcare than people living in urban areas do. The rural–urban gap in health expenditure in 1999–2000 was 1.03%, but by 2004–05 it had climbed to 1.42% (Jain 2010). Moreover, rural areas lack good health infrastructure. Being unable to pay for prolonged stays for treatment in high-cost urban areas, the poor have to invest significantly in travel costs, something they can also ill-afford.

OOPE has been rising steadily in India. In 2005, 74% of OOPE was due to outpatient treatment, 26% was for inpatient treatment, and 72% was for drugs. In 2004, 47% of hospital admissions in rural India were financed by loans and sale of assets. In 1993–94, health spending in rural households of India was 5.4% of total household consumption. By 2004–05, this spending had risen to 6.6%. Between 1993 and 94 and 2006–07, the cost of medical care tripled due to a sharp rise in the price of drugs. In 1995–96, 15% of ailments in rural areas went untreated because of financial reasons, but by 2004, this figure had risen to 28%. Thus to a certain extent, a reduction in demand for healthcare was driven by poverty.

Healthcare in India is financed substantially through OOPE payments by individuals and households, which accounts for 80% of total health expenditure and 97% of private expenditure (Baru et al. 2010). According to Berman et al. (2010), in 2004, around 11.8 million households or 63.22 million individuals were pushed BPL due to OOPE (Pramesh et al. 2014). Of this privation was due to outpatient care which involved relatively small, but frequent, payments, while the rest was incurred by inpatient care. Much of this impoverishment, affecting 76.5% of households or 77.4% of individuals, occurred in rural areas.

In an economically fast-growing state such as Maharashtra, 7.5% of the population fell BPL due to OOPE in 2004. In a state-wise ranking of the percentage of households falling BPL due to inpatient and outpatient costs, Maharashtra ranked second. With the focus on inpatient care costs alone,

Maharashtra, by accounting for 12.5% of impoverishment in India, ranked first in the percentage of households falling BPL. Growth has clearly not brought about equity.

According to Baru et al. (2010), in rural areas, the poorest quintile spends 87% of OOPE on medicines. Due to this fact, an additional 3.5% of the population or 35 million people fell BPL in 2005–06. Rural households have to borrow 40% of their hospitalization expenditure. To compensate, they often have to cut down on consumption levels of other members of the household. Since women are seen as caretakers of households, it is their health concerns that get axed first.

The above-mentioned issues of health expenditure and poverty are exacerbated by the fact that there are severe weaknesses in the delivery of public health services. The sector is plagued by lack of accountability, limited opening hours, absenteeism among medical and paramedical personnel providing health service in poor areas, indifferent and even disrespectful behavior by service providers, and corruption (Baru et al. 2010), lack of essential medicines, and inadequate facilities, such as obsolete and unusable equipment (Rath and Deb 2017; Welshoff 2007). According to Sabharwal (2010), the public sector is also bedeviled by discrimination towards low-caste women. Dalit (formerly ‘untouchables’) or SC women are often denied medical services or subjected to rude behavior. Hence, these women have to go into debt in order to gain expensive private medical attention. Debt burden, however, increases the level of poverty and inability to take care of health concerns.

In addition to public services being riddled with problems, the public sector often also simply acts as a referral portal for legalized private services. These private services are often also plagued with corruption, as evidenced in doctors getting commission from pharmaceutical companies for pushing certain drugs, referring patients for unnecessary diagnostic services, and non-compliance to investment conditionalities imposed by corporate hospitals even while receiving public subsidies (Baru et al. 2010).

Despite all-round corruption and the inadequately regulated nature of the private sector, people have no choice but to lean heavily on private services due to the poor quality and availability of public healthcare, particularly in rural areas. Statistics show that 80% of the population is dependent on the private sector for outpatient care. In 2004, a mere 21% of rural people utilized the public sector for outpatient services. Rural usage of public services fell from 60% in the 1980s (prior to liberalization) to 42% in 2004. At the same time, due to the unregulated nature of private healthcare, patients are subjected to huge variations in costs for the same types of interventions. For example, for a normal delivery the cost in the public sector is anywhere from INR 0–128. In the private sector, the charge varies from INR 472–1573. Unregulated care also means that there is a significantly poor quality of

healthcare and irrational practices in the prescription of medicines for treatment of communicable diseases such as malaria, diarrhea, and TB. This increases the potential of some strains of these diseases developing resistance. These facts not only lead to impoverishment but also to malnutrition (Baru et al. 2010).

According to Kumar and Prakash (2011), the growth of the private sector has been driven by several key factors. These include a new national economic policy, the rapid influx of medical technology, growing public sector hospital deficits, and a rising middle class. Women tend to switch over to private health services particularly following negative experiences with public care. National Sample Survey (NSS) 2004 data revealed that almost 97% of rural and 96% of urban inpatients in hospitals had received health treatment from private sources at some time during the 1 year before the survey. Between 1999–2001 and 2002–04, 94% of women in the sampled population had live births, 1% experienced stillbirths, 2% had spontaneous abortions, and almost 3% reported induced abortions. About 66% of induced abortions were performed by private services. However, within 6 weeks of abortion, 67% of the women had experienced health problems. In comparison, among the women who had used public services for this purpose, only 26% experienced health problems. Interestingly, despite the negative performance of healthcare provided by private healthcare centers, only 7% of women who had earlier had their abortions at private health centers went on to use public healthcare facilities for their second treatment. Regarding antenatal care, 49% of women continued to receive checkups from private services compared to 45% from public ones.

Research by Kumar and Prakash (2011) also indicated that public health services were heavily utilized for prenatal treatment. NSS 2004 data revealed that 55% of women received free iron and folic acid tablets during pregnancy from public sources, compared to 18% who chose to buy them from private suppliers. Overall, the usage of subsidized public healthcare shows that on average 67% of women in India utilized it for family planning services, 11% for delivery purposes and antenatal care services, 6% for the consultation and treatment of reproductive tract infections and other related problems, and 3% for child healthcare services. In the case of child healthcare where there were free services available, such as immunization, there was a clear preference for public facilities. Similarly, private healthcare was clearly more popular for treating diseases such as diarrhea and pneumonia. Overall, women irrespective of class overlooked the inconvenient location of services and preferred private clinics for induced abortions, despite the unregulated nature of the sector.

In utilizing private services, however, many have been pushed into poverty. An impoverished and sick populace can hardly provide for development of human capital as is predicted by the knowledge economy. Hence, the government needs to create public policies geared more towards developmental issues, such as provision of healthcare and reduction of poverty. Corporations can act responsibly if they are ‘fairly’ regulated. On their own, however, they are not public institutions of justice and cannot provide for the public good such as in healthcare. The state therefore has a significant burden to bear in promoting health equity.

Conclusion

The TRIPS regime has led to growth in the pharmaceutical and biotechnological sector in India. However, as the existing data demonstrate here, such expansion in the knowledge economy has not trickled down in the form of substantial welfare for the poor, as reflected by the state of women’s health. This lack of equity is also reflected in the lack of access to medicines and the high healthcare cost burden of the impoverished. Despite the generally poor state of health in India, the government refuses to invoke compulsory licensing clauses legitimized by the TRIPS regime. This is because in reality invoking compulsory licenses tends to provoke retaliatory actions, including market withdrawal by the patent-holding producer, informal pressure from foreign trade ministries to honor IPR or else face the threat of withdrawal of FDI, or even formal sanctions by the World Trade Organization (Beall and Kuhn 2012; Löfgren 2017; Serrano and Burri 2016). One possible solution is that the government actively takes steps to improve the provision of healthcare, despite such constraints, and makes equity a priority in its public policies. With widespread inequality, India’s growth can be significantly impaired (The Economist 2014). Hence it is not surprising that the current growth rate has fallen to 7% from 11% in 2010, precisely because development is non-sustainable without significant redistribution of the wealth generated.

Overall then, having a thriving private pharmaceutical sector has not benefited Indian women or the poor populace to any significant extent. Growth has not led to equity.

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