Designing fit-for-purpose regulation for evolving healthcare systems

Country report: India

Prasanna Saligram

Shrutika Murthy

Surekha Garimella

14th January 2019

Contents

List of Abbreviations

ADR	Adverse Drug Reaction
AIF	Alternative Investment Funds
ARPOB	Average Revenue per Operational Bed
ASSOCHAM	Associated Chambers of Commerce and Industry of India
BOP	Bottom of the Pyramid
B&M	Brick and Mortar
CAGR	Compound Annual Growth Rate
CCI	Competition Commission of India
DHO	District Health Officer
DIPP	Department of Industrial Policy & Promotion
EBITDA	Earnings Before Interest, Tax, Depreciation and Amortization
ET	Economic Time
FDA	Food and Drug Administration
FDI	Foreign Direct Investment
FICCI	Federation of Indian Chambers of Commerce and Industry
FMCGs	Fast Moving Consumer Goods
GDP	Gross Domestic Product
H&S	Hub and Spoke
HCG	Healthcare Global Enterprises
IBEF	India Brand Equity Foundation
ICRA	Investment Information And Credit Rating Agency
IHH	IHH Healthcare Berhad
IMA	Indian Medical Association
IT	Information and Technology
KI	Key Informant
MOHFW	Ministry of Health and Family Welfare
OTC	Over The Counter
PE	Private Equity
PWC	Price Waterhouse Coopers
RMP	Registered Medical Practitioner
SEBI	Securities Exchange Board of India
US	United States
USD	United States Dollar
VC	Venture Capital

Chapter 1: Methods

1.1 Landscaping

To inform this research, a landscaping exercise was conducted to identify 'hot topics' in terms of recent changes in the country's healthcare market. These included market structure changes, developments in financing mechanisms, and innovations in service delivery. Through a desk-based review of media, business and academic literature, a host of new developments were identified. Following discussion with the research team, three topics were chosen to study in more detail: consolidation in health markets; e-pharmacy and private equity financing in health care.

1.2 Key informant interviews

A set of key informant (KI) interviews were conducted in order to explore the chosen topics in more depth. The purpose of these interviews was to learn more about the nature of each topic, the scale and scope of each phenomenon, and the impact they have had on the health economy. Further, we explored the regulatory issues associated with each topic, focussing on the nature of the regulatory response, including regulatory structures and processes. Finally, we sought to identify the regulatory gaps and challenges associated with each new topic, as well as any regulatory opportunities they may present. The interviews were semi-structured in nature; based on an interview guide (guided by the research questions) to ensure each interview covered comparable matters but allowed for flexibility in the discussion thus providing opportunity to cover issues that arose freely.

1.3 Macroeconomic Context

In 2017, World Economic Forum placed India at seventh position with 2.1 Trillion USD but India has 17 per cent of the population and only 2.83 per cent on the world's economy making it for very low per capita income. There has been a consistent average 6 per cent growth in Gross Domestic Product (GDP) in the last 20 years. Despite this high economic growth, the unemployment figures are also growing making it a 'jobless growth'. The employment growth which was at 2 per cent in 2004 reduced to 0.7 per cent in 2009-2010 and to a further down of 0.4 per cent in 2011-2012 (Shaw 2013). A large workforce is also in the informal sector. At the same time this phase of growth has been synonymous with increase in inequalities with Gini coefficient rising from 45 to 51 between 1990 and 2013. At the same time welfare distribution has suffered. The total welfare expenditure as a per cent of GDP was a mere 7 per cent with education at 2.9 per cent and Health at 1.4 per cent (Motkuri,V and Khan, AU 2018).

The Global Burden of Diseases ranked India at 154 out of 195 countries on the healthcare index (Lancet 2017). India also has the 'triple burden' of diseases with the unfinished agenda of communicable diseases, increase in non-communicable diseases and certain emerging infectious diseases like Swine Flu (Motkuri, V & Khan, AU 2018).

On the Human Resources for health, there are substantial vacancies in the public health sector. The WHO norms are 4.45 health workers/1000 population. In India, according to the 2011 census (the last census), the total density is 3.8/1000 but when disaggregated between urban and rural has a huge urban bias with urban density at 6.6/1000 population and rural at 2.53/1000 population.

Between September and November2018 a total of 6 interviews were conducted with purposively selected private sector actors, health policymakers, regulatory officials, and other experts identified by the research team. These comprised an ex-bureaucrat, a hospital chain manager, a medical devices researcher, a pharmaceuticals industry actor, a senior industry researcher and a senior drug regulator. Interviews were conducted in-person by Prasanna Saligram, with the help of Shrutika Murthy in English, and lasted between 40 and 90 minutes. Verbal consent was obtained prior to commencing interviews, and, where permitted, interviews were electronically recorded to ensure an accurate record of the information collected from informants. In the instances where informants did not consent to be recorded, detailed notes were taken and written up soon after.

A priori themes according to the 'hot topic' identified were drawn up. Further a thematic data analysis was conducted of the interview data allowing for new themes to emerge from the data and the initial categories were refined throughout the process.

1.4 Document review

Alongside the key informant interviews, documents were gathered relating to the topics under study.

1.4.1 Consolidation

1. The Clinical Establishments Act, 2010
2. Medical Council Act
3. The Competition Act, 2002
4. Competition Commission of India's Policy Note on 'Making Markets Work for Affordable Healthcare'

1.4.2 E-pharmacies

1. Voluntary Code of Conduct by FICCI, 2016
2. Drugs and Cosmetics Rules Act, 1945
3. Information and Technology Act, 2000
4. Pharmacy Practice Regulations, 2015
5. Ministry of Health and Family Welfare Draft Rules, 2018

1.4.3 Private Equity Financing

1. Securities and Exchange Board of India (Alternative Investment Funds) Regulations, 2012
2. Securities and Exchange Board of India (Venture Capital funds) Regulations, 1996

Additionally popular media, industry documents and reports from ministries were studied.

Chapter 2: Consolidation

2.1 Background

There is an increasing tendency towards consolidation and vertical integration in India. There have been some larger regulatory measures, which have made the small, and medium health facility not able to survive this and big hospital chains are buying smaller firms leading to consolidation in the industry. Some of the recent policy decisions like demonetization - in which major currencies in the market were suddenly withdrawn- and introduction of a Goods and services Tax regime have led to the smaller facilities not able to sustain their operations. Another important move has been the move towards price regulation of medical devices like

stents and implants. Some states like West Bengal have also introduced price caps on procedures, which has made the outlook for the market uncertain. All these regulatory moves have resulted in struggle of small players. Recently IHH Malaysia acquired 31.1 per cent stake in a hospital chain Fortis Healthcare. Similarly Radiant Life care has announced that it is acquiring stake in another hospital chain Max Healthcare. Radiant-Max Healthcare merger would create a conglomerate of 16 hospitals and 3200 beds indicating the scale of consolidation that is happening (ET article, Dec 2018).

At the same time, ICRA data shows that the average revenue per operational bed (ARPOB) has grown only 2 per cent CAGR[1] in 2018 way below the 5 per cent CAGR experienced 2 years before. Earnings before Interest, Tax, depreciation and amortization (EBITDA) have also fallen from a CAGR of nearly 15.7 per cent to 11.4%. But the consolidation is also observed largely at tertiary level. Hence notwithstanding the above, the larger structural factors like shortage of beds (more so in rural areas), low public health investment makes healthcare industry still a viable proposition.

These consolidation moves provide the hospital chains the scale of operation, operational efficiency, economies of scale through better procurement bargains and rates and process optimization through the deployment of Information Technology (Moneycontrol, Dec 2018). Some of the innovations observed in the Indian hospitals are the use of hub and spoke (H & S) model to reach out to rural areas, cost-effectiveness driven through the economies of scale and task shifting to be competitive. There is a hub in the urban areas where all the high end equipment, major specialties and specialists are located. The spoke is located in a rural, semi-urban area and here only routine checkup, diagnosis, referral to the hub and follow-up happen resulting in cost savings which is unlike the US where everything is duplicated increasing the operating costs. For example, HCG is a high-end cancer cure hospital with nearly 17 spokes for cancer patients. All these contribute to higher volumes, throughput and economies of scale. At the same time, the hospitals are able to retain the specialists and physicians, as the variety of the cases they get to deal is a big attraction. This also allows for innovation and local adaptation (Govindarajan & Ramamurti 2013). The H&S model has the promise of reaching out to the Bottom of the Pyramid (BOP) segment of the population. They can leverage technology to integrate the H & S (Kapoor, A and Goyal, S 2013). Citing the H & S model of Arvind Eye care in India, Aman Bhandari et al detail out the model. The eye care model uses H & S modality and also conducts mass screenings and derive efficiencies. But they also point out that the H & S model does not necessarily work out for remote, hilly terrains where population density is less necessitating multiple screenings, interventions resulting in lesser efficiencies and hence the services might not be reaching there (Aman Bhandari et al 2008).

What has further aided the increase in multi-specialty hospitals or boosted consolidation is the volume of the patients that are seeking treatment at these hospitals. With most corporates offering a range of health insurance policies and the general public being in a better position (economically) to avail healthcare, the costs incurred by hospitals come down due to the volume of patients.

> "So, in a way, the big hospitals which are probably in the reach of the elite of the country are also able to attract the mid size or maybe below mid level people for the treatment, they're able to offer that treatment. So, that has caused the rise of multi-specialty hospitals across the country."(KI-3)

Many patients who suffer from multiple diseases prefer the multi-specialty hospitals in comparison to regular ones as these hospitals house a wide range of specialists ranging from orthopedicians to endocrinologists to plastic surgeons and more. However, it is important to note that each of these multi-specialty hospitals are known for a particular branch of medicine. For instance, the Metro group of hospitals specializes in heart care and therefore it houses some of the best cardiologists. However, as per the requirement of being a multi-specialty hospital, it also houses other specialties, despite being heart care-centric.

> So, what happens is that in case of people in multi specialty hospital, if a person has come and he has heart disease, but he also has for example sugar or diabetes, then he would probably want to get something from somebody better to deal with that. He will also deal with another hospital, which is specializing, in that particular thing. And that specialization created that vertical integration.(KI-3)

But the consolidation of this sort also comes with regulatory challenges. The competition commission of India (CCI) in its policy note of 2018 titled 'Making markets work for affordable health care', has one section devoted for the vertical consolidation of health care institutions. CCI recognizes that there is information asymmetry and that consumers in India lack agency to take decisions with regard to health care. It recognizes that hospitals have in-house pharmacies, diagnostic and also provide a bouquet of services to derive better efficiencies. But it also recognizes that this could lead to exercising of market domination and the customers might get exploited. In the absence of strong regulations for ensuring transparency, data sharing and ethical practices the ideal of promotion of competition between health care facilities on costs and quality is non-existent. The patients are forced to buy medicines from in-house pharmacies 'branded generics' and also instances where hospitals reject the test results of diagnostics done outside resulting in higher costs, duplication and inefficiencies for the patients. There is as of now no regulation to ensure portability of services and data sharing (Competition Commission of India 2018).

2.2 Regulatory Overview

2.2.1 Infrastructure and facility regulation through the various clinical establishment acts and rules

2.2.1.1 Federal level

Under the federal system of the Indian constitution, health is a subject devolved to states. So it is the prerogative of the states to regulate and enact the various laws pertaining to healthcare. So each of the states have their own clinical establishments bill to regulate the establishments of healthcare. However under a special provision of article 252 of the Indian constitution, if three states request the Federal government to enact a particular law, the Federal government can take necessary steps to enact such a law[2]. Accordingly, the Federal government passed a central clinical establishments act, 2010. This was applicable to the states of Arunachal Pradesh, Himachal Pradesh, Mizoram, Sikkim and the union territories initially and

later any other state could adopt this[3]. The definition of the clinical establishments includes hospitals, maternity homes, nursing homes, clinic or any other institution of any stream of medicine, that provides care for illness, injury, abnormality, deformity or pregnancy[4]. Also in a first for the country even government run clinical establishments are brought under the purview of this legislation.[5]

2.2.1.2 The National and State Councils

The Act provides for the establishment of a National council at the federal level and state councils for the states. The putative functions envisaged for this National council are compilation and publication of a national register of clinical establishments[6] and develop the first set of standards for ensuring proper healthcare by the clinical establishments within two years of the enactment of this Act[7]; categorization of the various clinical establishments[8]; establishment and periodic review of minimum standards[9] and collection of statistics from the clinical establishments[10]. At the state level the state council with the Director, health services of the state as its ex-officio secretary[11] have the putative functions to compile and update the state register for clinical establishments and to send monthly update to the national register; represent the state in the national council; hearing of appeals against the district registering authority; annual publication of report on the implementation status of the healthcare standards within the state[12].

Every Clinical establishment must confirm to the minimum conditions of standards of facilities and services, number of personnel, requirement of maintenance of records, reporting mechanisms[13]. Once the clinical establishment makes effort to confirm to the standards, it can apply to the district registration authority for registering the establishment to render services in the prescribed proforma and paying the prescribed fees. The district health officer (DHO, or called by any other name) of the district, as the convener of the District registration authority, has the main powers for taking steps for the registration of the establishments[14]. The DHO has the powers to issue a provisional registration certificate for a period of maximum twelve months[15]; to issue a permanent registration renewable every five years[16]; to cancel the registration if at any point in time it is found that the establishment is not complying to the standards[17]; to conduct inquiry or inspect the facility as and when required[18]. The registration authority also has the obligation to supply in digital form the list of establishments to the State council for entry into the state register[19]. The authority also has a role to monetarily penalize such establishments, which carry on activities without proper registration. The authority, subsequent to conduct of procedural inquiry, can impose a monetary penalty of rupees fifty thousand for first time conviction, rupees 200,000 for second offence and rupees 500,000 for subsequent offences[20]. In addition to the above, the act also makes it mandatory for the clinical establishment to examine and treat as may be required, for the stabilization of the emergency patient who comes or is brought to the establishment[21].

2.2.2 The Competition Act

The Competition Act of 2002 brought into force on 13th January 2003 is an anti-trust act enacted to prevent anti-competitive practices, to sustain market competition and to allow for a level

playing field for open and fair trade practices in such a way that the consumers shall benefit. The Act prevents agreements for production, sale, distribution, storage and such other trading activities, which produce what is termed as 'Appreciable adverse Impact' on the consumers.[22]It also prevents abuse of **dominant** position by any single entity, which operates independently of the market forces. This is to prevent predatory pricing, denial of market access to competitors and so on.[23]It provides for the prevention of combinations in order to prevent abuse, through mergers, acquisitions or amalgamations. It defines a limit of 30 Billion Rupees market valuation for Indian firms and 50 Million USD in case one of the firms is situated outside India and for mergers it is pegged at 10 Billion Rupees market evaluation.[24]The Act provides for the establishment of the Competition Commission of India (CCI) as a body corporate and an autonomous entity which is quasi-legal. This would have a chairperson and assisted by minimum of 2 and a maximum of 10 members.[25]In order to assist the CCI in studies and enquiries there is the provision for appointing a Director General.[26]CCI can levy penalties for various types of contraventions of the orders of the Commission[27]but can be applied by the aggrieved party to National Company Appellate Tribunal and finally to the Supreme Court of India.[28]One of the very important and interesting clauses is the provision for **Competition Advocacy**. Governments (both federal and states) can refer any of its policies to the CCI for its scrutiny and opinion vis-à-vis competition. But the ruling of CCI is not binding on the governments.[29]

2.2.3 Policy Note on 'Making markets work for affordable health care'

Competition Commission of India recommends the declaration of such vital data as mortality, infection rates and so on by the health care facilities to increase the awareness for customers and help them make choices and thereby promote curb anti-competitive tendencies in the health care market. It also recommends that the facilities should be stopped from the practice of forcing the customers to buy medicines from in-house pharmacies or use only in-house laboratory services. It calls for enforcement of uniform standards to achieve reliability of test results so that the patients could go anywhere and get their tests done which is acceptable for the health care facility. It also recommends a regulation for portability of data, with suitable data security features, to allow for facilities to accept the same and also thereby promoting competition (Competition Commission of India 2018)

2.3 Regulatory overview (tabular representation)

Agency	Role/responsibility
Competition Commission of India Director General Chairperson and the Council of Members	Director General and Chairperson and Council of Members (no regulation to ensure portability of services and data sharing) - **The Competition Act** provides for the establishment of the Competition Commission of India (CCI) as a body corporate and an autonomous entity which is quasi-legal. Assist the CCI in studies and enquiries pertaining to Anti-trust behaviour The CCI shall have a **chairperson** and assisted by minimum of 2 and a maximum of 10 **members**. CCI can levy penalties for various types of contraventions of the orders of the Commission but can be appealed by the aggrieved party to National Company Appellate Tribunal and finally to the Supreme Court of India. One of the very important and interesting clauses is the provision for **Competition Advocacy**. Governments (both federal and states) can refer any of its policies to the CCI for its scrutiny and opinion vis-à-vis competition. However, the ruling of CCI is not binding on the governments.
Clinical Establishments Act National Councils	The putative functions envisaged for this National council are compilation and publication of a national register of clinical establishments and develop the first set of standards for ensuring proper healthcare by the clinical establishments within two years of the enactment of this Act; categorization of the various clinical establishments; establishment and periodic review of minimum standards and collection of statistics from the clinical establishments At the state level the state council with the Director, health services of the state as its ex-officio secretary have the putative functions to compile and update the state register for clinical establishments and to send monthly update to the national register; represent the state in the national council; hearing of appeals against the district

State Councils	registering authority; annual publication of report on the implementation status of the healthcare standards within the state. Every Clinical establishment must confirm to the minimum conditions of standards of facilities and services, number of personnel, requirement of maintenance of records, reporting mechanisms.
District Health Officer	Once the clinical establishment makes effort to confirm to the standards, it can apply to the district registration authority for registering the establishment to render services in the prescribed proforma and paying the prescribed fees. The district health officer (DHO, or called by any other name) of the district, as the convenor of the District registration authority, has the main powers for taking steps for the registration of the establishments. The DHO has the powers to issue a provisional registration certificate for a period of maximum twelve months; to issue a permanent registration renewable every five years; to cancel the registration if at any point in time it is found that the establishment is not complying to the standards; to conduct inquiry or inspect the facility as and when required. The registration authority also has the obligation to supply in digital form the list of establishments to the State council for entry into the state register. The authority also has a role to monetarily penalise such establishments which carry on activities without proper registration. The authority, subsequent to conduct of procedural inquiry, can impose a monetary penalty of rupees fifty thousand for first time conviction, rupees 200,000 for second offence and rupees 500,000 for subsequent offences. In addition to the above, the act also makes it mandatory for the clinical establishment to examine and treat as may be required, for the stabilization of the emergency patient who comes or is brought to the establishment.
Autonomous Regulatory Agency (State Clinical Establishments Regulatory Commissions)	An autonomous regulatory agency model of West Bengal - West Bengal has also done some innovation by establishing an autonomous regulatory agency - West Bengal Clinical Establishments Regulatory Commission (WBCERC) as a quasi-judicial body under its CE Act but this is a recent development and not much experience has been gained and studies have not been done on it as yet.

2.4 Regulatory gaps and opportunities

2.4.1 Regulatory gaps and concerns

2.4.1.1 Inadequacies of Clinical Establishments Acts

The inadequacy of the regulatory environment prevailing in the country had been outlined by Sheikh et al (Sheikh et al 2013). That study had used the Roberts et al (2004) framework for analysing the design and implementation gaps. The framework defines the regulation of the four aspects - Costs of care, quality of care, conduct of the providers and accessibility (distribution) of care (Roberts et al 2004; Sheikh et al 2013). Substantial gaps were found both in design and implementation of regulations across each of them including the commentary on the inadequacies of Clinical Establishments (CE) Act 2010 which is only a registration/licensing regulation. Recently, some states like Karnataka and West Bengal have tried to bring in price caps under the ambit of the CE Act. West Bengal has also done some innovation by establishing an autonomous regulatory agency - West Bengal Clinical Establishments Regulatory Commission (WBCERC) as a quasi-judicial body under its CE Act, but this is a recent development and not much experience has been gained and studies have not been done on it as yet[1]. But, the irrationalities and unethical cases in the health care industry have continued. Recently In 2017, four hospitals in the Delhi National Capital Region came under the scanner for overcharging the patients. A recent government report has detailed the exorbitant profit margins of one of those hospitals to be as high as 1192% for scheduled formulations and 1271% on a non-scheduled device like IV infusion set (NPPA[2], 2017). Illegal kidney donation rackets are regular periodic events in the private sector despite the Human Organ Transplant Act having been amended to strengthen it further (Hindustan Times 2017)[3]. The physicians are paid commissions for the referrals of either diagnostics or specific medicines/treatment. And, tied to this is the absence of generic medicine prescription practices. In December 2107 an income-tax raid unearthed one such doctor-referral nexus.[4]The only major tool of regulation in vogue is the licensing and registration mechanisms through the CE Act (facilities) and the medical council act (for providers). The oversight organization for Medical Council Act, the Medical Council of India itself was under cloud for corruption and unethical practices and hence since been disbanded.[5] These are grossly inadequate to address the multiple irrationalities that have been highlighted. Some of the irrationalities, like the high treatment costs and unbridled profiteering by the private sector hospitals which have come to light recently, are not part of the CE Acts except in West Bengal state act. CE Acts are licensing acts and when one looks at it from the quality of Care lens in accordance with the Donabedian framework of structure, process and outcomes (Donabedian 1988), CE Acts only speak to

[1] The West Bengal Clinical Establishments Rules, 2017
[2] National Pharmaceutical Pricing Authority
[3]https://www.hindustantimes.com/delhi-news/kidney-racket-all-you-need-to-know-about-the-scam-busted-at-delhi-s-batra-hospital/story-1izebU2bRo8hA2laW2PJVM.html
[4] https://www.ndtv.com/bangalore-news/it-raid-exposes-doctor-referral-commission-nexus-running-into-hundreds-of-crores-1782811
[5] http://www.newindianexpress.com/nation/2018/sep/27/medical-council-of-india-dissolved-committee-to-run-medical-education-regulator-1877646.html

structure aspects. To this is added the layer of the consolidation of the hospitals, which CE Acts are definitely ill-equipped to handle.

The Competition Commission has been relatively pro-active in using its regulatory mandate. In 2014, CCI imposed a penalty of 38 Million rupees penalty on a private hospital for anti-trust activities (CCI, 2014). But these are far and few between and also the court processes in the country are too long drawn and tedious. Regulation is achieved through a mix of various regulatory instruments. Responsive regulation pyramid framework provides for an escalating hierarchy from the self regulation to the Command-and-control mechanisms allowing for compliance before pushing for adherence (Ayres & Braithwaite 1992). But in the absence of the self-regulation, voluntary regulation and meta regulation, there is an increasing dependence on these judicial processes:

> So, we seem to depend on a highly almost say everything in India ends up in the supreme court which it should not have to. These are it is a statement about the inability to have checks and balances well before things elevate and even if you look at the roster out here, almost everything ends up getting shunted because nobody everyone wants to pass the buck and nobody wants to have a piece of it (KI-1).

The medical negligence cases adjudicated through the consumer courts have been inordinately delayed as well. In 2013, a private hospital in Kolkata was ordered by the Supreme Court of India to pay damages of nearly 110 million rupees in a case of medical negligence that happened in 1998.[6]

The consolidation is largely happening in the high-end tertiary sector and it is largely an urban phenomenon. Even though the Hub and Spoke model offers some promise for overcoming the geographic inequalities it is still a semi-urban phenomenon and there is no regulatory architecture to correct this urban bias at present. The Industry key informant said:

> This consolidation has already started and is working and it is still in a nascent stage. It has not happened in the rural areas. Now, as of now, it is happening only in the urban areas. The problem with rural areas, from my experience is that the doctors are still not willing to go, they don't want to go there.(KI-3)

It is clear that when it comes to consolidation, the healthcare industry is necessarily motivated by profit considerations.

> For a corporate hospital, you will require a minimum area, unless it has got 50 beds or something, it does not make business sense to acquire. Or some hospitals do not even have an extension area. So, if you have a smaller nursing home but which has got an expansion area, I mean, if they have an area for them to build on, maybe hospital chains would acquire but predominantly in my experience also leaving apart a few big districts, they all have a very tight budget or maybe 4 or 5 beds facility, which usually takes care of emergencies.(KI-3)

So clearly from whichever framework we are approaching the issue of regulation there are gaps in the regulatory architecture for any of the parameters of costs, quality, distribution and conduct of the providers. At the same time, the health care industry feels that regulations stifle innovation and competition. The often quoted narrative is the recent move by the federal government to put in price caps for certain medical devices like stents and certain implants.

[6]https://www.dailymail.co.uk/indiahome/indianews/article-2475431/Kolkatas-AMRI-Hospital-pay-record-Rs-11-41-crore-compensation-NRI-doctor-wife-died-medical-negligence.html

> So, the competition has killed profit margins. Now the problem is that there are the overheads of the big hospitals is quite a bit and these are the you know implants which are to give better profit margin. So, that profit margin is now gone. So you find that major corporate chains are in the red these days. So, that is the impact. That is also causing a slowdown of the consolidation (KI-3).

The industry feels it is more prudent for the government to put a price cap on certain things and for a reasonable amount as there are patients who might prefer one particular product over the other but no longer have that choice due to the price capping. There is a call for differential pricing mechanism:

> Allow the people to have a choice, to take what they want, what they need. See whenever you do a very strict regulation of pricing, market does not flourish. That is the way it is. So, we also have to allow a limited market flourishing so that people can also benefit otherwise it will not. The idea is that there is a particular segment of the people who cannot afford that to use, but certain people want to use high quality stents, implants, they should be allowed. Those who are able to afford will be able to afford to make the payment. Markets should allow that. While I am not favouring not having, you know, price regulation, it has to be sensibly done, is what I feel.
>
> Stent is a one-time implant which is put right. Cancer drugs are used weekly, monthly, yearly, it is a recurring cost. And as you are saying the volumes are much more in that, in cancer drugs. So, that makes a huge difference. That (stent) is a one time cost (KI-3).

2.4.1.2 Healthcare is one more 'Industry'

It is important to realize and acknowledge that health is fundamentally different from other industries and cannot be regulated in the same manner as the others. A pertinent question arises from these discussions, which is as to why certain countries do it so differently as opposed to the rest. Health is a complex topic in addition to being a market failure with information asymmetries, principal-agent problems and so on. Because health is a complex topic and also not done the same way in every society, there is a call for 'light touch' to regulation in health to allow for these complexities. But one can have 'heavy touch' and at the same time deal with complexities. But increasingly health care is dealt in the same manner as any other industry.

> You know the sad truth is that the health industry these days is regulated in increasingly common ways, and I think that is noteworthy because that says something about industry dynamics, it says some things about pressures of current construction under which rents are extracted, investments are made, so it is managed in a way similar to other industries and therefore its regulated in increasingly similar ways.(KI-1)

Markets do exist even if they are exchanged without large profits. While at one level it can be argued that markets and profits may be needed as an incentive, it could still be that there could be price caps on excess profits. Any industrial policy is not just about 'building' the sector, it is about 'shaping' it and regulation is not just about curtailment but about 'shaping' the sector. Also, health sector is increasingly seen similar to, for instance a garment industry, where creation of jobs and contribution to GDP growth has become important rather than moving populations on the path of health. *"No, I do not think there is any regulation about the market consolidation. On the contrary, the policies which they make tend to help us."*(KI-3) echoed the industry person.

The superstructures being created by certain players in the market needs to be regulated. For instance, there are big conglomerates who are into service delivery and now entering the

insurance sector controlling the whole supply chain and this would need a different way of looking at regulation and 'business as usual' is not going to help.

2.4.1.3 Public Private Partnerships

Public private partnerships (PPP) are service provision arrangements between the public sector and the private providers. Where the public sector is unable to provide health care services, either geographically or technologically the government (health department) typically enters into a contract with the private providers for delivering specific services. This could be one of the instruments to overcome inequalities. But the evidence base for PPPs is generally mixed with respect to delivering either access or quality of care to the people. There are various types of arrangements including publicly funded health insurance mechanisms, giving land at concessional rates in lieu for free treatment to economically weaker sections (EWS) both for ambulatory care and inpatient care. Governments have also handed over publicly constructed hospitals for the private provider to run the hospital at pre-determined rates. The key informant from industry was part of one such arrangement. The informant highlighted the *laissez-faire* attitude of the government towards the contractual management. The informant mentioned the lax attitude of the government towards ensuring the partnerships to succeed. The issue being highlighted by the informant was about price revisions and losses accrued due to the PPP arrangement. The informant mentioned how it was becoming difficult to run a hospital efficiently and provide good quality services without increasing the costs of the services that one is providing.

> I found that the PPP model majorly they all fade. After some stage the private players is not expected to sustain losses. If he is coming into a partnership, he expects some profit right. You can ensure that. But if you do not allow I mean if you make him you expect him to lose money every year on year then how would he survive? It is a sustainability issue. We are facing a sustainability issue now (KI-3).

Even though the issue highlighted is from a financial sustainability angle, it is indicative of a larger malaise of the hands-off attitude of the governments and weak capacities to implement when it comes to ensuring adherence to the contractual performance. For instance, the free beds for EWS patients was followed more in breach necessitating a court stricture[7] or the increased irrationality as in unnecessary hysterectomies due to these PPP arrangements[8] or in making the partnerships work with private players.

2.4.2 Regulatory Opportunities

The previous sections highlight the inadequacies of the regulatory mechanisms for the phenomenon of the market consolidation that is happening in India. Notwithstanding the above there still presents opportunities for improving the regulatory scenario in the country. Some of the opportunities are highlighted in the subsequent sections.

---

[7]Thomas, G. & Krishnan, S. (2010). 'Effective Public-Private Partnership in Healthcare: Apollo as a cautionary tale', *Indian Journal of Medical Ethics,* Vol VII, No. 1,January - March 2010, pp 2-4

[8](Xavier et al 2017)

2.4.2.1 Meta Regulation with state as a monopsony buyer

The federal government of India has recently announced a nationwide scheme called Ayushman Bharat (AB) where the government is planning to involve private sector at an all India level to provide access to health care services at the secondary and tertiary level (https://www.pmjay.gov.in/). This provides a huge opportunity for the government to step in as a big buyer of services. Government could use its position as a high volumes purchaser and thereby their monopsony power to drive down costs, improve quality, for instance by fixing the prerequisite standards, or for driving proper geographical redistribution of both the human resources and the infrastructure to make it more equitable. This can also be used for driving such quality improvement measures such as evidence-based medicine or following the standard treatment protocols. The government could also put in accreditation as a pre-condition for empanelment under AB. The way public policy is discussed in India, as only some sort of legislation, is one of the biggest downfalls of the system.

> We do not discuss public policy in India unlike other countries in terms of planning, foresight, exercises, iteratives, problem solving, we do not look at public administration processes, we do not look at contracting devices, we do not look at any of these things and then we are surprised that there is a gap to implementation. I mean, why are we surprised?(KI-1)

2.4.2.2 Autonomous regulatory agency or a Medical Tribunal

One more regulatory opportunity is the establishment of an autonomous regulatory body, sometimes called 'medical tribunal' or 'health tribunal'. This should be independent of the directorate of health services but under the ministry of health. High Level Expert Group (HLEG) on Universal Health Coverage had named such agencies as National Health Regulatory and development Authority and State Health Regulatory and development authority[9]. This could be of a quasi-judicial nature with adequate checks and balances built into it through appellate provisions. For example, West Bengal Clinical Establishments Regulatory Commission (WBCERC) as a quasi-judicial body even though it does not have appeal provisions. Such an autonomous agency has to be, of course, adequately financed and staffed. Regulations cost money and the governments have to ‘invest’ in order to drive through the purchasing and contract management as well. It is also interesting to note that there are such autonomous agencies for some of the services like Telecom, banking, civil aviation in India but missing for health and education sectors.

> I would say that you need a medical tribunal and that medical tribunal can then keep on giving work to other people, do it this way, do it that way. But not just a danda-lagaaoing(punishing) body. It has to have teeth and knowledge also. I mean you need a regulatory body which is completely honed into systems which says this is how you will give (financial) returns, some way of looking at the returns and looking for the red marks, where something is glaring and then clamping down, the way the electricity regulatory commissions do or the central electricity and the appellate bodies to whom you can apply in case of misconduct or doing any kind of you might say financial mismanagement at the cost of the patient, you need a regulatory body, you do not have that in the health ministry at all (KI-6)

[9]High Level Expert group on Universal Health Coverage

2.5 Information gaps

We have paucity of actual data pertaining to consolidation. There is very little objective data about the extent of consolidation. One is reliant on either industry or the ministry sources to get some data. We also had to look for popular sources to get some data regarding consolidation. The authors also did not find enough research done in this area and in specific the effects on population health of consolidation.

2.6 Research questions arising

Can an inter-disciplinary group of people come together comprising of not just physicians, not just economists, not just researchers but a combination including the policy makers, consumers, advocacy groups to evolve a group to think through the problems of regulation and engaged in co-creation of regulatory mechanisms (deliberative methods? 'learning sites'?)

2.7 Topic Guide

1. Could you describe what is happening with regards to market consolidation and vertical integration in India?
2. How would you describe the scale of market consolidation and vertical integration?
3. In which geographic areas is this more prevalent
4. Who is responsible for regulating market consolidation and vertical integration?
5. How is the regulation of market consolidation and vertical integration carried out?
6. Would you say this regulatory strategy has been effective?
7. What would you say are the challenges of regulating market consolidation and vertical integration?
8. Is there anything about market consolidation and vertical integration that facilitates regulation?
9. If regulation is happening, what is your experience with regard to that
10. If regulation is not happening, then what is your experience with regard to that and what the reasons for the regulation not happening?
11. What are the other alternatives with respect to regulatory frameworks and institutions?
12. Is there any other information that you would like to share with us regarding to market consolidation and vertical integration?

Chapter 3: E-pharmacy

3.1 Background

The pharmaceutical industry in India is very well developed and the industry is a global player as well. India is poised to be the sixth largest pharmaceutical Industry by 2020 with 2.4% of the global pharmaceutical market in terms of value and 10% in volume. (IBEF[10] 2017) The domestic pharmacy retail market is around 980 Billion Rupees of which nearly 70% of the market is generic drugs, 21% is over-the-counter (OTC) drugs and patented drugs make up 9%. There are around 850,000 pharmacy stores in the country. The total pharmaceutical industry market is growing at 11-12% per year. Total industry size is 2000 Billion rupees of which 55% is exports revenue (Sub-committee report on E-Pharmacy). India exports its drugs to more than 200 countries in the world and hence rightly called as the "pharmacy of the developing world" (Horner 2013).

3.1.1 E-Commerce in India

India is currently under a grip of digital revolution. Increasing number of people are having access to internet. The number of internet users increased by 100 million between December 2014 and December 2015 from around 300 Million to 402 million (FICCI document). There has also been an increase in the mobile internet users to around 370 million by 2016. The online marketplace has become a reality for people to do market transactions be it buying train and flight tickets, buying apparel, groceries and even matrimonial services. People do a lot of activity online and this has driven the growth of E-commerce to about 30 Billion USD and growing at a CAGR[11]of 44.77%. The government has also provided an enabling environment for transactions over internet through the IT Act of 2000. It has also encouraged the use of the online platforms through such policies as 'Digital India'. At the same time this sector is also plagued by data integrity issues, data security issues and misuse of information technology by criminal elements. The online pharmacy or E-pharmacy as it is interchangeably used, bases its existence on the development of E-commerce platforms. Hence it becomes relevant to look at how the larger regulatory scenario, vis-à-vis E-commerce, is operating.

3.1.2 Online Pharmacy or E-Pharmacy

Online pharmacy is a relatively new phenomenon in India. This is riding on the development of the e-commerce platforms and the existing boom in the internet users and applications for online marketplaces. The E-pharmacy players allow for ordering of the medicines online and deliver the medicines home at a convenient time for the customer. The customers can pick a time and place for delivery providing convenience and also helps patients who are not in a position to go to the retail shops to buy their medications. This is also particularly helpful to patients who have chronic conditions and need to regularly buy medicines. Families in India

10 India Brand Equity Foundation
11 Compounded Annual Growth Rate

are increasingly becoming nuclear and E-pharmacy is advantageous in helping elderly chronic patients living in nuclear families. It also removes the middlemen and the savings could potentially be transferred to the customer directly through discounted prices. E-pharmacy provides for traceability of the batch of medicines with batch number etc. which helps in easy recall of the batch of medicines in case an adverse reaction has been reported. Each of the transactions could be easily tracked which helps in increased tax compliance. Also prescription compliance of drug dispensation could be ensured. There is also the potential of improving health care awareness through targeted messaging since the patients can be easily identified. Online pharmacy also overcomes the need for maintaining huge inventory of medicines and reduce wastage through expiry of medicines on the shelf. This would also give a fillip to the ongoing government's 'Digital India' policy objectives (FICCI document). The government has also enabled digital signature authentication through the IT Act of 2000 paving the way for validating such electronic transactions as E-Prescriptions (Electronic Health Records 2016).

3.1.3 Risks of E-Pharmacy

The emergence of online pharmacy is an inevitable development of the availability of technologies, which also provide certain advantages as above. But notwithstanding these advantages, there persist risks like fake and illegal online pharmacies. Drugs and Cosmetics Act 1945 is one of the few regulatory instruments available for regulating the pharmacies. According to the Act the stamping of the prescription is needed to prevent abuse through repeated buying of the same medicines and thereby drug addiction. But for online pharmacies since the scanned copy of prescriptions are needed (without the stamping of the prescription), the same prescription could be used on multiple portals and the abuse of quantities could happen. Risk of increased drug addiction among youth and the danger of self-medication, over and under medication could occur. Another additional risk is the sale of spurious and sub-standard drugs. In the absence of data security laws there could be breach of data confidentiality with regard to patients' data and shared with third parties for a financial gain (Sub-committee report 2016).

In depositions before the Sub-committee formed to evolve the regulatory contours for online pharmacy, Indian Pharma Alliance has warned that online stores should not be allowed to be selective in delivering and they need to be also forced to deliver to rural and remote areas. There was apprehension expressed by Confederation of Indian Industry that the storage facilities could be suspect and called for exclusion of vaccines and other productions which need cold chain. All India chemists and druggists association opposed the regularization of the online pharmacy citing that many developed countries with better regulatory capacities have not encourage online pharmacy. It also has pointed out that it is tough to regulate the whole supply chain of aggregators, deliverers and pharmacies as they fall under different regulatory domains. It also pointed to the monopolistic nature of the online pharmacies which might crowd out the Brick and Mortar (B & M) pharmacy outlets. As a result of this, B & M outlets could become unviable in rural areas affecting access (Sub-committee report 2016). The Indian Medical Association has also expressed strong reservations regarding online pharmacies. It has cited a case against snapdeal.com (an online market) by Maharashtra state FDA for sale of

specific drugs. It also extensively cites the legal provisions under Drugs and Cosmetics Act which makes E-pharmacies untenable for instance, it says the pharmacies are regulated by Drugs and Cosmetics Act while online transactions are under the IT Act. Further section 18c of the Drugs and Cosmetics Act prohibits anyone from selling medicines without proper license and since online transactions are not the 'license' to sell in the sense of the Drugs and Cosmetics Act it is prohibited and even carries penalties and imprisonment (Section 27) (IMA document). Given these concerns expressly stated about the risks involved in the online pharmacy it follows naturally that regulation is very much needed and a *sine qua non* for mitigating the risks. The following section shows the policy landscape that is existent currently in the country for regulating online pharmacies.

3.2 Regulatory Overview

3.2.1 Voluntary Code of conduct 2016

The federation of Indian chambers of commerce and Industry (FICCI) came up with a voluntary code of conduct for the operation of the online pharmacies in 2016. Some important provisions are disbursal of medicines only against proper prescriptions and ensuring the appropriateness of the medicines to the patient[12]. It calls for no sale of Schedule X drugs (narcotic, psychotropic and habit-forming drugs as listed under the Drugs and Cosmetics Act)[13]. Further it proposes that the pharmacies must have adequate processes to prevent sale of such medicines[14] and suggest due diligence in physically checking of prescription and confirming it from the doctor[15] and exhorts for working with the government to build proper surveillance mechanism for such drugs.[16] It calls for dispensation of medicines only from a registered pharmacy, which is domiciled in India.[17] The delivery of medicines shall be in proper packaging and that cold chain shall be maintained.[18] Online pharmacies shall work with public health initiatives of the government of India for instance in supporting proper recall of medicine in case of an Adverse Drug Reaction (ADR).[19] Online pharmacies shall establish customer grievances cell with an ombudsperson attached to it.[20]

3.2.2 E-Prescription

[12] § 1- FICCI Voluntary Code of Conduct
[13] § 2 - FICCI Voluntary Code of Conduct
[14] § 2.1 - FICCI Voluntary Code of Conduct
[15] § 2.2 - FICCI Voluntary Code of Conduct
[16] § 2.3 - FICCI Voluntary Code of Conduct
[17] § 3 - FICCI Voluntary Code of Conduct
[18] § 4 - FICCI Voluntary Code of Conduct
[19] §5 - FICCI Voluntary Code of Conduct
[20] § 6 - FICCI Voluntary Code of Conduct

Pharmacy council of India has come up with guidelines for E-prescriptions in its pharmacy practice regulations of 2015. It recognizes the use of electronic means of prescription and thereby the provisions that are applicable for regular prescriptions hold good for e-prescriptions as well. It calls for a digital signature of a registered medical practitioner (RMP), which should also be in a non-repudiated fashion and confirm to all the digital authentication processes.[21] This enables the use of E-prescriptions for the purposes of online pharmacies.

3.2.3 Sub-committee report on regulation of selling of drugs over internet

A sub-committee consisting of drug regulators and experts was constituted in 2016 to look into the issue of regulation of selling of drugs over the internet. The sub-committee while acknowledging the power of technology to be a game changer for potential health benefits cautions that drugs are not ordinary commodities like FMCGs[22] and calls for caution to be exercised in allowing the unbridled sales of drugs over internet. It calls for allowing of sales in a limited manner and acknowledges that the capacity for supervision, vigilance and regulation is currently absent. It calls for a central portal/cloud, apps for patients, doctors and pharmacies (Sub-committee report 2016). It calls for suitable modification of the Drugs and Cosmetics Rules 1945 to enable regulation of online pharmacies. It suggests that a national portal for registering and monitoring the online activities be established and that online pharmacies need to be prevented from stocking and selling of drugs.[23] Provisions should be made for patients to be in a position to easily contact in case of ADR, expired drugs and so on.[24] An important recommendation is that Schedule X drugs should not be allowed to be sold online.[25] It suggests that provisions have to be made to maintain absolute patient information confidentiality[26] and calls for adherence by online pharmacies to Good Distribution Practices (GDP). [27]

3.2.4 Drugs and Cosmetics (Amended) Rules, 2018

The Ministry of health and family welfare notified draft rules in August 2018, amending the Drugs and Cosmetics Rules of 1945, to regulate the sale of medicines online (MOHFW 2018). This has not yet come into vogue. Some of the recommendations from the sub-committee have been taken on board and provide a legal basis for the online pharmacy phenomenon already operating in the Indian market. It is a registration and licensing act allowing for registrations of the online pharmacy providers. The online provider has to be registered through e-pharmacy portal in order to be able to sell, distribute or stock medicines.[28]Registration is through a formal application process to the Central Licensing authority.[29]Dispensing of drugs is only allowed

[21]§ 2 (j) - Pharmacy practice regulations 2015
[22]Fast Moving Consumer goods
[23]§ 7.6 - Sub-committee report
[24]§ 7.14 - Sub-committee report
[25]§ 7.17 - Sub-committee report
[26]§ 7.18 - Sub-committee report
[27]§ 7.20 - Sub-committee report
[28]§ 67J(1) - MOHFW
[29]§ 67L *ff*- MOHFW

against the prescription and has to be within the time limit specified on the E-pharmacy portal.[30]The E-pharmacy portal must provide for customer support and grievance redressal, which shall run for a minimum of 12 hours a day on all the 7 days of the week.[31]The registration holder should not disclose any of the patient information to any other person[32] except when the state and national governments so desire for public purposes.[33]The registration holder must be domiciled in India.[34]Supply of any drug shall be against a cash bill/credit memo and have complete details of the patient, drug, batch number, manufacturing date and expiry date, exact amount and such other details.[35]Most importantly the rules excludes the sale of narcotics, psychotropic, tranquilizers and such other drugs under Schedule X of the Drugs and Cosmetics Act.[36]The Act provides for periodic inspection of the premises, once in two years, of the online pharmacy from where it is operating.[37]The validity of the registration shall be for three years[38] and later has to be renewed using the proper renewal processes.[39]The Act bans any type of advertisement or promotion of any medicine by the registered portal in any media.[40]The registered provider's registration could be suspended or cancelled in case of any of the actions by the provider is in contravention of any of the provisions of the Act and the Act also provides for remedial measures.[41]In case of sub-standard supply of drugs or any such issue, the Act provides for a Customer Redressal Mechanism to whom the customers might submit their complaints in writing to the State licensing authority.[42]The registered provider must retain all the bills, prescriptions and such other data for monitoring purposes and must be produced to either a state licensing or central licensing authority during audits[43].

[30]§ 67J(3) - MOHFW
[31]§ 67J(4) - MOHFW
[32]§ 67K(1) - MOHFW
[33]§ 67K(2) - MOHFW
[34]§ 67K(3) - MOHFW
[35]§ 67M(3)*ff*- MOHFW
[36]§ 67M(5) - MOHFW
[37]§ 67O - MOHFW
[38]§ 67Q - MOHFW
[39]§ 67R - MOHFW
[40]§ 67S - MOHFW
[41]67T*ff*- MOHFW
[42]67U*ff*- MOHFW
[43]67V*ff*- MOHFW

Regulatory overview (tabular representation)

Agency	Role/responsibility
Drug Controller General of India (DCGI)	In accordance with the Drugs and Cosmetics Rules 145, the DCGI is expected to lay down the standard and quality of manufacturing, selling, import and distribution of drugs in India. It acts as appellate authority in case of any dispute regarding the quality of drugs; it works towards the preparation and maintenance of national reference standard; it is supposed to bring about the uniformity in the enforcement of the Drugs and Cosmetics Act; it is supposed to trains drug analysts deputed by State Drug Control Laboratories and other Institutions; (5) it performs the analysis of cosmetics received as survey samples from CDSCO (central drug standard control organization). With the notification of Medical Device Rules 2017 by the Government of India, DCGI will also act as Central Licensing Authority (CLA) for the medical devices which fall under the purview of these rules. Out of four Classes of medical devices from Class A to Class D, DCGI will be the direct licensing authority for Class C and D devices, whereas it will coordinate licensing for Class A and B devices through State drug controllers, who will act as State Licensing Authority or SLA
Federation of Indian Chambers of Commerce and Industry (FICCI)	It came up with a voluntary code of conduct for the operation of the online pharmacies in 2016. Some important provisions are disbursal of medicines only against proper prescriptions and ensuring the appropriateness of the medicines to the patient. It calls for no sale of Schedule X drugs (narcotic, psychotropic and habit forming drugs as listed under the Drugs and Cosmetics Act). Further it proposes that the pharmacies must have adequate processes to prevent sale of such medicines and suggest due diligence in physically checking of prescription and confirming it from the doctor and exhorts for working with the government to build proper surveillance mechanism for such drugs. It calls for dispensation of medicines only from a registered pharmacy which is domiciled in India. The delivery of medicines shall be in proper packaging and that cold chain shall be maintained. Online pharmacies shall work with public health initiatives of the government of India for instance in supporting proper recall of medicine in case of an Adverse Drug Reaction (ADR). Online pharmacies shall establish customer grievances cell with an ombudsperson attached to it.

Pharmacy Council of India	It has formulated guidelines for E-prescriptions in its pharmacy practice regulations of 2015. It recognizes the use of electronic means of prescription and thereby the provisions that are applicable for regular prescriptions hold good for e-prescriptions as well. It calls for a digital signature of a registered medical practitioner (RMP), which should also be in a non-repudiated fashion and confirm to all the digital authentication processes. This enables the use of E-prescriptions for the purposes of online pharmacies.

3.3 Regulatory gaps and opportunities

3.3.1 Regulatory gaps and concerns

This section draws from the data collection done through Key informant interviews and the themes that emerged from the analysis of the interviews. This section also draws from the different regulatory frameworks elucidated in the literature.

3.3.1.1 Prevalence of irrationality in the offline pharmacies

There have been latent issues plaguing the brick and mortar (B & M) pharmacies in the country. Some of the issues are the rampant over-the-counter dispensing of medicines without proper prescriptions leading to such issues as Antibiotic resistance, drug addiction and so on; improper documentation of the medicines dispensed and hence it is difficult to track the medicines sold; Recall of drugs in case of adverse drug reactions is also problematic; The medicines are sold without proper bills and cash transactions result in losses in tax revenues; counseling and awareness generation mechanisms for patients are non-existent; retail pharmacists have to maintain huge inventory and hence the drugs are susceptible to expiry on the shelf (Sub-committee report 2016). One key informant highlighted the fact that any prescription given is legally valid for only 4 months but the chronic patients do not go back to the physician for a fresh prescription and keep reusing the same prescription over a longer time of nearly 1-2 years or till there is some other health scare and hence even though technically valid, the prescriptions for which the pharmacists are dispensing medicines are legally not valid (KI-4). A larger irrationality is that most of the B & M pharmacies operate without a qualified pharmacist. He mentioned the example of a big hospital chain openly flouting the norms of not having a qualified pharmacist. "*That is the kind of organized thing that even the best or the biggest chain in India is doing"* (KI-4). So, compliance to regulations have been a huge issue.

3.3.1.2 Weak regulatory environment

The pharmacy sector is mainly regulated through the Drugs and Cosmetics Act. The KIs were of the opinion that the Drugs and Cosmetics Act was quite comprehensive and the weak regulation is not due to want of proper guidelines but due to poor implementation (KI-4, KI-5). There is an overall acknowledgement among the KIs that there is very little capacity both with staff and infrastructure to enforce compliance by the pharmacies.

> ..And the drug controller is not doing it for the actual grounded pharmacies (offline). They are not visiting all these chemist shops, they are not looking at whether they are stocking them properly, whether they are looking for prescriptions, how many people were given antibiotics and all with all their red marking and all, nothing like this is happening on the ground in any of the states..(KI-6)

A senior regulator entrusted with regulation acknowledged that there is very limited staff and infrastructure and hence suggested a 'light touch' approach to regulation. *'Rules should be implementable and whether we have the necessary manpower and infrastructure to implement*

such rules should be looked at' (KI-5). The regulatory bodies are not staffed enough and do not have enough autonomy for effective implementation. "*The state drug controllers are also doubling up, somebody is doing somebody else's work, they are not all independent also*" (KI-6). It is also distressing to note that in a court case with Madras High court, pertaining to the ban on online pharmacies, the federal government as early as 20th December 2016 had given an undertaking that suitable legislation will be brought out but even by December 2018 there was no legislation in place forcing the judge to make the following scathing observation "*The Central Government had already been given a longer rope by the order of the Division Bench, which was passed as early as on 20.12.2016. Though around two years have passed from the date of the said judgment, the rules are still at the draft stage.*"[44]

It is also noted that since the B & M are very scattered, small and isolated, ensuring compliance has been a huge issue (KI-4). The overall weak regulation prevailing in the health care sector is reflected in the pharmacy sector as well. For instance, the physician-pharmaceutical nexus that exists. The lack of regulation of the physicians, for instance, of not writing generic medicines in the prescriptions and writing brand names result in the medicine available in only the pharmacies of the nearby areas rather than universally available. As a result of this the availability of medicines is always in question even though due to the thriving generic medicine market in the country availability should not be an issue at all. But this is an issue which goes beyond the immediate sector of the pharmacy regulation that we are engaging with.

> One of my clients got operated in Pune in some hospital for a liver transplant. He was prescribed a brand which is locally manufactured for a immunosuppressant. It is locally manufactured by a company and I gave him a cheaper thing from a national company. The doctor refused, blatantly. A doctor refusing so blatantly, that too in a place like Pune, so this is not a problem of availability, it is a problem of marketing (KI-4).

3.3.1.3 Regulation and E-Pharmacy

It is interesting to note that there is no specific regulation currently which regulates the e-pharmacy. The evolution and existence of e-pharmacy has largely been in a regulatory vacuum. But with the dangers that have got highlighted in section 3.1.3 it is imperative to have proper regulations in place. Section 3.2 highlights the policy landscape for online pharmacy. But most of these is either voluntary code, recommendatory or in discussion. The industry has come out with a voluntary code, the sub-committee drew up recommendations and the ministry has drawn only draft regulations and not formal ones. In the absence of any formal regulations the growth of e-pharmacy in the country is largely uneven and have also been tendencies of irrationality observed.

One of the first casualties is the need for a proper prescription for the dispensing of medicines (in accordance with the Drugs and Cosmetics Act). In an effort to dodge this practice, the online pharmacies have hired doctors who simply write prescriptions, in order to keep up with the

[44] https://economictimes.indiatimes.com/news/politics-and-nation/madras-high-court-bans-online-sales-of-medicines/articleshow/67129896.cms

demand, irrespective of whether or not they have personally examined the patient. This practice is prevalent not just in the case of normal drugs, but even in the case of highly toxic drugs like cancer drugs. Unfettered access to such drugs without any cross-checking is a major cause of alarm.

> I ordered a drug from one of the bigger guys and ordered a cancer drug, right? Because there was a 35% off that drug was highly price controlled so the margin that I get as a retailer is only 5% and these guys were giving a 35% discount. So, I said let us try ordering it and if it is a serious drug, cancer, it is not, one should not be procuring it just like that. The doctor said hi hello and then she just said and wrote a prescription without even knowing without even taking a name whatever, she just said hi hello, all is fine, thank you, bye. This is how the online guys are actually dodging (KI-4).

Industry players in order to create product differentiation set standards, exercise self-regulation and drive best practices in the industry. But the funding pattern of these online pharmacies does not allow them to be amenable to this. These are financed largely by venture capitalists (VC) who can dictate the behavior of the provider. A big online player in Ahmedabad had been pulled up because of all of its prescriptions being written by a physician from Hyderabad who had not even seen the patients. The provider was censured but still received 50 Million Rupees VC funds (KI-4).

3.3.1.4 Regulatory gaps

One of the frameworks for regulation in health care has been the one by Roberts et al. The framework defines the regulation of the four aspects - Costs of care, quality of care, conduct of the providers and accessibility (distribution) of care (Roberts et al 2004; Sheikh et al 2013). The regulation of e-pharmacy thought of is largely a licensing/registration instrument. While it is an important regulatory instrument it is not enough and when mapped against the framework has considerable gaps in design. With respect to the costs of care, E-pharmacy at present seems to provide some advantages. Discounts that are meted out to customers, making it both affordable and convenient at the same time. But if the market moves towards generic medicines then the margins fall drastically and hence even out once the market settles down (KI-4) and the current regulatory draft does not have explicit provisions for ensuring affordable costs of care. Rather than depending on the market mechanisms to regulate the prices of medicines, as health care is a known case of market failure, one could think of such mechanisms as pooled public procurement, which would also make use of economies of scale and drive down costs as the state of Tamil Nadu has shown (Lalitha 2007).

Regarding the quality of care with the instances of no physician-patient interaction and very little cross-verification of validity of the prescription make the danger of self-medication, over or under usage of the treatment very real and there is nothing in the landscape of legislations to look at such aspects thereby compromising the quality of care. Schedule H drugs under the Drugs and Cosmetics Act are those drugs whose sales are restricted and cannot be sold over the counter. This is important to tackle such issues as antibiotic resistance. Interestingly the policies talk of Schedule X drugs but are largely silent on Schedule H drugs again compromising on the quality of care. The instances of the ease with which drugs can be ordered

online much like the groceries and the fact that remote doctors are writing in the prescriptions, without even having seen the patient, exposes the unethical conduct of the providers - both pharmacies and physicians - which the current regulatory mechanism is not able to tackle. The online pharmacies seem to provide the accessibility for patients, with medicines conveniently delivered home to the patients. But this is a largely urban phenomenon as of now. The online pharmacies are starting to spread to Tier II and Tier III towns. But not to the remote and rural areas. Any regulatory policy has also to tackle geographic inequity and evolve policies to ensure access to the hard-to-reach areas. But the current regulatory landscape does not seem to have any mechanism to ensure equitable access of medicines.

The policies of regulations prevailing in the country are treating medicines like one more FMCG product and for promoting the industry rather than for the health and wellbeing of the population. There is an obvious mismatch of objectives. The policies reveal considerable gaps when measured against the desirable regulatory mechanism for health care. Interestingly a senior government functionary entrusted with regulation conflates the role of regulation and service provision. The regulator, much like the industry, expressed that regulation would stifle the development of the industry.*"Misuse should be countered by public awareness, not by regulation - the moment you come out with more regulations, it will not be practical to implement"* or "*..strict implementation of a prescription to be necessary might not solve the problem at hand. It will lead to the non-availability of drugs for patients*" (KI-5).

When the regulatory pyramid framework of Ayres and Braithwaite is applied (Ayres and Braithwaite 1992), even though there is a voluntary code of conduct developed by the industry it suffers from the absence of hierarchical escalation and concomitant regulations higher up in the Pyramid, for instance, of meta regulation and Command-and-control mechanisms, resulting in the voluntary code also not implemented as could be seen from the irrationality currently prevailing in the sector.

3.3.2 Regulatory opportunities

Notwithstanding the regulatory gaps highlighted in the previous section, the move towards online pharmacy provides opportunities for better regulation of the pharmacy sector if done properly.

3.3.2.1 Size of the market

The nature of the online business lends itself to aggregation. As a result it is easier to make online pharmacies comply to certain standards/norms, because of their size, which is not the case in say mom and pop/standalone pharmacies."*It is easier to make a bigger person compliant rather than a small person compliant*"(KI-4).

3.3.2.2 Online transactions

E-pharmacy brings in some potential opportunities for regulation. They have the inherent advantage that they are transacted online. Online transactions make it much more transparent

and also all the information is available in one place without having to go to each and every provider as is the case with the offline providers. Also the data would be real time and hence at any point in time the regulators would have an overview of the market and hence it can facilitate better monitoring and supervision. The online sale of medicines furthers the cause of Digital India – where the transactions are safe, secure, and traceable thereby avoiding illegal payments. This also ensures that the medicines that are being sold are both genuine and authentic.*"IT enabled services bring in transparency, predictability and accountability*" (KI-5).

3.3.2.4 Tracking of the transactions

The biggest advantage of the online pharmacies is that each of the transaction happening could be tracked. The traceability of the transaction helps in the identification of such details as the batch number of the medicines, manufacturing date, expiry date and the price at which the drug is sold. This facilitates, for instance, quicker recall of medicines in case of adverse drug reactions. The regulator could also track whether spurious drugs or sub-standard drugs are sold to the patients. It can also track whether Schedule H or Schedule X drugs have been dispensed without proper prescriptions. "*Online pharmacies can be forced to comply to the norm of not giving out medicines without a prescription, unlike individual standalone pharmacies"* (KI-4).The tracking also helps in ensuring tax compliance.

3.3.2.4 Prescription practices

One of the main hindrances for utilization of the full potential of online pharmacies is the inconsistency pertaining to the prescriptions. While the scanned prescriptions might get abused by the use of same prescription on multiple online portals, the other method evolved by the online pharmacies, of having remote doctors for prescription writing, have been equally disturbing. One way out of this could be the move towards E-prescriptions, which has now been enabled through the pharmacy practice regulations of 2015. One more potential instrument would be to push the online pharmacies to have a list of empanelled physicians (even making the physicians to go to the patients if need be) in their areas of operation who could then provide prescriptions on having physically established contact and that there is an authenticity level added to the prescriptions and also for the patient to go back to the physician in case of any issues with the delivery of medicines. Of course this might then make such phenomena as telemedicine redundant. Another game changer would be the regulatory move towards generic prescriptions, which would then break the physician-pharmaceutical-pharmacy nexus leading to more rational drug use.

3.3.2.5 Overcoming the geographic inequities

Online pharmacies have still not been able to deliver the medicines to rural and remote areas as they are also not very profitable at present making it inequitable. An innovative possibility came from the regulator talking about the possibility of collaboration between the online pharmacies and the Indian Postal Service. Online pharmacies have opened up the potential of getting the medicines delivered to the last mile through the post offices. Post offices are there in the remotest corners of the country. "*This will ensure that people living in the remote corners of India, especially is villages can avail the convenience and affordability of purchasing drugs online. The reach of the Indian Postal Service will certainly benefit those who reside in remote places.*" (KI-5). The reach of the Indian Postal Service will certainly benefit those who reside in remote places and thereby overcoming geographic inequities.

3.4 Information gaps

Since there is no regulations put in place, there is very little empirical data in the literature regarding E-pharmacy and regulation. Even just on E-Pharmacy, there is very little objective data about the extent of consolidation. One is reliant on industry reports to get some data. We also had to look for popular sources to get some data.

3.5 Research questions arising

As there is a paucity of empirical studies in this area, and since the current narrative seems to be largely around the industry angle, one of the research questions would be to do a situational analysis of the health equity effects of E-Pharmacy and the implementation of the regulations vis-à-vis E-Pharmacy.

3.6 Topic Guide

1. Could you describe what is happening with regards to e-pharmacies in India?
2. Are e-pharmacies an emerging threat to offline (brick and mortar/mom and pop) pharmacies?
3. Have e-pharmacies penetrated rural areas, or is it still a largely urban phenomenon?
4. Do you think the current regulatory frameworks are capable of handling the rise of e-pharmacies?
5. What are your opinions on the emergence of e-pharmacies in India in the absence of a strong regulatory framework?
6. What risks do you associate with e-pharmacies?

7. What would you say are the challenges of regulating e-pharmacies?
8. Is there any move by the online pharmacies to regulate themselves?
9. What prevents the government from regulating e-pharmacies in India? Why is there no inclination to regulate anywhere in the government machinery?
10. Even though there are laws in place, where are we with the implementation of it?
11. How has the government been successful in regulating sectors like telecom, aviation, etc. but not health?
12. Is having an autonomous regulatory institution for the health sector a good starting point?
13. What are the other alternatives with respect to regulatory frameworks and institutions?

Chapter 4: Private Equity Financing

4.1 Background

The health care industry in India is around 100 billion USD and expected to grow to 280 billion by 2020 with a very high CAGR of around 22.9 per cent (Ganeshan, L & Veena, SR 2018). It employs around 4 million people making it one of the largest service sector in India (Chanda, R 2015). Hospitals comprise of 71% of the total health care revenues, 13% from pharmaceuticals and around 9% is equipment. 100% Foreign Direct Investment (FDI) in hospital sector under the automatic route was allowed since January 2000. Between April 2000 and February 2015 India's health care sector received about 6.8% of the total FDI inflows into the country (Tikku, P 2017).

In 2016, total FDI inflows has been to the tune of 45 billion USD of which the health sector received 2.25 Billion USD making it around 5% of the overall FDI. But in 2013, it had gone up to as high as 11% of the total FDI and subsequently there has been a dip. Of this the pharmaceutical sector has major continuation of about 2.3% in 2016 (DIPP[45] 2017). The current Indian government has brought out a 'Make in India' policy to encourage foreign investment into the country and making India a manufacturing hub. 25 sectors have been identified and health care sector is one of them.

The health care industry growth in India is more private than public unlike the developed countries where it is more public in nature. This can be gauged from the fact that 75% of dispensaries and hospitals, 51% of hospital beds and 80% of all qualified physicians are in the private sector. This leads to a situation where 60% of Outpatients and 80% of inpatients are serviced by the private sector (Sehgal & Hooda 2015) with a concomitant Out-of-patient expenditure of around 70% (Motkuri, V & Khan, AU 2018). This makes India as one of the countries with the most inequitable health care delivery in the world.

4.1.1 Private Equity (PE) and Venture Capital (VC) investment

Leading hospital chains have shown revenue growth. started to look at Tier II and Tier III cities like Vatsalya, Glocal healthcare, Premia Healthcare etc., Private Equity (PE) interest in health care delivery is increasing. In 2017, 57 investment decisions were closed worth 277 billion USD (Sindhu Kashyap, ASSOCHAM report). There are nearly 110 Private Equity (PE) and Venture Capital (VC) investors in Health care space in the country (PWC 2018 report). As can be seen there is an increasing interest in the PE and VC in the healthcare delivery segment.

[45] Department of Industrial Policy and promotion

4.1.2 Favourable conditions for Foreign Direct Investment

Some of the favourable conditions which foster FDI are historically weak public investment in health care and FDI provides the investment for increasing infrastructure, capacities, technological availability, higher standards and in creating jobs in the health sector (Ganeshan, L &Veena, SR 2018). India also does not have 1 bed/1000 population when the norm is 3 beds / 1000 and needs an investment of USD 204 Million in order to reach this stage (ASSOCHAM Report on PE).

4.1.3 Factors constraining Foreign investment in health care industry in India

The number of players in the hospital sector are very less and there are competing markets. The gestation periods are very long. There are supply side constraints like outside country doctors cannot practice in India. There is a heavy dependence on imports for medical devices with the indigenous industry being weak and finally the penetration of medical insurance is very low. As a result of this despite of the hype around FDI in health care sector FDI constituted less than 20% of the investment in hospitals (Chanda, R 2015).

4.1.4 Impacts of FDI in hospital sector

The impacts of FDI on hospital sector have major equity implications. A study published in 2015 highlighted some of these aspects. The focus has been more on the high end and super specialty services. There has been more focus on curative than preventive aspects of care. The tendency is to invest in high-end technology and replacing human power with machines. The hospitals would have better processes and usage of Information Technology. Most of such hospitals would have national/international accreditation. The salaries for staff is higher and hence the danger of skewing the labour market and the tendency of the resource to flow from public to private. Costs of care would be comparable to the non-FDI high hospitals. FDI tends to drive consolidation of the hospital segment. Some of these are also a result of the some of the structural issues with the Indian health care sector like the low public sector investment, lack of medical insurance and inadequate regulations (Chanda, R 2015). Hence an important consideration would be to look at whether the regulatory mechanisms are in place to correct these market distortions and move towards more equitable health care services.

4.2 Regulatory Overview

4.2.1 Regulation of Private Equity (PE) funds

Regulation of the Private Equity and Venture Capital funds are dealt by The Securities and Exchange board of India (SEBI) under the federal ministry of Finance. SEBI has come out with regulations for the operations of both Private Equity funds. The regulation is called as Securities and Exchange Board of India (Alternative investment funds) Regulations, 2012. This section highlights some of the relevant clauses of the regulations to provide an overarching idea about the regulatory scenario and is not meant to be a comprehensive one. This is majorly

for registration of Alternative Investment funds (AIF) through certification (SEBI 2012). The regulation allows for application by entities for certificate of registration as an Alternative Investment funds (AIF).[46] Any AIF fund which does not have certificate shall cease to function with immediate effect.[47] The regulations also define different categories of AIF[48] and defines eligibility criteria for application[49] and defines the process of the grant of certificate.[50] The regulations then define the criteria for the grant of certificate such as the minimum amounts that have to be invested by an investor, the minimum quantum of corpus funds and such other.[51] It has a provision for overcoming conflict of interest issues[52] and finally procedures for proper winding up of the entity.[53]

4.2.2 Regulation of Venture Capital (VC) funds

As with the Regulation of PE funds, this is also dealt by SEBI. The regulation is called as Securities and Exchange Board of India (Venture Capital funds) Regulations, 1996. This is also essentially for registration of Venture Capital funds (VC) through certification (SEBI 1996). Certificate shall be obtained by a company or a trust in order to operate as a VC fund.[54]Provides a detailed criteria for application[55]and defines the procedures for grant of the certificate.[56] It further defines the investment criteria for a company to qualify as a VC fund.[57]One important clause is that it prohibits public listing for a window of 3 years since the grant of the certificate.[58]

[46]§ 3(1) - Securities and Exchange Board of India (Alternative investment funds) Regulations, 2012
[47]§ 3(3) - Securities and Exchange Board of India (Alternative investment funds) Regulations, 2012
[48]§ 3(4) - Securities and Exchange Board of India (Alternative investment funds) Regulations, 2012
[49]§ 4 - Securities and Exchange Board of India (Alternative investment funds) Regulations, 2012
[50]§ 6 - Securities and Exchange Board of India (Alternative investment funds) Regulations, 2012
[51]§ 10 - Securities and Exchange Board of India (Alternative investment funds) Regulations, 2012
[52]§ 21 - Securities and Exchange Board of India (Alternative investment funds) Regulations, 2012
[53]§ 29 - Securities and Exchange Board of India (Alternative investment funds) Regulations, 2012
[54]§ 3(1) - Securities and Exchange Board of India (Venture Capital funds) Regulations, 1996
[55]§ 4 - Securities and Exchange Board of India (Venture Capital funds) Regulations, 1996
[56]§ 7 - Securities and Exchange Board of India (Venture Capital funds) Regulations, 1996
[57]§ 11 - Securities and Exchange Board of India (Venture Capital funds) Regulations, 1996
[58]§ 13 - Securities and Exchange Board of India (Venture Capital funds) Regulations, 1996

Regulatory overview (tabular representation)

Agency	Role/responsibility
Securities Exchange Board of India (SEBI)	It is the only regulatory actor that is present. It has formulated guidelines for both alternative investment funds (Securities and Exchange Board of India (Alternative Investment Funds) Regulations, 2012) and for venture capital funds (Securities and Exchange Board of India (Venture Capital funds) Regulations, 1996.

4.3 Regulatory gaps and opportunities

4.3.1 Regulatory gaps and concerns

The sorts of impact Foreign Direct Investment (FDI) or Private Equity (PE) or Venture capital (VC) can have on the domestic health sector was seen in section 4.1.4. But the regulatory mechanisms in place as seen in the section 4.2 does not speak to some of the issues raised regarding the impacts of FDI. The regulatory mechanisms in place is only speaking to the investor or business or industries rather than to the specific issues pertaining to the FDI in health sector. These set of regulations suffer from the same issues talked about in section 2.3.1.2 in which health care is not differentiated from the other industries and specific mechanisms not evolved for regulating the health care sector.

4.3.1.1 Health department not the locus of decision making

The attitude of the government towards the private healthcare providers has been one of 'holy cows' that are not to be touched. In a sense, the health ministry is supposed to concern itself with largely 'medical' matters such as national programs for malaria, TB, leprosy, etc. and not concern itself with the financial aspects of health. The health departments are caught in the conflation between developmental roles (clinical functions) and regulatory roles with the former trumping the latter (Sheikh et al 2013). The financial aspects of health care are considered to be in the domain of the finance ministry alone. A senior bureaucrat who was in the health ministry at the federal and state levels had this to say (KI-6):

> You were never consulted about anything happening on the financial policy side front of the you might say investment in health, whether it was FDI, whether it was reduction in customs duty exemption, whether it was even land at concessional rates….And finance ministry would take them completely in isolation, I mean not even, there was not even a paper, which came into the health ministry on this because I know. I was a JS (Joint Secretary) there, an AS (Assistant Secretary) there, I've attended God knows how many meetings, parliamentary briefings, so I would know if it existed. Not a scrap of paper was even referred to you because it is not treated as a 'health' matter, it was treated as industry. If it is industry, you give permissions as a policy. How does it have anything to do with the health ministry? Even insurance, it is not treated as a health issue.

Just general regulations dealing with just the financial matters is not going to help the health care sector. "*The industrial policy should have a set of regulations on venture capital funding, in specific relation to the health industry. And overarching set of regulations will not do the job."*(KI-1)

4.3.1.2 Federated nature of health decision making

In India, health is a federated subject under the Indian constitution in which health is a state subject and rightfully so since more devolved health is, more responsive it would be to the local context and needs. So within the constitutional spirit of federation, the federal government

cannot intervene in state matters but at the same time, industrial policy is in the domain of the federal government and hence the varied objectives vis-à-vis FDI in health care sector

> Despite the increase in cases of medical negligence, the government machinery is still passive about bringing in medical regulation. One of the reasons for this is that health is a state subject under the constitution. So, the central government by itself does not have the authority to do anything until and unless the states are brought onboard. Since the health ministry is not administering these aspects, thanks to the overarching nature of the NITI Aayog, medical regulation is not taken up (KI-6).

While the federal and state governments have found ways to work together on many health related matters as in National Health Mission (formerly National Rural Health Mission), but the lack of champions to take up the cudgels of regulation and lack of public outrage (debate) in this sector has hampered evolution of the regulatory mechanisms. *"I think the state of political debate about public health expectations of progress in our country is so poor across so many domains of activity."*(KI-1).

> In order to get the vehicle of medical regulation moving, you need somebody who is proactive, a champion for the cause. In the sense that, you need a champion pushing for medical regulation at a state level, so that others can lead by example. For instance, 'X' a former health minister, was a champion for tobacco; he was the first one to bring in a legislation against tobacco in Delhi and all the other legislations came after that. (KI-06)

The issue of medical regulation gathers more and more steam each time there is an issue of medical negligence. The more noise that the media and public at large create about this issue, the more pressure it will put on the government to realize the seriousness of the situation. Community pressure as a means towards action with media playing an active role. "*So, only if there is huge public pressure will governments act and and/or there has to be I am sorry to say, some huge calamity. But calamity.*"(KI-6)

4.3.2 Regulatory Opportunities

The same regulatory opportunities that were enumerated for consolidation of hospitals in particular and health care sector in general is valid for this aspect as well.

4.4 Information gaps

We have paucity of actual data pertaining to consolidation. There is very little objective data about the extent of consolidation. One is reliant on either industry or the ministry sources to get some data. We also had to look for popular sources to get some data regarding consolidation. The authors also did not find enough research done in this area and in specific the effects on population health of consolidation

4.5 Research questions arising

The regulation sphere is also caught in the crossfire of ideologies and hence strictures on private capital must come from the government alone. One of the research question idea came up by a Key informant (KI-1). The research idea is bringing together a community of people/convene

a group of people to come up with a few white papers on 'critical state of Indian private equity in healthcare' and do this with a range of opinions/viewpoints.

4.6 Topic Guide

1. Could you tell me what you know about the regulation of the whole private equity venture capital vis a vis health?
2. Is there a mismatch in goals between what the industry wants as regulation and what the regulation of a healthcare sector should be?
3. What are your thoughts on the current regulatory frameworks with regards to private equity financing in healthcare?
4. Do you think that the regulation of the industry is very market-oriented, in a way? The dialogue and discourse around regulation seems to have a largely commercial angle.
5. Why do you think the regulatory instruments for the industry are archaic despite the industry itself having moved on?
6. Why don’ t the concerned regulatory agencies think about the ‘health’ aspect and not the investment part?
7. Is self-regulation of the industry on the cards? If we were to start, how should we do it?

5. Appendices

5.1 List of interviewees

Key Informant	Role
1	Senior Industry Researcher
2	Medical Devices Researcher
3	Hospital Chain Manager
4	Pharmaceutical Industry Actor
5	Senior Drug Regulator
6	Ex-Bureaucrat