Rethinking Business Responsibility in India

A Review of Pharmaceutical & Private Healthcare Sectors

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CUTS International

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Abbreviations

ABRR	Annual Business Responsibility Report
AMC	Ahmedabad Municipal Corporation
APIs	Active Pharmaceuticals Ingredients
APPCB	Andhra Pradesh Pollution Control Board
BBIA	Baddi-Barotiwala-Nalagarh Industrial Area
BDMA	Bulk Drug Manufacturers Association
BIS	Bureau of Indian Standards
BMW	Bio-medical Waste
CAGR	Compound Annual Growth Rate
CBWTF	Common Bio-Medical Waste Treatment Facilities
CDSCO	Central Drug Standard Control Organisation
CEA	Clinical Establishments (Registration and Regulation) Act, 2010
cGMP	current Good Manufacturing Practices
CII	Confederation of Indian Industry
CIPA	Confederation of Indian Pharmaceutical Industry
CME	Continued Medical Education
COPRA	Consumer Protection Act, 1986
CPCB	Central Pollution Control Board
CROs	Contract Research Organisations
CSP	Corporate Social Performance
CSR	Corporate Social Responsibility
CTRI	Clinical Trial Registry-India
CWTF	Common Waste Treatment Facility

DCGI	Drug Controller General of India
DIPP	Department of Industrial Policy and Promotion
DoP	Department of Pharmaceuticals
DPCO	Drugs Prices Control Order
EFI	Economic Freedom Index
ESRC	The Economic and Social Research Council
FDA	Food and Drug Administration
FDCA	Food and Drug Control Administration
GCP	Good Clinical Practices
GDP	Gross and Domestic Product
GLP	Good Laboratory Practices
GMP	Good Manufacturing Practices
GPCB	Gujarat Pollution Control Board
HAI	Hospital Acquired Infection
HCU	Healthcare Units
HPPCB	Himachal Pradesh Pollution Control Board
ICT	Information and Communication Technology
IDMA	Indian Drug Manufacturing Association
IICA	Indian Institute for Corporate Affairs
IIM	Indian Institute of Management
IPA	Indian Pharmaceutical Association
IPRs	Intellectual Property Rights
MCI	Medical Council of India
MINAS	Minimal National Standards
MNPCs	Multinational Pharmaceutical Companies
MoEF	Ministry of Environment and Forests
MR	Medical Sales Representative
MSME	Micro, Small and Medium Enterprises

NFHS	National Family Health Survey
NPPA	National Pharmaceutical Pricing Authority
NRHM	National Rural Health Mission
NUPI	Norwegian Institute of International Affairs
NVGs	National Voluntary Guidelines on Social, Environmental and Economic Responsibilities of Business
OPPI	Organisation of Pharmaceutical Producers of India
PCBs	Pollution Control Boards
PCCs	Pollution Control Committees
PPP	Public Private Partnership
R&D	Research and Development
RFD	Results Framework Document
RuD	Rational use of Drugs
SEB	State Electricity Board
SEBI	Securities & Exchanges Board of India
SMEs	Small and Medium Enterprises
SPCB	State Pollution Control Board
STP	Standard Treatment Protocol
TRIPs	Trade Related Aspects of Intellectual Property Rights
UCPMP	Uniform Code of Pharmaceuticals Marketing Practices, 2011
WBPCB	West Bengal Pollution Control Board
WHO	World Health Organisation

Acknowledgement

This study on the interplay between business regulation and responsible business conduct will impart better understanding about the roles the various stakeholders need to play in promotion of responsible business practices in the pharmaceutical and private healthcare sectors in India (and indeed other such key sectors). The findings of this research are expected to initiate a discourse on ways in which business can be more relevant and responsible in the present Indian society.

We express our sincere gratitude to the Norwegian Ministry of Foreign Affairs and the Royal Norwegian Embassy, New Delhi for their support in implementing this project. We are particularly thankful to our project partner Norwegian Institute of International Affairs (NUPI) for collaborating in this project and Jens Andvig for his frequent trips to India and contributing a chapter.

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- Gunjan Organisation of Community Development, Himachal Pradesh
- Centre for Climate Change, ESCI, Andhra Pradesh
- CUTS Calcutta Resource Centre, West Bengal

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Many other names deserve mention, but could not be referred here for want of space. A large number of stakeholders have participated in various activities and gave valuable suggestions for taking forward the agenda of responsible business in India. We thank all of them.

Foreword

Two years ago CUTS invited me to guide its project entitled, 'Exploring the Interplay between Business Regulation and Corporate Conduct' in India (referred to as the BRCC project). This was around the same time that the Planning Commission was developing its thinking on how to design an enabling regulatory framework for business in India to accelerate growth and sustainable development in the country. Socially and economically sustainable development requires rapid creation of jobs and for this India's manufacturing sector must grow much faster. One of the constraints on growth of the manufacturing sector is the condition of the business regulatory environment.

CUTS was engaged by the Planning Commission to assist one of the key Working Groups shaping the Plan for Industry and Manufacturing. This Working Group concentrated on two related subjects: the Business Regulatory Framework, and enhancing Business Responsibility. Thus I have been associated with CUTS on the subject of Responsible Business over the last couple of years in two ways: firstly, through the work CUTS did for the Planning Commission; and secondly as Chair of the Project Advisory Committee of the BRCC project. I have appreciated the blend of policy analysis and practical information that CUTS brings to the table, and CUTS' ability to facilitate a discourse on the basis of good information. The lack of good evidence muddies processes of policy making and policy implementation too – so CUTS' contributions have proven very valuable to the Planning Commission.

"CSR" has come to occupy a very visible place on the stage, in policy development and public debates in India on account of the Indian Government's push to include compulsory expenditure on CSR in the new Companies Bill 2012. It has raised deeper questions about 'CSR', such as the association of CSR with expenditure of money, and CSR by law rather than through moral and ethical compulsion. Fortunately, along with the compulsory expenditure mandate in the new Companies Bill, the Ministry of Corporate Affairs also developed the National Voluntary

Guidelines on Social, Environmental and Economic Responsibilities of Business (popularly referred to as the NVGs), thus highlighting the other view of voluntary and ethical business responsibility. Moreover the process by which these guidelines were developed, through an extensive process of systematic stakeholder consultations, deepened understanding of the multi-faceted issues that must be addressed.

The next step of policy ideas and guidelines has to be 'implementation'. This requires ideas and guidelines to come to the ground, to translate into the specifics of sectors.

The research of the BRCC project observed lack of cooperation among regulatory agencies in sectors at the state level as a key barrier to better regulation. Another was the role of business associations, and particularly sectoral associations. One of the recommendations of the project is the need to strengthen the ability of these associations to act as a bridge between the government and regulators on the one hand and firms on the other. Sectoral associations can provide good platforms for engaging with public stakeholders (consumers, citizens) of the industry too.

The other issue that the report highlights is for debates on responsible business in India to recognise the plurality in India. Historical and cultural differences across states have considerable implications on how each state perceives its interaction with business, especially in terms of meeting their social and economic developmental objectives. The arrangement of regulatory institutions in India (between the national and the state levels) introduces a lot of variations across regulatory institutions in different states, even if the regulatory frameworks adopted across them are largely similar, if not the same. Such diversity and variation is often forgotten in economic governance processes. I am particularly happy that this report has highlighted this issue. It shows again how grounded the evidence and analysis in this report is.

The report has also introduced the concept of 'complex self-adaptive systems' to frame a system in which there is innovation and voluntary action by independent agents, as well as regulation of the system to prevent predatory behaviour that can destroy the balance between stakeholder needs and thus make the system unstable. Policymakers and private business associations (especially sectoral associations) may understand their system in terms of the principles complex adaptive systems in this sector in order to develop the architecture of an effective regulatory apparatus.

Arun Maira
Member, Planning Commission, Government of India

Preface

Deregulation of Indian economy since the 1990s has played a big role in the impressive growth of the private sector, along with other sectors. However to ensure that the growth trajectory continues and benefits all segments of society, it is important to sort out regulatory bottlenecks for the private sector and promote the culture and values of being '*A Responsible Corporate Citizen*'. A fundamental question is how to maximise the contribution to growth from the private sector for socio-economic development of the country? To achieve this objective it is necessary to ensure that suitable conditions exist for stimulating private sector development on the one hand; and inculcating responsible business behaviour on the other – so that benefits from the growth of the private sector can accrue to the largest number of Indians.

Businesses' contribution towards society has generally been looked at under the purview of corporate social responsibility (CSR) in India. The subject has a long and evolving history in the country. However, the present external environment, growing stakeholder awareness and improved access to information has prompted a re-look into the concept of CSR and its tenets.

Thinking on CSR in India has undergone considerable metamorphosis, since the early times. Annals of Indian history suggest that the country has consistently defied the relatively narrow notion that 'the business of business is business'. The evidence is witnessed in the words of great thinkers and visionary leaders of the country – right from Kautilya in the 4th century B.C. (as recorded in the Arthashastra) to Mahatma Gandhi and Jamshetji Tata in the post-independence period. The urge to promote business responsibility has been central to the Indian tradition of doing business.

However, there is a growing recognition that businesses need to be not just profitable, but more importantly sustainable in a broader context pertaining to the stakeholders, the commons and the community. To bring in these dimensions and to help the private sector in their efforts towards

inclusive development, the Government of India developed the National Voluntary Guidelines on the Social, Environmental and Economic Responsibilities of Business (NVGs) in mid-2011. The development of the NVGs is a welcome move and indeed provides a consistent framework for defining and operationalising business responsibility in India. The NVGs is expected to help firms identify areas in its core business model that need improvement from a 'responsible business behaviour' perspective.

While the NVGs have developed a framework of good business behaviour, the relationship between business regulation and responsible conduct requires further investigation in the Indian context. To this end, there is an apparent need for initiating such a discourse in the country that can enable the regulatory regime aimed at promoting economic growth to facilitate responsible business. Efforts to grow on a sustainable basis (and make sustainability a core element of the 'business strategy'), while ensuring fairness to all stakeholders and the society at large – need to originate from within the private sector.

In this backdrop, a project entitled, 'Exploring the Interplay between Business Regulation and Corporate Conduct in India' (BRCC project) was conceptualised to delve into the interplays between business regulation and corporate conduct and raise awareness thereof. It was operationalised by undertaking research to comprehend business regulations at the national and state levels, and find ways to best motivate corporate entities to emerge as champions of responsible conduct.

Pharmaceutical and private healthcare sectors were chosen under the project to explore the linkages between business regulation and corporate conduct in four Indian states, namely, Andhra Pradesh, Gujarat, Himachal Pradesh and West Bengal.

Andhra Pradesh, Gujarat and West Bengal were chosen given the high concentration of pharmaceutical firms and also the large presence of private healthcare sector. Himachal Pradesh was selected as an otherwise 'pristine' state that is attracting significant investments in these sectors. It was felt that having one 'pristine' state among other states with 'mature' presence of the industry, would provide an understanding on how the growth trajectory of the sector could impact business behaviour over a period of time.

The pharmaceutical and the private healthcare sectors in India offer interesting opportunities to examine how regulations influence business conduct. Of particular significance is the fact that both the sectors pose stern challenges to regulators and legislators, especially since public interest elements associated with various aspects of the business conduct is high.

Based on CUTS' prior experience in the sector and the feedback gathered through the 'research dialogues' and 'round table meetings' conducted under the BRCC project, it was decided to focus on two 'key issues' in the sectors – the environmental responsibility; and the ethical aspects of marketing and distribution.

This report contains six chapters – the first chapter contains an overview of the theoretical foundations of the interface between business responsibility and corporate conduct from an international context linking it with the Indian perspective. The second chapter analyses the policy and institutional framework in the two sectors in India and identifies implications for responsible business. The third chapter contains a description of the research problem and methodology used for undertaking the study. A detailed analysis of the data collected from the four states is provided in the fourth chapter. The fifth chapter highlights key emerging conclusions of the study and the sixth presents some thoughts on the way forward.

Business regulation is often understood in the narrow sense as public regulation only. However, a more holistic understanding of business regulation from the perspective of business behaviour is important and should also comprise self regulation and co-regulation. The research looked at all the three components of business regulation.

This is perhaps the appropriate time for this report to be out as the current debate on CSR in India among government, civil society and business community seems to be raising more questions than answering them. Various quarters have approached the issue differently, leading to this confusion. There is such a variety in these discussions that many in the audience (including people who are expected to promote business responsibility in India), seem confused. It is important that some of the basic tenets of businesses' contribution to society are clarified, to initiate an informed discussion.

The research used the framework of NVGs and applied its nine principles and core elements in both the sectors. A key lesson which emerged from this experience is that businesses do not have to go out of their way to be socially responsible and relevant. Indian businesses can meet their societal expectations by continuing to consistently operate by abiding applicable laws of the land.

The project report has mapped the institutional context of the two sectors, gathered data from different stakeholders to understand the realities and challenges, and presented findings on different facets of regulation that has implications for business behaviour. The research is expected to contribute in promotion of the understanding about elements

of 'responsible business behaviour' and stimulate thinking about ways in which not only these two but other sectors of the economy can adopt certain measures without affecting their bottom-line and emerge as pioneers of responsible business.

Pradeep S Mehta
Secretary General
CUTS International

Executive Summary

Introduction

Since the 1990s, the role of the private sector as an integral partner in the discourse on sustainable development has received considerable attention globally. In recent years, there has been a shift in the discourse on the manner in which the participation of the private sector has to be viewed. In developing countries like India, there is an emerging agreement across actors for the private sector's agenda of rapid economic growth to be recalibrated with consideration for responsible and inclusive business strategy. In particular, the involvement of the private sector in providing public goods like health, drinking water and education has raised the need for a more careful scrutiny and understanding from a regulatory perspective.

It is in pursuance of this mandate that CUTS designed a project entitled, *'Exploring the Interplay between Business Regulation and Corporate Conduct in India'* referred to as the *BRCC project* (www.cuts-ccier.org/BRCC). The BRCC project has been implemented over the period 2011-13 with support from the Ministry of Foreign Affairs, Norway through the Royal Norwegian Embassy in Delhi (India). CUTS teamed up with the Norwegian Institute of International Affairs (NUPI) for developing the theoretical framework and evolving the research outline of this project. The fieldwork and analysis was undertaken by CUTS in collaboration with local civil society organisations in the select states of India. The project was designed to pursue the overall goal of assessing the determinants of responsible business behaviour in India (national level and in selected states), and initiate a discourse among key stakeholders about the need for promoting balanced business in certain important sectors of the country.

The pharmaceutical and the private healthcare sector in India offer interesting opportunities to examine how regulations in these sectors

influence business conduct. Of particular significance is the fact that both the sectors pose stern challenges to regulators and legislators, especially since public interests associated with various aspects of business conduct is high. The study focussed on two particular areas related to 'responsible business behaviour' in these sectors; on its environmental implications, and on its marketing and distribution processes. Specifically, the *objectives* of the study were to:

a. Understand the role of the different actors in the healthcare and pharmaceutical sectors in promoting responsible business conduct.
b. Identify the key challenges and conflicts faced by the actors in managing the interaction between regulation and their conduct.
c. Identify key gaps between the intent of the regulation and its implementation to strengthen the regulation, policy and the procedures both at the Centre and State level

Research Design and Methodology

Since the research was exploratory in nature and the processual aspects of the interplay between regulation and business behaviour was being investigated, a case study approach was felt to be most appropriate. The project was designed such that research would be undertaken in four states across India to identify issues at the interface of business regulation and business behaviour in them. Each state would be treated as a case study. The research design of the project posed several challenges and has been emergent and iterative. The contours and the emphasis in the project were determined by expert inputs and stakeholders' insights. In the initial stages of the project, it was decided to arrive at the choice of the states based on an analysis of the economic performance of the states and using data from the 'ease of doing business' in India (state-wise rankings). The shortlisting of the sectors was done based on percentage growth in revenues in the sector and their contribution to state-level GDP.

However, there was unanimity among project Advisers and other experts that given the objective of the study, the choice of the sectors should precede the selection of the states. After examining several sectors like financial, automobile, pharma, mining and retail, it was decided that the *pharmaceutical* sector and the *private healthcare* sectors should be chosen. The argument in favour of these sectors was that they were engaged in providing public goods and services, and their impact at the societal level was significantly high. Further, both these sectors had witnessed significant growth particularly in the last two decades. The choice of the sector was also defined by CUTS' prior expertise and experience and familiarity with

issues that had bearing on responsible conduct of firms operating in these sectors.

After further research and discussions within and outside the CUTS team, a list of four states for undertaking the fieldwork was arrived at. These were Andhra Pradesh, Gujarat, Himachal Pradesh and West Bengal. It was also decided that CUTS would implement the project in collaboration with civil society partners in each state, who had good understanding of the context at the state level. Broadly, the methodology of the project comprised a mixed multi-method research design.

While secondary data was used extensively to identify the critical issues (for examination), a combination of in-depth interviews, questionnaires survey and analysis were used to gather primary data. Data analysis was done using descriptive statistical analysis of the questionnaire data and the content analysis of the qualitative data. Insights from the four state level partners who had prior nuanced understanding of the context was used to describe comprehensively how the regulatory aspects determined business behavior in the states. A situational analysis was undertaken with the help of state-level practitioners from each of the two sectors to offer a background for the research.

Overall Findings

Broadly, this report consists of two parts. In the first part, it presents analysis of international perspectives on CSR and presents a theoretical overview applicable to the two sectors. The second part presents empirical evidence about determinants of business responsibility in pharmaceutical and private healthcare sector gathered from four Indian states. The key findings of the study in the pharmaceutical industry related to the environmental aspects and marketing and distribution processes are presented below:

Environmental issues in the pharma sector:

In the case of the pharmaceutical sector, the three significant findings were:

(1) There exists a high variation across states in terms of the infrastructure available at the firm-level to manage environmental aspects.
(2) Awareness on Good Manufacturing Practices (GMP) was found to be high, but compliance with relevant regulation was rather weak.

(3) Gaining attention of their senior management and bringing environmental issues in the board-room discussions was critical for creating long term support to environmental issues by the companies.

There were variations across states on how the sector should be regulated. In Gujarat, a majority of the firms surveyed thought that self-regulation was the way forward for dealing with their environmental responsibilities. In West Bengal, however, there was no clear direction on the most effective method of regulation. Nearly a third of the surveyed firms were in favour of some government intervention. However, in Himachal Pradesh and Andhra Pradesh firms largely supported strict enforcement of rules and regulations.

Environmental issues in the private healthcare:
Three key issues pertaining to private healthcare were:
(1) Awareness on Bio-Medical Waste (BMW) regulation was high among hospitals but reporting on BMW was very weak.
(2) Different states adopted different models for treatment disposal of BMW.
(3) State pollution control boards are expected to carry out too many roles which pull them in different directions.

Marketing and distribution related aspects in pharma sector:
Some of the key issues pertaining to marketing and distribution in the pharma sector were as follows:
(1) There is a widespread prevalence of sponsorship of events for doctors. It appears that this practice is endemic to the industry. While the conflict of interest is apparent, the extent to which the practice has direct bearing on the doctors' willingness to prescribe, requires deeper investigation. If all the companies are engaging in the practice, then what is the basis for the doctor to recommend a particular drug?
(2) Data collection on the salary structure of the medical sales representatives (MRs) proved very difficult. This is a professional service/sector that requires much deeper examination and attention.
(3) Awareness and adherence to the voluntary codes like the Uniform Code of Pharmaceuticals Marketing Practices (UCPMP) 2011 is low across the states.

Marketing and distribution related aspects in private healthcare
The three key issues that emerged from the analysis are:

(1) Among the healthcare sector, the awareness of the Medical Council of India (MCI) guidelines is quite high, but there is a lack of systematic and consistent in-house mechanisms to track adherence to these guidelines.
(2) Understanding and application of principles of 'Rational use of Drugs (RuD) was a weak link.
(3) Regulatory arrangement is ill-developed in case of marketing and distribution and requires an urgent review.

Emerging conclusions

The study clearly shows that promotion of responsible business practices in the pharmaceutical and private healthcare sectors in India (and indeed other such key sectors) depends not only on certain key internal factors pertaining to firms themselves, but also on a number of factors pertaining to the external environment within which firms in these sectors operate. Five key emerging issues pertaining to the external environment are presented below:

Firstly, there is no direct relationship between the level of economic development of a state and levels of compliance witnessed across India.

Secondly, there is evidence that absence of coordinated enforcement of laws across several agencies often provide opportunities for the actors to more easily circumvent the law.

Thirdly, the regulatory gaps that exist in the field of pharmaceutical and private healthcare services in India, has implications on business behaviour.

Fourthly, quality and number of staff needed to enable effective regulatory system is insufficient at the state-level. However, this is not considered while allocating additional regulatory responsibilities in these institutions.

Finally, there is ambiguity in the roles and responsibilities of the various actors. There are conflicts of interests in case of the State Pollution Control Board and the State Drug Controller.

In the internal context, which pertains to the actors within the sector, four key issues emerged:

Firstly, the role of industry associations in both the sectors requires strengthening, and consistent attention across states.

Secondly, there are no incentives for the private healthcare sector to foster compliance.

Thirdly, the role of MRs in private healthcare context requires further investigation.

Finally, the notion of business responsibility as different from philanthropy and community development, needs greater attention and stakeholder awareness.

Way forward

While the report could appear to be an enumeration of the weaknesses that need to be fixed, it is heartening to note that it also points out several 'good practice' initiatives at the state level that have been quite successful.

(i) Use of ICT tools (e-governance) has proved quite useful for the FDCA, Gujarat in monitoring the activities of the drug inspectors in the state.
(ii) The Pollution Control Boards have a crucial role to play in ensuring that firms comply with the relevant environmental regulations. In Gujarat, for example there was a change in the approach taken by the Gujarat Pollution Control Board (GPCB) as it transformed itself into a 'doctor' from being a 'policeman'.
(iii) The Himachal Pradesh Government has adopted the Clinical Establishment Act, 2010 and has initiated the process of implementing the same. The state government seems to have realised the gap that existed in effective enforcement and monitoring of regulations/ legislations pertaining to healthcare in the state and therefore created a dedicated Directorate of Health Safety and Regulation in the year 2009.

The findings of the study clearly show that while reforms in the regulatory environment of the two sectors are vital and urgent, other conditions for creating a culture of responsible business behaviour are equally important. Therefore, the report does not contain any recommendations; rather the intent is to identify threads/themes that allow for "meaningful conversations" to take place within and across sectors and stakeholders to foster responsible business behaviour.

It is evident that the pharmaceutical and healthcare sectors are complex and deeply embedded in the social systems with far reaching impact on the health of the people of India. There are several interrelated systems in the sectors interacting with each other – the Ministries (Centre and State), the Judiciary (laws and regulations), enforcement agencies (Central and State), the private and public sector pharma firms and hospitals, the diagnostic clinics and device providers, the drug manufacturers, the pharmacists, the drug distributors/traders, the BMW disposal agencies, the quality certification agencies, the global buyers in pharma and finally the consumer.

Effective healthcare delivery requires both the private healthcare and pharmaceutical sectors to engage in a collaborative and mutually reinforcing manner. This presupposes the existence of a shared purpose, well understood norms, well defined codes of conduct, comprehensive information systems, robust monitoring and feedback processes, comprehensive reporting systems, trust based mechanisms for reconciliation of conflicts and finally incentive structures that breed cooperation. In such systems, rules and regulations define the boundaries of the game and set a level playing field for the actors. The behaviour of other actors needs to be managed through leadership, dialogue and peer influence, well-defined measurements based on outcomes rather than outputs and finally, focussing on interdependent gains and collaborative goal setting across the partners in the network.

A key finding of the study highlights considerable differences across states in the manner in which the regulations (of similar purpose and construct) get interpreted, managed and enforced by similar institutions. While the contrast between states is especially striking in the context of our study, there is also dramatic variation in perceptions both in the quality and the nature of delivery of public goods and in institutional outcomes more generally. The question then is what causes this variation? While a simplistic answer would be the variations in institutional structures, our findings suggest that other factors like the attitude of the entrepreneurs, history and nature of businesses' interaction with the state machinery, their prior experience with regulation, the cost associated with compliance of the regulation, the extent to which reputation risks are perceived as critical, the advocacy of professional associations, the role of civil society and the strength of the local media contribute even more significantly to ultimate business behaviour in these sectors across states. Institutions developed to manage/monitor the behaviour of these sectors need to be well aware

of these factors in dealing with firms at the state level. This implies that all such information should be available to these institutions before they initiate actions, etc.

Looking through this lens, it emerges that while the regulatory framework conceptualises, "a single India", the enforcement mechanisms show us that there are "multiple co-existing Indias". The differences in the socio-cultural attitudes and perceptions of the stakeholders in the different states and regions pose challenges for top down "one size fits all" regulatory enforcement. Both scholars and practitioners of Indian political economy are aware that political institutions operate more effectively in some parts of the country than in others. More discussion is needed to answer questions such as: "*What is the minimal level of compliance that should be incorporated within the regulatory framework as non-negotiable? How should institutions be strengthened to deliver this outcome? What would be the accountability structures of different agencies to manage this minimal regulatory requirement across different states? How should the non-regulatory aspects be structured to get the business to go beyond compliance?*

A possible way forward arising out of the complexity would be to engineer an operational strategy that combines elements of public regulation, co-regulation and self-regulation for the two sectors, under the overall regulatory framework in these sectors. The study further suggests there is an increased role for two actors in improving business behaviour in the sectors: (i) the firms themselves (driven either by or a combination of – internal values and quest for a market clinching business case) and (ii) the sectoral associations (empowered by the government to monitor their members, and be accountable for their behaviour in the market).

International Perspective & Theoretical Overview

– Jens Andvig

1
Can Regulation Stimulate Private Firms to Serve Public Interest: Introduction and Theoretical Overview

Introduction

There is enough evidence to suggest that the economic growth witnessed by India in the last decade has not translated in terms of equitable distribution of the benefits to all sections of the population. The large majority of the country's population still remains disconnected from the 'growth story'.

The wealth of 69 individuals (dollar billionaires) in the country (US$300bn) equalled a fifth of the country's Gross Domestic Product (GDP) of US$1,500bn in 2010. The need for a lasting and inclusive growth in order to address problems pertaining to poverty and low standards of living for the vast majority of its population has been discussed at various levels in the country. One key emerging question is how to effectively leverage the private sector for sustainable development of the country.

To achieve this objective it is necessary to ensure that suitable conditions exist for stimulating private sector growth on the one hand and ensuring an equitable distribution of economic development, through jobs and better access to essential goods and services, on the other. A movement needs to originate from within the private sector driven by a core ambition to grow on a sustainable basis (and make sustainability a core element of the 'business strategy'), while ensuring fairness to all stakeholders and the society at large. Given that stalwarts of responsible business in India mostly originated from within the Indian industry, there is perhaps not much doubt in the ability of the champions of the industry to catalyse such a movement. However, there is a need to analyse if existing conditions are favourable and 'other' actors such as the government, the regulator and civil-society too are aware of their roles to support this movement.

There is considerable variation in the enabling business environment across Indian states. Further, given the federal system of administration in the country, several discussions at the level of Central Government on creating a sustainable growth of private enterprises with a need to be socially responsible, requires alignment with the interests of the State Government and its various departments/agencies.

The tagline of the current (12th) Five Year Plan (2012-17) of the Government of India is 'Faster, Sustainable and More Inclusive Growth'[1], which conveys a commitment of the Government about the nature and type of socio-economic growth that it envisages for the country. While the intention of the Planning Commission of India should be commended here, experience shows that it is often the implementation of such policies/ commitments that poses difficulties. This is often aggravated by the relations between the Central and the State governments, where political undercurrents play a significant role. The weak institutional structures and the resources – physical, financial and human - allotted to them are insufficient to make a significant impact in translating the vision of the planning process.

BRCC Project: Context & Objectives

Consumer Unity & Trust Society (CUTS International) through its various interventions aspires to make economic progress in India efficient, inclusive and responsible. It is the endeavour of CUTS to make a contribution towards shaping the environment and capacity in India to foster sustainable development and inclusive growth. In its pursuit of this mandate, CUTS designed a project entitled, ***'Exploring the Interplay between Business Regulation and Corporate Conduct in India'*** referred to as the **BRCC project** (www.cuts-ccier.org/BRCC).

The BRCC project has been implemented over the period 2011-13 with support from the Ministry of Foreign Affairs, Norway through the Royal Norwegian Embassy in Delhi (India). CUTS teamed up with the Norwegian Institute of International Affairs (NUPI) for undertaking the research activities under this project. As a research institute, the role played by NUPI through its research on governance issues is significant. CUTS could draw lessons and experiences of NUPI and develop the project in the Indian context. NUPI contributed in evolving the theoretical framework. NUPI's interactions with the CUTS project team helped enrich the research undertaken in this project.

The project was designed to pursue the overall goal of assessing the determinants of responsible business behaviour in India (at the national and the state levels) and initiate a discourse among key stakeholders about the need for promoting balanced business development in certain important sectors of the country.

As its credo, CUTS believes that private sector participation is crucial for inclusive growth and tackling poverty in India and other developing countries. However, there is also a strong and simultaneous need to ensure that the private sector demonstrates good corporate citizenship. Hence there is a need to have a hybrid approach of education, incentives and market regulations to ensure that corporations perform their role as important and responsible members in the society.

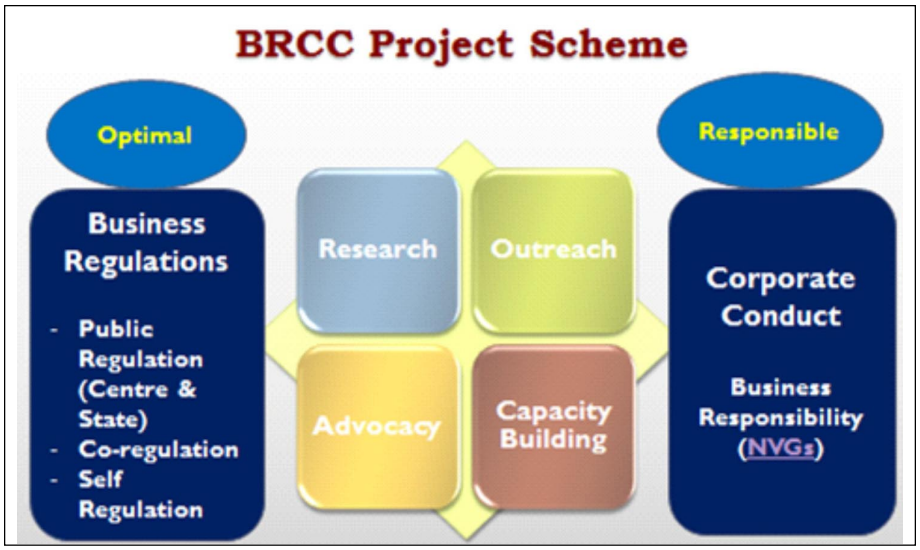
The private sector has been the main engine of growth for the Indian economy and has contributed significantly to various sectors of economy. In the last two decades, private sector has responded positively to the challenges of sustainability and some of the Indian models of integrating sustainability in core business processes are being showcased as the best in the world. CUTS recognises the role played by the private sector and has experience of having worked closely with the business community on various issues pertaining to economic and social development proactively.

It is this confidence that persuaded CUTS to develop the current project in a sector, where it has had prior expertise, namely the pharmaceutical and private healthcare services industry, in order to facilitate a discourse in the country that policies aimed at promoting economic growth can also promote responsible business conduct.

The following are the ***objectives*** of the BRCC project:

- Evolve a policy discourse between the business community and policymakers to facilitate appropriate business regulation and corporate conduct.
- Motivate firms to adopt 'good corporate practices.'
- Address regulatory and operational constraints faced by businesses in India.

In order to meet these objectives, the project relied on a mix of research, advocacy and capacity building activities. The key aspects pertaining to the abovementioned areas are provided below:



Research

- Interface between business regulation and corporate conduct (corporate social responsibility and corporate governance).
- Identification of critical elements of business regulation in the pharmaceutical and private health care services sector that would need to be addressed in order to enhance the ease of doing business.
- Field research in four states namely Andhra Pradesh, Gujarat, Himachal Pradesh and West Bengal to identify 'good practices' (and establish benchmarks) characterising responsible business conduct.
- Collation of experiences from the state level and sectoral studies for the development of policy inputs.

Advocacy

- Awareness generation among policymakers, government representatives/regulators, business community, academia and the civil society in select states on the interface between business regulation and corporate conduct.
- Promotion of approaches in select states which would involve governments to address constraints faced by businesses.
- Promotion of approaches in select states which would involve businesses to demonstrate and adopt responsible conduct.
- Engage with policy/administrative reforms at the State and Central levels promoting a holistic approach to sustainable business development.

Capacity Building

- Development of modules for training stakeholders from select states on approaches to promote dynamic and sustainable businesses.
- Involvement of a range of relevant stakeholders (from across the country) through the project who would imbibe lessons from this initiative and replicate it in other states (based on its results).

The project is intended to achieve the following ***outcomes***:

- Identifying specific constraints in business promotion in select Indian states.
- Identifying 'good practices' related to corporate conduct in two sectors.
- Providing State level policy inputs for sustainable business regulation to promote corporate conduct.
- Providing National level policy inputs for balancing business regulation and corporate conduct.

BRCC Project: Theoretical Overview of Research and Issues

The purpose of the BRCC project was to throw more light on how regulation of pharmaceutical and private healthcare in India (national and state levels) influenced behaviour of firms (of these two sectors) and implications on society. It was necessary to review the global literature (and evolution of thinking) and experience on regulation of pharmaceutical and private healthcare and identify implications for India. Further, it was also necessary to examine how the thinking on corporate conduct (or corporate social responsibility) has evolved – especially from the point of its application in these two sectors. This chapter makes an effort to provide an overarching theoretical framework by closely examining these aspects.

In the process, it emerged that one of the main underlying questions was: Whether it is realistic that the welfare of the Indian population will be enhanced if the private enterprises involved are given increased responsibilities for supplying and redistribution of public services towards the poor? The question seems reasonable to raise against the background of an Indian policy debate where the possible roles of private enterprises in supplying public goods are heavily contested both in a new Companies Bill containing corporate social responsibility (CSR) provisions[2] and in the planning of India's future public health system where the role of the private sector has been both advised to shrink and to expand.[3]

Both industries chosen for the research study deal with the delivery of health services to the Indian population. The general CSR and public health discussions are important from the perspective of the two sectors,

especially to understand how the firms are likely to operationalise them. It is therefore critical to study not only views of the pharmaceutical firms and private hospitals, but also that of relevant regulators and other non-state actors.

The study with its strong empirical focus on the health care and pharmaceutical sector in the four states namely Andhra Pradesh, Gujarat, Himachal Pradesh and West Bengal provides insights to understand more deeply the variations in institutional contexts. The study attempts to highlight impact of the central and state level regulations, varying pharmaceutical industry structures and increasing private ownership in healthcare services on behaviour of firms in this sector. The two industries are linked in several ways, viz.:

(i) the output from the pharmaceutical industry is an input to private hospitals;
(ii) the incentives given to doctors by the pharmaceutical industry raise ethical issues in both industries.

In both industries profits are a major incentive and so an underlying issue is how profit-making is linked to CSR activities in these two industries. Since the focus is on the private sector, the study does not deal with governance issues related to *public* hospitals.[4]

Understanding CSR in Different Markets

When looking at business conduct the study relates it to existing research on CSR with some focus on the Indian context. The first part of this section discusses some of the different concepts of CSR, mainly the ones that regard it as forms of charity and the ones that look at it as forms of ethical conduct.

However, the emphasis is on the latter where the section analyses how different ethical systems may have different implications for what should be considered ethical conduct. This emphasis implies that the overall business conduct would have to be considered.

The idea is to show that ethical implications of conduct may differ according to the nature of the goods and services produced/provided by the enterprises and the quality variation in public regulation applicable on them. The CSR analysis is followed by a brief discussion of some of the roles of public regulation for the different CSR concepts. The section raises Laffont's question of whether the theory of public regulation may differ when applied to developing countries without going into the

technicalities of that strand of research (cf. Estache and Wren-Lewis, 2009).[5] As would be seen, even for the definitions of CSR itself, the *modus operandi* of the public sector is a key.

Scope of Application of CSR in Pharma and Private Healthcare

The concept of CSR is examined by looking at how it may apply to the conditions of the pharmaceutical industry and private healthcare in India. Business conduct in both these industries as well as their regulation have to be regarded against the background of two legitimate, but partly conflicting Indian policy aims: (i) to develop affordable public health services to many of India's poor and (ii) to develop a regulatory infrastructure that may enhance the capacities of two of India's most promising industries for export and further grow. The two aims may conflict.

The empirical exploration in this study will mainly focus on three aspects: (i) responsibility for the environment, (i) role of regulating authorities (central and state levels) and (ii) responsibility towards Indian consumers. Finally, it is clarified that the paper is exploratory in nature, and would raise a number of questions as well, in the process of trying to answer some of them.

Private Participation in Dealing with Public Goods

The present international surge in the interest in CSR activities has somewhat contradictory origins, as pointed out in a special report on CSR in *The Economist* (January 17, 2008). This report confirmed that the CSR movement has reached a stage where public attention to it has become significant and some public impact on behaviours and policies are imminent. Questions about corporations' responsibility to society have become urgent with the large number of business scandals including Enron, Worldcom, and others that have arisen in the aftermath of the deregulation of financial markets.[6]

Given the above, corporate charity is now being looked at with considerable scepticism by the society. As with the oil and tobacco industries, this is true in the case for the pharmaceutical industry as well. After a conflict between several of the leading multinational pharmaceutical companies and the Government of South Africa regarding the pricing of antiretroviral drugs, the global public became aware of these companies' willingness to let HIV/AIDS patients in developing countries go untreated and die in order to keep their patent protected

profit margins high.[7] The overpricing became clear after an Indian company was able to deliver the medicines at only a fraction of the ruling prices that made the drugs accessible to a majority of the HIV patients in South Africa, who were otherwise doomed to a slow death.

These scandals reflect the major ideological thrust of the last three decades which has seen the growth in power, scale and prestige of private business and a corresponding loss in the prestige of public organisations thereby leading to the need for using instruments of command and force. The consumer demand for many of the services traditionally supplied by the public sector has been increasing with the growth in citizens' income. This has also necessitated a need for regulation of the private sector firms that provide these public services.

It has then become natural to ask whether these private sector firms can do more? Can they not supply more public services and adopt self-regulation on a voluntary basis while occupying traditional public sectors of health and education on a profit basis? Like the government most private businesses are multi-tasking organisations that may be technically capable of shifting into new fields such as solving various social or public tasks.

Finally, an important part of the increasing power of private business has been the increased cross-country mobility of its income and activities, assets and employees. While the government for the most part is confined to keep its employees, its activities, and its income inside its geographical borders (with the minor exception of foreign aid), private business is not restricted in that way. While this freedom may create increased possibilities for misuse of power and unethical behaviour, can it also not give increased scope for international business to contribute to a levelling of the grossly unfair distribution of economic opportunities across countries? A case in point is the Indian pharmaceutical industry's supply of affordable medicines to South Africans as described above, in the year 2000.

Definition of CSR – Behaviour Driven by Cost

Most definitions of CSR have both descriptive and normative components either explicitly or implicitly. In one descriptive approach, CSR is simply defined as the set of charitable activities performed or financed by business enterprises. Typical examples include the building of schools for the poor in some of the communities they operate in, or the building of churches and temples. Somewhat more complex is when CSR activities are defined as the above plus all forms of costs that the enterprise *voluntarily* incurs to improve the conditions of its workforce, reduce the negative

externalities of its activities and increase its positive externalities alone or in cooperation with other enterprises in the industry *over and above what follows from legal compliance.*[8]

The latter definition is difficult to make operational. It implies that one, in principle, has to determine *both* what the costs of legal compliance will be and what the actual costs incurred by the corporation are. In addition one needs to understand that the connotation of CSR can be different in different contexts – so a nuanced understanding of the same (especially in developing countries) is necessary.[9] In practice a regular procedure is to present a list of observable components of activities one should include in a *social responsibility vector*.[10]

In addition to such cost items, the list may contain negative components, qualitative variables[11] and variables where the 'social' components are locked in with regular ones. Of particular significance regarding the latter are the investment decisions that maybe ascribed to public service or may be simply re-distributional. External agencies have made many estimates that have been used in empirical work. It has been observed that increase in these (classified) CSR expenditures has been suspiciously fast on many occasions.

As reported in Benabou and Tirole (2010) the value of assets in the US classified as socially responsible investments grew at annual rates of about 12 percent in the 1995 -2005 period and at 18 percent in 2005 -2007. By the end of 2007 these socially responsible investment assets constituted 11 percent of the total assets. While this increase may be real, partially, it also indicates that measurements are influenced by shifting perceptions. We may have a 'classification cascade'[12] – the same form of investments may increasingly be classified as 'social'. This possibility is supported by the fact that a large number of different agencies have become involved in their empirical assessments.[13]

A major question raised in the empirical research has been whether CSR activities pay for themselves or not - do they increase or reduce the financial rates of return? If they increase, presumably it may be easier to get more enterprises to adopt CSR behaviours. If the financial returns decrease as a consequence, other lines of arguments will be needed. This issue is closely related to the definition of CSR itself.

An article that summarises much of this research till late 2007 (Margolis *et al*, 2008) points towards a weak positive relationship between the enterprises' social responsibility indicators and their financial results. The

relationship may work in both directions, but appears stronger from financial results to CSR activities than the other way around. However, the correlation varies across the different components of CSR. Over all, the authors find that these positive correlations may support *normatively* that enterprises spend resources on CSR.

In a recent work Baron *et al* (2009) find that the corporate financial and social rates of return appear rather unrelated at the aggregate level. That is, some enterprises with low financial rates of return may yield high social returns, but those with high financial returns may also do so. Not all may move together in the same direction. Whether to spend resources on CSR activities or not may not then be decided on the basis of their effects on profits – other normative concerns need to be considered.

Broadly, CSR may include all sets of actions, rules or principles of actions that a corporate leadership may follow or induce among their employees to make the enterprise conduct its business in an 'ethical' way. Note here that whether a corporate leadership displays ethical conduct or not is not only a question of private, individual ethics of individual business leaders. The leadership is responsible for allocating decision-making powers internally, controlling information-streams internally as well as, within limits, externally.[14]

In the case of pharmaceutical enterprises the relevant incentive structure that may induce ethical misconduct is not confined to the internal. The external non-price inducements to sellers and prescribing doctors are matters of ethical concerns when judging any corporate social responsibility of a pharmaceutical company.

Since different ethical principles may presumably apply and CSR at its widest must span all these possibilities, so if leadership action A is ethical according to ethical principle X, but non-A is ethical to principle Y, both A and non-A are candidates for a CSR action.

For example according to one reasonable *motive*-based definition of CSR, business leadership should *sacrifice* part of the corporation's income for some ethical purpose to make the expenditures on genuine charity (Reinhart and Stavins, 2010). A well-run company has a *duty* to spend some income or set aside some organisational capacity to improve the living conditions or capabilities of its employees and other 'stakeholders' involved over and above its regular activities. Otherwise charity may be regarded as a regular public relations activity/expense only.

Moreover, simple compliance with legal regulations will not suffice either. Costly over-compliance will be necessary for the enterprise to sacrifice profit in 'the social interest' (*ibid*) of which environmental regulations have received most attention in the CSR field. This kind of ethical argument is related to so-called deontological ethics.[15]

A related deontological argument will lead to the opposite conclusion. However, it is the *duty* of an enterprise leadership to maximise profits, so charity or over-compliance performed by a firm is only acceptable if it *does not* sacrifice profits in the long run. Since the roles of profit maximisation are important for both the explanations of actual enterprise conduct and for its ethical judgments, a closer look at the latter is needed. It will then be seen with the major competing ethical system, where the normative status of an action is based on its expected consequences.

According to Amartya Sen (2010: 23-24) the distinction between these two forms of ethical reasoning are rather cross-cultural and well known by students of Hinduism and in the cultural environments in which Indian enterprises operate.[16]

A third kind of approach to ethics is to be skeptical about any all-embracing set of arguments, arguing like Walzer (1983) that the ethical forms of circulation of goods and services may be shaped differently in different parts of the society. For example, the motive of profit maximisation may be OK (deontological OK) in most market situations and improve welfare (consequential OK). If an enterprise bribes a public official for profit (the same motive as before) sometimes that may also improve welfare[17] so from a consequential point of view it is still OK.

Nevertheless, it may be objectionable from an ethical point of view besides being illegal. A market mechanism – to buy and sell political or bureaucratic decisions – is considered unethical in itself in this case. The motive has to be considered in its context. The same applies to child labour.

In many cases allowing it will increase the welfare not only locally when the economy is trapped into an avoidable poverty equilibrium (Basu, 1999), but also more generally. Kanbur (2003) suggests why it may appear unethical to operate in markets where one side of it lacks agency. Both corruption and employment of young children are important cases of what is considered as unethical business conduct, but the main arguments against it would be violation of local laws.

In a famous article Milton Friedman (1970) argued that businesses in "free-enterprise system" had no social responsibilities. Firstly, a business is an organisation and cannot have any responsibilities, only people can. Secondly, the only responsibility business managers may have is to maximise profits for their owners under the legal restraints. If they spend money on some unnecessary social expenses, they would steal from their owners, which would be an irresponsible act. Only the owners could legitimately indulge in such out-payments, and that also only in their personal capacity.

Less noted is that the same basic policy conclusion would follow from a completely different view on ownership rights such as left wing views in the Walras (Arrow-Debreu) tradition. Here firms are organisations, whose main task and responsibility to the society is to transform inputs into outputs as economically as possible. In a market economy that implies profit maximisation as the goal. Hence, under the ideal conditions of free competition, CSR is either non-existent or simple in principle: maximise profits. If the government so wishes, it may tax away the profit and spend it on socially desirable ends (or take over the ownership of the assets – market socialism). Only the government needs to make ethically difficult decisions. If the firms spend money on social ends, it might result in public wastage.

CSR and Stakeholder Satisfaction

A strand of the research on CSR emphasises the role of 'stakeholders'. According to Edward Freeman (1988), stakeholders are those groups who have a stake in or claim on the firm. This includes suppliers, customers, employees, stockholders, local community and the management in its role as agent for these groups. The conduct of a private enterprise is not everyone's business, nor is it concern only of the owners.[18] From a normative point of view, the most striking side of the stakeholder perspective is the symmetrical way the different groups are considered. Traditionally, the normative principles for the workers' claims have been quite different from the claims from customers which again have been different from creditors. In the stakeholder approach they are brought onto the same footing.

Normative aspects of the CSR activities may be deduced from the stakeholder approach and the stakeholder-enterprise interactions that have been applied in empirical, positive research. For example, when studying mechanisms that may impact 'Corporate Social Performance'(CSP) that is closely related to CSR activities[19] Baron *et al* (2009) club the impact of all primary and secondary stakeholders into a 'social pressure' variable.[20]

They have a measure of profit referred to as 'corporate financial returns' (CFI). Social pressures may harm profits so in order to stave off this pressure an enterprise may increase its social activities. Social pressures may either originate in the public or private sectors. In their simplest estimations they show that increased social pressure reduces profits (CFI), and increases CSP. When disaggregating the stakeholder groups into the public and private actors and CSP into profit-seeking and pressure-sensitive components they showed that the relationships could become more complex. In particular, the interaction between the private groups' pressure and the pressure-sensitive CSP appear to be the strongest.[21]

Returning to the normative aspects of stakeholder symmetries and the distinction between stakeholders and the rest of the society, how may these be defended? Cappelen (2004) suggests two approaches to this. The first is the 'relationship approach.' The second, which he considers as an alternative (and better grounded in ethical theory), is the 'assignment approach.' Here the distribution of responsibilities follow a set of pragmatic rules derived from a general moral theory.

Regarding relationships, one way to vision an enterprise is as a kind of nexus of *voluntary contracts* made by the managers with capital owners, creditors, owners of labour power, and its customers. All who possess such contracts become stakeholders to whom the enterprise has special obligations and who may own some form of claims on the eventual surplus. The public authorities may not possess such claims since its relationship to the enterprise may be based on force, not such voluntary contract. However, going further along these lines, the very establishment of this nexus of contracts may be given by an initial contract between the immediate controllers of the nexus and the authorities where the controllers of the nexus and the authorities make a contract where the rules under which the nexus should operate are stipulated. For a private enterprise to hold a special ethical obligation towards an organisation, a group or to an individual it is not a sufficient condition that it interacts directly with it.

It is also argued that it is not a necessary one. It is important to explore what the conditions are for ethical conduct in the Indian pharmaceutical industry. Here it is impossible to avoid an ethical responsibility towards a group where no direct interaction takes place: humans who have got the illness against which the enterprise produces a remedy, but who are unable to pay for it.

When describing the assignment approach Cappelen emphasises that it assumes "that we have the same obligations towards every human independently of the relationship to them." The actual distributional matrix of duties may be done along *pragmatic* lines with many zero elements. How many will hinge upon the particular characteristics of the enterprise and the actual discharge of duties across organisations and individuals. They should be given by the institution where they may be best performed. Of particular interest will be the assignment of duties between the government and enterprises. When a well-organised multinational company enters a country with a weak government naturally the scope of its responsibilities (fewer zero elements) should expand.

However, not all ethical considerations of individuals or enterprise leadership may be articulated strongly as duties or obligations. In a more general context (than enterprise behaviour), Fishkin (1984) distinguishes between actions that are (a) morally neutral (adiaphorous in the Christian terminology), (b) laudable or (c) morally obligatory. Only in the last case is it a question of moral duty in a strong sense. An action may be classified as (b) because the ethical issue is not important enough, or several conflicting ethical principles may be involved or the ethical obligation may become so costly that its fulfillment will demand heroic efforts to make it a reasonable ethical demand.

As argued by Fishkin the latter may easily happen when we are dealing with large, complex economies such as our globalised one. For example, if we look at a specific kind of charity service that may appear as a reasonable obligation for any well-managed enterprise to supply, the extension of the obligations to all the qualified receivers globally may demand a heroic sacrifice. An example close at hand for a multinational pharmaceutical company is to make a low cost life-saving drug for any needy poor. If there is no way to do so without causing the company to go bankrupt or to make insufficient profits for the financing of innovations of new lifesaving medicines, that moral obligation may enter Fishkin's (b) zone of indifference.

The ethical problem for enterprises (and employees) delivering medical services[22] is that *at the margin* it will always be possible to save one more life at a minor cost to the company. Moreover, if the local state is weak, poor or inefficient, and therefore unable to pay on behalf of the poor, the responsibility is difficult to avoid.

Ethical Dilemma in Pharmaceutical and Private Healthcare

In the case of the global pharmaceutical industry it becomes difficult to restrict stakeholders to any narrow set of groups because any direct interaction-based limitation on responsibility will work unconvincingly. Any human who happens to become seriously ill with an illness that can be treated effectively by a medicine that the company supplies, becomes *ipso facto* a responsibility of that company whether he/she actually uses/ purchases the medicine or not. Their 'stake' in the company may be their life.

For a number of illnesses the number of potential users may be very large, but rather clearly defined. The argument for limiting the set of stakeholders from the consequences of enterprise action as the distance to the impacted agents increases, does not apply. Here the uncertainty about the effects of any action does not significantly increase with the social and economic distance from the company. Within each illness specter only a few companies have patents to produce any relevant medicine. Since these companies operate on global markets everyone that the medicine may have significant positive effect on are their 'stakeholders', irrespective of the fact whether they are their actual customers or not.

The key dilemma is the following: in order to develop a new medicine a pharmaceutical company has large outlays on research, innovation and development. Many attempted inventions will be unsuccessful. When the medicine is ready for sale, the actual costs of producing it, the running marginal and average costs will be comparatively low. In order to recover the research and development costs the price will be set high enough to cover its research and development outlays (and to cover the expense of several unsuccessful innovations).

Under free competition new entrants might be able to copy and be able to produce the medicine close to its marginal costs. Hence, a company would not initiate any invention if there was no government intervention or informational or technological constraints to prevent immediate copying. In order to make research and development for new products feasible, the government grants *patent rights* to the inventing enterprise for a specific period (usually 20 years) that in practice acts like a temporary monopoly[23] over an illness specter.

Moreover, when granted such temporary monopoly, profit maximisation implies the setting of a monopoly price if the price for that period can be set with little regard to the risk of new entrants, and will normally be set way above running marginal costs. At that monopoly price a large share

of potential users, the poorest, may not be able to buy the medicine in question.

If the medicine is effective, the illness deadly, and the government unwilling or unable to pay for it, the patients will have to die for that reason. This clearly raises an ethical dilemma for the pharmaceutical companies. Hardheaded monopoly pricing may appear quite an unethical behaviour in this case, but in order to stay in business, the prices cannot be so low that the fixed research and develop costs for the medicine are not covered.

So there are three different relevant prices in operation: (1) a temporary monopoly price, (2) a price equal to long run marginal costs, i.e. a price that covers fixed costs and allows sustainable private business, and finally (3) a price equal to short run marginal costs. When the medicine is life-saving, the distribution of poverty and government strengths across the globe ensures that even at the lowest price, (i.e., at option 3) a number of people will have to die because they are unable to pay that price, but the number of deaths caused by lack of access will increase significantly as the prices increases to (2) and (1).

While the industry itself will claim that price (1) is equal to price (2), and that patent regulation does not lead to economic inefficiency, but is a necessary condition for the invention of new medicines - the ethical dilemma persists. It is technically possible for the pharmaceutical companies to supply life-saving medicines at (option 3) prices without incurring any loss. Doing so many lives could be saved.

Note that this ethical dilemma has an inter-temporal (periodical) dimension that sharpens it. At any given point of time, **t**, there exists a stock of medicines that still are patented based on inventions taking place sometimes in the period **t – 20**. These may save the lives of existing individuals suffering of illnesses at **t**. Expenses made on research and development at **t** is covered by the prices charged at **t**. The expected outcome of these will only be available in the future and not help (save) the life of actual identifiable individuals at **t**. It would only be useful for an unknown mass of people living under unknown conditions in the future.

Hence, living individuals today, mostly either poor or living in countries with poor public health systems have to be sacrificed today in order to help unknown people living with unknown ailments in the future, but many likely to be well-off in the first two decades when the new inventions remain protected by patents. Only when the patent periods have passed are the new medicines likely to be widely available.

As suggested above the mass of individuals sacrificed while keeping a marked-based pharmaceutical industry will be the difference between the number of people who could have acquired the medicines when sold at prices equal to marginal costs and the number who could afford to buy it at prices equal to the temporary monopoly price at **t**.

To fix a medicine price at (option 1) is clearly unethical from any consequential point of view: What the companies gain cannot compensate the loss that potential patients unable to pay incur. In addition there is a general efficiency loss. From a utilitarian point of view (option 3) is clearly the one to prefer: more people may survive or improve their life than when the companies fix it at (option 1) prices. Pricing a medicine (option 2) is the difficult: from a utilitarian point of view as it leads to lower welfare than (option 3). But the problem is that it (option 3) may not be sustainable, so from a utilitarian point of view (option 2) is possibly the correct price. The reason being that it makes the industry generate the stream of new medicines of that makes the (option 3) price behaviour a possibility. Dynamic efficiency should overrule the static one.

This rule-utilitarian argument is clearly the one embraced by the industry, but the ethical trade-off implied becomes too harsh to be publicly accepted: sacrificing living people today in order to ensure company survival and the creation of unknown medical inventions for the future. Seen from the companies' point of view they reach here an intractable ethical dilemma: to display ethical conduct, an enterprise should price its life-saving medicines at the short-run marginal costs, but that may undermine its own long run existence and more importantly, few life-saving drugs would be produced. This dilemma has of course made a deep impact on the pharmaceutical companies' CSR policies (or how it views its business responsibility strategy).

The dilemma came to a head and caught global public attention when 39 multinational pharmaceutical companies sued the South African government in 1998 for a law allowing it to purchase drugs at the lowest rates anywhere in the world (*New York Times*, April 20, 2001), which implied the authorisation of parallel imports of patented pharmaceutical products. The drug cocktail (antiretroviral combination therapy, ARV) used against HIV in South Africa did cost around US$12,000 a year – clearly out of reach for the poor and for the NGOs working with HIV patients. As the court case built up in 2001 CIPLA, the large Indian pharmaceutical company, announced that it could supply the same at about three percent (US$350 per year) of the prices charged by the leading brand-name based companies. In the end the 39 companies did withdraw

their lawsuit, recognising the reputational disaster it had become, and maybe also the seriousness of the ethical dilemma involved in their pricing strategies.

We may note the strong inter-temporal characteristics of the case: High prices in the late 1980s may have been necessary for the innovating pharmaceutical companies involved to develop the HIV medicines that could save lives around 2000. When including the development costs in the 80's it is possible that the prices may not have been so far away from the long-run marginal costs for the inventing companies.

Furthermore, without those medicines there would not exist any ethical dilemma in 2000 since poor or rich at that time would not have any possibility to save their life through these medicines since they would not have been invented. Without the new knowledge it would not have existed.

While the international companies did give in in this case, they continued to fight serious attempts to undermine their high price strategies. For example, the Swiss-based firm Novartis, after having obtained exclusive marketing rights (EMR) for its cancer drug Glivec in India in 2004 (Kapczynski et al, 2005), the only one treating a special kind of leukemia, the company charged prices ten times higher than the generic versions that formerly had supplied the Indian market.[24] In April 2013, however, the Supreme Court of India rejected Novartis plea to have exclusive manufacturing rights of Glivec in India, thereby providing opportunity for others pharmaceutical companies to supply cheaper alternatives. Novartis had engaged in a legal battle for over 7 years in India to debar such cheaper drugs to be supplied. The Supreme Court verdict came as a relief to a large number of cancer patients in the country.

The knowledge existed, however, and the public would not accept that one should simply let a large number of people die until the patent period expired. To repeat: seen from a strict consequentialist ethical perspective, the increased wellbeing of future unknown individuals receiving at present unknown cures developed by innovations developed today and financed by high prices today should then justify the causing of death of present, living individuals. The lofty aims for the future would justify the harsh means of today. Needless to add, only a few people (it at all) would accept this as a convincing ethical position. As pointed out by Amartya Sen in many contexts (e.g. Sen, 2009: 210 -221) to ethically judge an arrangement, means such as a strict adherence to a patenting rule for pharmaceutical products only by the final outcomes, is too narrow an interpretation of its consequences. A more comprehensive understanding of consequences should include the means of reaching them.

Then one of the persistent consequences when the enterprises follow the monopolistic price setting protected by the product patenting rules is the reproduction of the ethical dilemma described above. For life saving medicines the static loss of consumer welfare net of producer's gain will be underestimated in regular economic analyses[25] since it will not calculate in the economic welfare loss due to the deaths caused by lack of access.

We have seen that even when we accept that protecting patents is necessary and does not cause pure monopoly profits, the protection raises serious questions about its ethical consequences. That pricing behaviour becomes even more difficult to legitimise when we take into consideration that the claim that product patenting stimulates innovation, is itself highly contested.[26]

Moreover, many other ways to reshuffle institutional solutions including regulatory systems appear possible that may delink any tight causal correspondence from temporary monopoly pricing and inter temporal rates of medical innovations – if they at all exist. Leading academic economists, who have no relationship to the industry such as David Levine, present statistical and historical arguments (Boldrin and Levine, 2009) that seem to indicate that the prevailing patenting rules with their monopoly pricing may even reduce rather than stimulate the innovation rate in the pharmaceutical industry.[27] There are strong economic efficiency arguments that throw serious doubts on the Trade Related Aspects of Intellectual Property Rights (TRIPs) rules as they apply to patenting in the pharmaceutical industry.

To explain the prevalence of product patenting, one should rather look at the structure of the lobbying market than on its innovation making capabilities. The Ministry of Corporate Affairs (2011) is pointing out in its overview of desirable CSR policies (in the National Voluntary Guidelines on Social, Environmental and Economic Responsibilities of Business, 2011 referred to as the NVGs), that lobbying behaviour should be assessed and has included it with other aspects of corporate conduct under the NVGs.

While the doubts around the dynamic efficiency of the present patenting rules may not have so much impact yet on the policy debates around the global 'Big Pharma', our basic ethical dilemma has had so. Given that, it is not surprising that like the petroleum, tobacco and the weapon industries, the pharmaceutical industry has been exposed to exceptionally persistent ethical criticism. In the case of the former it is the nature of the product as such, that they generate public harm, that is the major cause

of concern. This is obviously not the cause of reputational worry in the case of pharmaceutical products; on the contrary, medicines save lives. The main cause of worry is that the way medicines are priced often prevents their access for the global poor.

CSR and Regulation

Let us illustrate the question by using a real life illustration of an exemplary CSR charity behaviour described in the NVG booklet (Ministry of Corporate Affairs, 2011).

It is a story about a cellular technology firm that at its own initiative developed its own take-back infrastructure for its old sold devices, paying the operating costs from its own profits. This is clearly an illustration of socially responsible conduct. If the customers had to pay for delivery and the scheme proved profitable, it would have been a kind of social invention, a good idea, but more or less ethically neutral.[28]

This scheme would be more effective if all the cellular firms had agreed upon voluntarily to join a common take-back infrastructure; each enterprise that joined would have displayed a certain degree of social responsibility, although the degree of agency and voluntary choice would be lessened. Compared to the single company initiative the relative costs of the choice will decrease since the costs of *not* joining will increase from both the customers' and the fellow enterprises' side. On the other hand so will the strength of the ethical signalling as the enterprise just is just joining a group or the compliance to a set of voluntary *private* group rules.

In the example an implicit assumption is that no public regulation exists in the matter. If it did, the introduction of the take-back device would simply be a case of compliance of the *public* regulation, not a case of voluntary CSR conduct. We may consider this a case where public regulation may *substitute* CSR and make it unnecessary. Little agency and deliberate choice needs to be involved, hence an arena for ethical conduct may be considered closed. Nevertheless the existence of a regulation makes it easier to act in a socially responsible manner, and to follow more ethical conduct seen from a consequentialist point of view. To follow the regulation may also be considered as a case of responsible conduct. The public regulation and CSR behaviour become *complementary* in creating this public good.

In situations where income assessments are imperfect, an enterprise may choose to pay more taxes than would be the outcome when maximal

investment on tax avoidance is expended. The difference between the minimum tax and actual tax paid may be considered as CSR expenditure assuming that the actual tax paid follows more closely the intention of the lawmakers. It rightfully should be considered as a part of the enterprises' CSR portfolio; at least if we follow the Commission of the European Communities that according to Beltratti (2005: 377) defines CSR as a concept by which 'companies decide voluntarily to contribute to a better society and a cleaner environment'. Presumably at least part of the resulting extra tax income will be spent on some public goods or services that otherwise will not be forthcoming or would have to be paid by others.

Summing up; if most public regulation of the pharmaceutical industry is made for good reasons, any weakness in the public institutions administrating them is likely on average to lead to more enterprise misconduct in several directions in addition to the formality of non-compliance itself: more pollution and employee exposure to harmful working conditions, more low quality products and low quality sales promotion, and so on. When regulation becomes really ineffective its compliance may become almost heroic. While weak regulation is likely to decrease the average level of ethical conduct (in consequence terms) it is likely to increase the ethical variance across companies.

Asymmetric Information in Healthcare – Implications for CSR

So far we have focused on the role of patenting in a very general way – for innovation and invention on the one side and pricing and access to medicines on the other. The properties of the goods involved that drove our discussion were their potential lifesaving or pain relieving attributes. We argued then that the question of access was underlying much of the normative debate of the industry about the pricing strategy and the large firms' CSR behaviour. So far we have not touched two other traditional areas of normative concern: the incentive structure developed for sales of pharmaceutical products, and the risks of fraud, particularly quality frauds.

The seriousness of the fraud is like the ethical consequences of high prices clearly linked to medicines' potential for lifesaving and/or pain relief, and even more obviously so. Otherwise fraud appears quite different: pricing is mostly public, fraud is done in secret. Excessively high prices are mostly set by large enterprises; some of the major frauds are more likely to be more frequently performed at the competitive fringe of smaller unregulated enterprises.

The bribe-like way of selling drugs to doctors and pharmacists that seems to characterise the incentive structure developed in the industry is another common cause of ethical concern, but the kind of ethical considerations are somewhat different and maybe more clearly within the companies control than the pricing. Their survival is not at stake with any choice of sales incentives to the same degree. Nevertheless we will argue that a large part of unethical sales practices in the pharmaceutical industry are related to some of the same properties of the medical goods and services as the monopoly-like price setting and the scope for fraud.

The popular perception that governance issues in the pharmaceutical and health care industries as caused by 'greed' and profit maximisation is limited to this sector is not true, since it applies equally to any other industry. Here it can be argued that the three forms of normatively questionably forms of conduct (and therefore also potential CSR issues) are closely linked through the informational characteristics of the health markets. These are not only shaping the ethical issues in the pharmaceutical industry, but some are also shaping those for the private hospitals, the other set of institutions to be considered here.[29]

The main reason for this state of affairs is that consumers in most serious cases of illness are not in a position themselves to judge the substantial medical quality of the goods and services in question. They lack the necessary knowledge in these situations. Patients may become better through spontaneous healing when using the wrong medicine and will conclude it is the right one. The correct medicine or treatment may be applied, but the patient may still get worse due to some unknown factors and wrongly conclude that the medicine is the wrong one.

The asymmetry of information between suppliers and final consumers is obviously the most severe one, such as treatment of patients at hospitals, although mitigated somewhat by the growth of medical information on the internet. Asymmetry is, however, also present in the interaction between doctors and the pharmaceutical industry; in the relationship between the suppliers of drugs and the agents of the consumers, i.e., mainly doctors and pharmacists. Behind most pharmaceutical products there is specialist research knowledge in chemistry, biology and a number of their sub-disciplines that medical doctors may not be expected to share. This is of course even more pronounced in the case of consumers buying Over-The-Counter (OTC) medicine. An additional set of agency issues arise when the goods and services are paid by the government or through insurance companies.

This asymmetry or lack of information has been exploited by suppliers of health-related services from time immemorial. Quackery is old and dominated the supply of medicines even in several industrialised countries (then unregulated) till the late 19th century. The scope for irresponsible corporate conduct by manipulating information and to gain profit by the manipulation is widespread. It is no coincidence that modern economics of information may be said to have begun with Arrow's (1963) analysis of health care. The importance of asymmetric information reached first a wider audience of through Akerlof's (1970) famous analysis of 'lemon' markets illustrated by the market of used cars.

A brief comparison with the used car analogy may also shed some light on the medical markets. In case of both information about the quality of goods and healthcare services, the prospective seller has more information. Sellers of used cars *know* whether their car is good or not. That he has found out by his own *experience* with the car. The buyer does not and cannot find that out through simple *inspection* of the looks of the car, but may only determine the quality after she has used itself for a period of time, but then it is already bought. The market price for used cars may reflect the expected average quality. If so, the price would be too low for the car owners who know their car is good while the owner of the bad car will certainly sell it. Hence, the risk would be that this market would disappear since only bad cars will be supplied, and knowing that, no one will buy them. Cars may only be sold if the seller and owner knew each other, and maybe not even then.

This is not a major risk in the market for health care goods and services, however, for a number of reasons.[30] The obvious ones are (1) that the provider of the specific health good or service has no use for it himself and accordingly cannot cancel his supply; (2) a seriously ill person has no choice but is looking for a (hopefully) relevant treatment or medicine. Consumers will respond to situations where they frequently are scared and fear their lives. They may manage without a used car, but not without life. Finally, (3) the demand for a particular drug is time-specific and cannot be postponed.

Seen from the point of view of the buyer it is even more difficult to decide whether she has bought a 'lemon' for reasons indicated above. She may believe a treatment or medicine is working, but it is not. Plain experience with it may not decide.[31] Hence, the demand for 'lemons' may persist in health care markets even for medicines and treatments that never work.[32] When it is not working, the patient may not – unlike the unlucky buyer of a 'lemon' - conclude that the medicine as such is a fraud. It may rather be

the doctor who has prescribed a wrong medicine, or maybe it is some peculiar properties with a particular patient that makes it ineffective?

The interaction systems in human bodies are of course extremely complex. While a qualified doctor knows those systems better than a patient, and may register the effect of a given medicine on a number of patients in similar conditions, her information will be imperfect and the number of relevant patients, where the effects on the given illness can be observed by each doctor, will be limited. Moreover, given the complexity of any human body-mind system, whenever a set of chemical impulses are injected through a medicine, they are likely to create a lot of other effects, some quite harmful. When we take the present institutional structure, a pharmaceutical company possesses more information about a medicine than the average medical practitioner. It will possess information about the effects collected from a much larger sample of patients under much more stringent conditions.

The asymmetric information that characterises the *doctor-patient relationship* is to some degree reproduced in the *pharma company-doctor* relationship. Hence, if a drug prescribed by the doctor is not working in a given case, she cannot tell for sure whether this is because something is wrong with the medicine, an individual aberration of the patient in question, a wrong diagnosis made by her, or a wrong application of the medicine to a correct diagnosis. Under each class of possible non-effect, lurk several possibilities. We will not delve into those, but just repeat that a pharmaceutical company will possess more information about the supplied drug: its quality variations (whether it is a fraud in the worst case), the expected individual variation in patient's degree of responding and in the kind of diagnoses it is correct to apply the medicine.

Note that in the case of pure fraud a small firm is not likely to be caught by any doctor since its particular batch of drugs is unlikely to be used many times by the same doctor. A larger company on the other hand cannot afford to consistently make a fraudulent product since this is likely to be discovered although the risk is low in each case due to asymmetric information structure outlined above. The larger, global companies will, however, be tempted to suggest that the drug in question is applicable to a wider set of diagnoses than they actually should be prescribed for. This is a regular form of enterprise misconduct made by even the large enterprises with the most extensive CSR programmes.[33] An important reason for this kind of behaviour is the temporary monopoly that creates a wide spread between the price and short-run marginal costs as long as the patent protection lasts. If the drug can be sold for a wider set of

diagnoses than it is prescribed for ('off-label')[34] within that period, large additional profits can be made. To expand the area of use outside the permitted area the doctors and hospitals (and the pharmacists) have to be informed and incentivised. The motivation for making large and costly sales efforts is strong here as generally in the doctor-enterprise dyads.

The reason is the same: the large difference between the price and marginal costs that makes each new sale very profitable and worth large and costly sales efforts, including partly unethical ones (as the companies themselves admitted in a number of the court cases referred to in the preceding footnote) to persuade doctors and other medical personnel to buy another unit. In addition there is a more direct effect of the asymmetry of information regarding the effects of the medicine and uncertainty about it, which makes doctors liable to company persuasion. Here a number of persuasion techniques have evolved including gifts[35] and even bribes.

According to Gagnon and Lexchin (2008) the pharmaceutical industry in the US spent about US$61,000 in 2004 on each of the 700,000 doctors residing in the country. As a percentage of the US domestic sales of US$235.4bn, 24.4 percent was spent on sale promotion while 13.4 percent was spent on R&D.[36]

In a later article Light and Lexchin (2012) argue that the pure research costs only constitute 1.3 percent of sales income. When they re-estimate the standard industry claim of 1.3 billion R&D costs for each successful drug innovation (based on research at Tufts University) they find it to be only 1/4th of that.[37]

Even so, it is the research and development costs that constitute the basic legitimacy for any patent-protected temporary monopoly. Moreover, while the companies may exaggerate these costs for lobbying purposes (they may legitimise longer patent protection periods and acceptance of looser invention definitions) as well as tax saving purposes, these costs remain substantial for good reasons rooted again in the nature of pharmaceutical products: after all they represent chemical compositions intended to shock complex mind-body systems of which science has only imperfect knowledge and where substantial individual and group (children vs. adults, male vs. females, and so on) variation across future patients is to be expected.

This implies that before any successful invention is eventually achieved, a number of time consuming trial and error processes have to be made ranging from laboratory experiments to controlled field studies of the

effects of the prospective medicine involving hundreds of doctors and thousands of patients in the final stages. To finance all these trial and errors processes through one private company before any patented and marketable product is achieved, may even under the best of circumstances demand hundreds of million US dollars. Only large private companies will be able to do this.[38]

At present a patent creates a right to a temporary monopoly which is threatened as soon as it expires mainly because the actual production costs are low, so a large number of firms are interested in capturing some of the difference between the monopoly price and the cost price during period before competition moves it closer to the cost price.

The large multinational pharmaceutical companies' (MNCs) behaviour has monopolistic features of a more lasting character, sometimes even behaving as a kind of a global cartel. The main reason is that the large R&D costs involved imply that only the large companies may shoulder them each possessing a revolving stock of patents. When any smaller company develop some innovative ideas, it becomes more sensible to sell them off to one of the relevant oligopolies than to try to join the club.

In addition to performing research, their research departments shoo away potential competitors. Moreover, since they together possess most of the existing stock of patents they share an interest in *de facto* extension of them which they can do legally if loose criteria for what should be considered a patentable invention are used. Their lobbying here has been quite successful both with regard the practices of FDA and with regard to international agreements such as the so called TRIPs+ interpretation of the TRIPs agreement.[39]

Another aspect of the developments in the industry that tend to move the patent stock owning MNCs in a monopolistic direction is the high sale costs; according to some estimates this is twice the size of their R&D costs. These have increased even more than the latter costs which are to be expected when a larger share of the patented goods does not represent genuine invention.[40] Then more efforts are needed to make doctors and other medical personal to prescribe the patented and presumably substantially more expensive brands of medicine.

This practice is again rooted in the situation where the final consumer miss the essential piece of information about the goods and services in this market. The doctor who represents him is not the one who will pay the price for the medicine, but she is the one who determines which

medicine and which brand of that medicine to buy. Depending on the actual medicine and the country in question the one to pay is either the consumer or a public organisation or both. While a normally empathetic doctor will certainly take her patient's ability to pay in consideration, she for her own part is likely to gain more the more expensive the medicine is.

There are more means to somehow reward a doctor if the medicines cost Rs. 1000 and not Rs. 50. Strong incentives for persuading doctors will of course also apply for generic, competitively supplied medicines. Since they are generally less known and of more uncertain quality, the smaller suppliers may have even stronger incentives to present information and inducements to the doctors, but the scope for emitting rewards are generally smaller.

Summing up, the fact that a large part of effective demand decisions are made by doctors, while the final patients pay for these goods knowing that any quality deficiency may prove fatal, tend to make the price sensitivity for well-known, branded medicines produced by the patent-holding firms to be quite low.

Hence, we may observe the coexistence of branded medicines together with close generic substitutes at substantially different price levels. At the patent-stockholding[41] end of the medicine markets entry is difficult and characterised by oligopolistic behaviour within each illness segment, while at the other end price competition may be fierce, entry has been quite easy and the number of enterprises large. The main explanation of this tendency towards a dual structure in the global pharmaceutical industry is the high fixed costs in keeping a revolving stock of patents at the same time as the marginal production costs in many of the relevant industrial activities are low. Both the CSR and the regulatory issues look different at these two ends. So far we have focused at issues relevant for the large companies', since most of the prevailing analyses deal with them, but we will briefly look at what ethical conduct may imply for low profit firms operating under fiercely competitive conditions. Finally, at the Indian national level the question of how to regulate the *interaction* between the large and small enterprises has proved difficult to answer and is at the moment highly contested. The outcome of the contest, key parts of the ruling regulatory structure to come, is also strongly influenced by their interaction.

This regulation is and should, however, be considered together with both the Indian growth strategy and India's overall public health system. To

see this, just disregard the TRIPs agreement for a moment and let the patent protection be cancelled: prices in the oligopolistic structure will then move towards the free competition, generic prices. The profits of the patent holding firms will be reduced so they may lose much research capacity and capacity for expansion. Indian industrialisation strategy will be impaired. That is, and particularly so, if the patent protection has the innovation generating features generally assumed. Hence, the regulation should be considered together with the growth strategy.

On the other hand if the public health system does not carry any public price subsidies or public income support for citizens hit by serious illness, a price fall will increase the income of patients who formerly had paid the high prices, and will increase the number of people who now can afford to be treated by the actual drugs. If the government does subsidise it, this effect of increased access of the poor and increased disposable private income for the not so poor disappears, while public budgets will be strained. Hence, the welfare consequences for this regulatory change will be strongly influenced by the prevailing public health system. In actual fact, the TRIPs agreement cannot be abolished in any simple way; the dual structure sketched above is much too simplified, as is the set of regulatory instruments.

Current CSR Context in India

While we will still look at the CSR issues of the pharmaceutical industry and its regulation from a bird's eye, we will seek to fill in some Indian institutional details and relevant data in the following chapters of this report based on information gathered from selected states. In recent years, there has been a renewed interest on the part of the Government and other stakeholders in India to engage in a more substantive discourse on CSR.

There is a growing recognition that developing country government should play certain roles in promoting CSR (Fox, Ward & Howard 2002).[42] In addition to the four specific roles (*Mandating, Facilitating, Partnering and Endorsing*) they recommend, a fifth role (*Demonstrating*) is critical in the context of India. The five specific roles that the Indian government needs to play to propagate the uptake of business responsibilities are elucidated below:

i. *Mandating*: formulating laws, regulations, norms, etc. that relate to control of certain aspects of business operations;
ii. *Facilitating:* developing appropriate policies and conditions to enable investment in CSR activities;

Box 1.1: PM's Ten Point 'Social Charter' (2007)

First, have a healthy respect for your workers and invest in their welfare. In their health and their children's education, give them pension and provident fund benefits, and so on.

Two, corporate social responsibility must not be defined by tax planning strategies alone. Rather, it should be defined within the framework of a corporate philosophy which factors the needs of the community and the regions in which a corporate entity functions.

Three, industry must be pro-active in offering employment to the less privileged, at all levels of the job ladder. The representation companies give to Scheduled Castes, Scheduled Tribes, other Backward Classes, Minorities and Women in their workforce and staff must increase.

Four, resist excessive remuneration to promoters and senior executives and discourage conspicuous consumption.

Five, invest in people and in their skills. Offer scholarships to promising young people. Fill young people with hope in their future. High rates of growth mean nothing for those who are unable to find employment. We must invest in skill-building and education to make our youth employable.

Six, desist from non-competitive behaviour. The operation of cartels by groups of companies to keep prices high must end. It is unacceptable to obstruct the forces of competition from having freer play. It is even more distressing in a country where the poor are severely affected by rising commodity prices. Cartels are a crime and go against the grain of an open economy.

Seven, invest in environment-friendly technologies. India's growth must be enhanced and, yet, our environment and ecology must be protected and safeguarded for our future generations. Industry has an enormous role to play in this regard.

Eight, promote enterprise and innovation, within your firms and outside. If our industry has to make the leap to the next stage of development, it must be far more innovative and enterprising.

Contd...

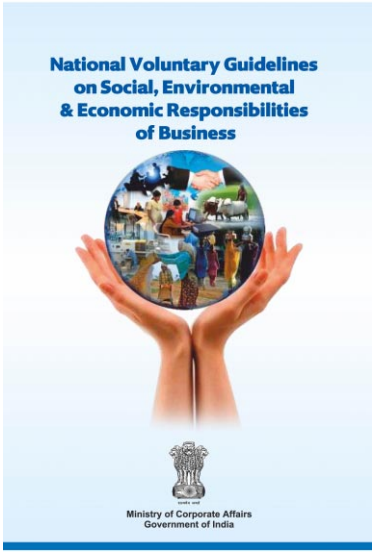
Nine, fight corruption at all levels. The cancer of corruption is eating into the vitals of our body politic. For every recipient of a bribe there is a benefactor and beneficiary. Corruption need not be the grease that oils the wheels of progress.

Ten, promote socially responsible media and finance socially responsible advertising. Through your advertisement budgets and your investments in media you can encourage socially responsible media to grow and to flourish.

iii. Partnering: combining skills and expertise within the public sector with that of private entities to undertake CSR activities or deal with CSR-related issues;
iv. Endorsing: recognising CSR activities through award schemes, or showcasing 'cases' to motivate firms for their uptake; and
v. Demonstrating: leading the way by ensuring that public sector firms undertake CSR activities.

India has had a rich history of CSR which spans from 4th century B.C. to the present times. While in most parts leading up to the post-independence period leaders of the Indian business and society have been the flag-bearers on CSR issues, over the last couple of decades, the Indian government has taken more and more interest in looking at how to better regulate the impact of Indian industry on its workforce, the local communities and the environment. The CSR agenda seem to have received unprecedented government attention over the last few years. A renewed interest on this issue was articulated by Prime Minister Manmohan Singh in his *Ten Point Social Charter on Inclusive Growth* presented at the Annual General Meeting of Confederation of the Indian Industry (CII), in 2007.

Figure 1.1: National Voluntary Guidelines on Social, Environmental & Economic Responsibilities of Business (NVGs)



This set the ball rolling on a contemporary and modern re-thinking on CSR, which resulted in the development of a set of *Voluntary Guidelines on CSR* by the Ministry of Corporate Affairs in December, 2009.[43]

These guidelines comprise six *core elements* presenting a common framework for Indian Inc. to pursue CSR practices. These guidelines were developed following the global financial meltdown, the *Satyam* scandal and several conflicts between business and society in India. In recent years, the conflicts between private businesses and society have accentuated especially in the infrastructure projects. These events have led to an erosion of trust in the society about the ability of Indian businesses to help achieve economic progress and social development in the country.

Subsequently, under the aegis of the Ministry of Corporate Affairs, the National Voluntary Guidelines on Social, Environmental and Economic Responsibilities of Business (NVGs)[44] was developed. The process was managed by the Indian Institute for Corporate Affairs (IICA)[45] constituting a working group[46] of stakeholders from business, government and civil society who through a consultative process arrived at the guidelines. Lessons were drawn from experiences in other countries and the NVG was adopted in mid-2011. The NVGs present a framework comprising 9 Principles and 48 Core Elements and is intended to provide a holistic idea of how CSR can be operationalised across different sectors in India. It is not only applicable for companies operating in India, but also for Indian TNCs operating outside the country.

As is evident from the section above, the thinking on Corporate Social Responsibility in India has undergone considerable change. *Business Responsibility* is now being considered as one of the most appropriate (and comprehensive) delivery mechanisms for businesses to meet their societal expectations. Currently, IICA has set up an *Expert Group (2012)*, which would develop a blue-print for the application of the NVGs, in a few key sectors of the Indian economy which have a high public interest element.

The *Companies Bill 2011*,[47] which is awaiting passage by the Rajya Sabha (upper house) of the Indian Parliament, urges companies of a certain size to invest a percentage of their profits on CSR, practices, or explain if they are unable to do so. The latest version of this Bill has a section on CSR (Section 135) that urges companies of net worth more than rupees[48] five hundred crore, or turnover of more than one thousand crore, or annual profit worth more than five crores in a financial year to make efforts to spend two percent of its average annual profit (of three immediately

preceding financial years) on CSR activities. Schedule VII of the Bill enumerates activities that can be considered as CSR. An emerging concern, however, is the lack of cohesion between the two above-mentioned processes (NVGs and application of Section 135 of the Companies Bill), which seems to have progressed in parallel.

The Ministry of Corporate Affairs has developed the Annual Business Responsibility Report (ABRR) to get companies to report on their CSR activities. In August 2012, the Securities & Exchanges Board of India (SEBI) – the market regulator made it mandatory for 'Top 100' listed companies (by market capitalisation on the Bombay Stock Exchange and National Stock Exchange) to submit their business responsibility reports using the ABRR format.[49] Ministry of Environment & Forests (MoEF), Government of India has initiated a process for encouraging companies to develop their annual Corporate Environmental Responsibility Policy – using the NVGs framework.

In summary, it is evident that the field of CSR in India is being shaped by the following aspects – the global discourse of CSR and its contested history; the recent performance of the industry; the high information asymmetry related aspects and their impact on both business regulation and corporate conduct; and finally the unique and peculiar challenges in the Indian context. The two sectors chosen for this project (pharmaceutical and private healthcare) have been identified as important and critical for the economic and human development agenda in India.

Given the above theoretical overview, the next chapter explores the regulatory framework in the pharmaceutical and private health care sectors in India to highlight issues pertaining to business responsibility that the fieldwork has examined. The report then examines implications of the regulatory framework on behaviour of pharmaceutical firms and private hospitals across the four states by gathering information and analysing the same using the evolved methodology.

Endnotes

1. http://planningcommission.gov.in/plans/planrel/12appdrft/appraoch_12plan.pdf
2. A focal point for debate has been whether a proposed 2 percent charge on net profits (average last three years) of large private enterprises (of a certain turnover bracket) for CSR expenditures should be mandatory or not. This has been proposed in the new Companies Bill developed by the Ministry of Corporate Affairs and is awaiting passage in the upper house

(Rajya Sabha) of the Indian Parliament. An exposition of the proposal and the debate in a wider context of norms for proper interactions between private enterprises and public regulators is in Van Zile (2012).

3. A high level expert group made an important recommendation to the Planning Commission of India (in November 2011) where they proposed a dramatic expansion of the role of the public sector for health services delivery (Planning Commission of India, 2011). After several rounds of discussions it was decided that the prevailing expansion of the private sector contributions should prevail (Planning Commission of India, 2012).
4. If the single focus had been on the delivery of health services to the population, the focus on private hospitals may appear rather arbitrary, but for a study of the links between CSR and profit motives the focus is appropriate. Moreover, an underlying motivation for the choice of these two sectors is due to the concern about the major policy direction of India: the pharmaceutical industry in India has become an international business success, and the export of medical hospital services (health tourism) might become so, but both are riddled with ethical doubts and concerns. Are these expansionary paths the ones worth following?
5. While India has sufficient resources to construct a public apparatus at least at par with any OECD country in any field it chooses to prioritise, on broader fields the administration shares many of a developing country characteristics.
6. For some of the basic mechanics of these frauds cf. Krugman (2002).
7. Empirical support for a theory that CSR activities are at least partly explained as an offset to corporate social irresponsibility - negative economic external effects or conflict making aspects from regular enterprise activities is presented in Kotchen and Moon (2011).
8. In the CSR literature 'compliance' may either refer to adherence to public regulations or to a wide range of voluntary standards.
9. For example, below market rate wages may in some context reflect CSR where employees are willing to accept such low wages due to the high ethical standards of the enterprise in question. Alternatively, the enterprise was willing to sacrifice profits to improve the living standards of their employees. In some other context the above may reflect unethical exploitation of the labour.
10. A typical list is presented in Margolis et al (2008) and embraces charity, environmental performance, regulatory misdeeds, and transparency of company information together with a number of other items.
11. The need for subjective assessments is partly related to the intention of adding the heterogeneous components of which some are qualitative into single ratings. Moreover, subjective assessment might be needed due to the peculiar role of norms in the social responsibility measures as can be seen in the wage assessment case alluded to above. A simple equation relating an objective CSR measure to wage rates will not work without further normative specifications.

12. Bikchandani et al (1992) opened up the study of 'informational cascades' where each actor is confronted by a very noisy signal of a phenomenon and hence tends to rely on the others' responses to assess the size of the variable in question. They showed how this may give rise to a situation where the perceptions of the underlying reality may start to diverge widely from that reality. Stock markets were initially an important field, but it has been applied to widely different phenomena such as participation in popular uprisings. Andvig (2005) is a popular exposition of how this may apply to corruption – an important subfield of the 'compliance' aspect of CSR (the degree to which enterprises adhere to public laws and regulations - and how the lack of reliable information may explain the highly increased policy concern with corruption when the underlying issue is likely to have been rather unchanged). Chatterji and Levine (2008) explore this possibility for the social investment classification ratings.
13. Most of the classifications and resulting measurement of CSR aspects of expenditures and inputs have been left to external commercial or non-profit NGOs. Their numbers have mushroomed and are of varying quality. Schäfer *et al* (2006) present a descriptive overview. Many indices are mainly meant for prospective 'ethical' investors or consumers so they may take various ethical aspects into consideration when investing or purchasing. Others are mainly to be used to guide the local management about the situation in their enterprise. They may even be applied by the public authorities when granting the enterprise licenses to produce. The most frequently applied in econometric research is based on a set of indices developed by the research firm Kinder, Lydenberg, Domini Research & Analytics (the KLD index). Their measurements are now incorporated among the indices owned by MSCI Inc. It is based on observations (constructed as ratings) from a collection of larger US enterprises. Like many of the other ratings it includes a number of different 'social' components ranging from human rights to environmental issues. The rankings are highly subjective and the enterprises considered are rated much in the manner known from the financial rating of Moody's an others - from AAA and downwards.
14. An example of the former is to tie the rewards to local leadership of a multinational company tightly to the success of gaining concessions in a highly corrupt country. Knowing that local leaderships on average perform corrupt acts more frequently than other decision-making points, the incentive structure here induces misconduct, although it is the local leadership that performs it. The role of incentive structures is often neglected in the anti-corruption polices of private and public enterprises.
15. Deontological ethics is regularly defined as an ethical system based on the idea that the ethical subjects should be judged on the basis of the degree to which they obey the norms assigned to them ('deon' means obligation or duty). More generally, it is the kind of motives that guide their conduct, not the consequences of their actions that define the ethical content of the actions as well as the ethical status of the subjects making them.

16. According to Sen, Krishna, Arjuna's adviser, argues that it is Arjuna's *duty* to fight whatever the consequences while Arjuna himself is more concerned with the bloodshed and misery (the *consequences*) caused by fighting to the end.
17. This does not imply that corruption in general improves it. Most data suggest the opposite.
18. Much of the discussion of the role of stakeholders in the governance of private enterprises (of which eventual CSR expenditures are a part) has been rather unclear, but an early, lucid analysis of the issues involved when their governance is moved from shareholders to stakeholders is Tirole (2001).
19. They distinguish CSP from CSR by defining the latter to be morally motivated while parts of CSP may be induced by profit maximisation. Hence CSR implies CSP, but not the other way around. CSP includes activities that are beyond the requirements of law and regulation and involve private provision of public goods or private redistribution (charity). The CSP variable is constructed as an aggregate of various items in the KLD Social Ratings Database.
20. This variable is also operationalised by using the KLD surveys.
21. While thought provoking regarding the potential roles of the NGOs and the public authorities, there are too many rather arbitrary classification decisions of the KLD components into the different variables to firmly deduce behavioural structures from their statistical interactions. But as they stand it appears as if NGOs tend to approach and 'blackmail' the enterprises that are more sensitive to it. So much so that it tends to hurt their profit. On the other hand, the public authorities appear to behave in surprisingly Weber'ian manner. "Public politics social pressure is unaffected by CPS and CFP, which suggests that the government basically enforces the law" – they conclude (*ibid*: 30) - while possible for an OECD country it is difficult to believe that this will hold for countries like India.
22. This ethical dilemma was originally raised in the case of individual responsibilities for supplying funds to charities in case of famines (Fishkin, 1982: 71), but applies equally and more strongly to corporate leadership of pharmaceutical companies (and private hospitals) due to the fact that they command larger and more directly relevant resources.
23. In practice there will be some overlapping in use between different patented products, so for any illness specter that only is covered by so-called branded drugs, oligopolistic competition will rule. When a new patent is granted to an enterprise it will normally allow access to an oligopolistic supply structure to that illness specter. In practice the length of the patent protection period will be much shorter, often close to 10 years,
24. *Ibid,* footnote no. 161. This drug is also marketed under the name 'Gleevec' in the US and some other countries. The company also sued the Government of India for its 2005 patenting law for containing parts which violated the TRIPs rules and that allowed CIPLA to still manufacture its generic version of Glivec.

25. See, for example Lanjouw (1998), figure A.
26. A clear recognition of the fact that the ethical dilemmas outlined have made the pharmaceutical industry globally strongly exposed to criticism for being immoral is Capaldi (2008). He considers the criticism misplaced, however constituting a 'demonisation' of the industry and to be explained by "the present inability and unwillingness of the public to understand the economics of contemporary healthcare."
27. In an Indian context it may have interest to note that the authors point to European history where the pharmaceutical (and chemical) industry before World War II developed faster in countries like Germany and Switzerland that either had process patenting or no patenting at all than in the UK, France and the US that had product patenting. As part of allied victory companies in the latter gained access to the German companies' (often unpatented) knowledge. After the war countries like Spain and Italy had displayed higher innovation rates before they had to introduce product patenting in the late 1970s as a consequence of their EU membership.
28. From strict consequence- oriented norms economic sacrifice will not matter: The society would experience less harmful litter.
29. In the following discussion we take the prevailing institutional structure for given and consider only market based organisations. It is obvious, however, that what is proper fields for CSR concerns hinge essentially on the roles assigned to public organisations and their the capabilities. For example, when emphasising the ethical role of MNC's pricing behaviour, we have assumed that the public sector is unable to provide the support so in practice the decision to let patients live or die is left to the markets and their organisations. Similarly, what to expect from private hospitals regarding their CSR policies depend on what the public organisations may supply. For, example if no public hospital is available, rejections of seriously ill patients because of any inability to pay implies that decisions about citizens' life/death destinies may be left to the market place. Many will consider this unethical. It is unfair to let ability to pay decide these kinds of outcomes. The principles for such decisions should be guided by public deliberations and publicly known rules among which the patients' ability to pay don't belong. It clearly violates medical doctors' professional ethics. When alternative public hospitals exist or sufficient public subsidies to the treatments are available, such stark consequences of private, market-financed hospitals need not arise, and will not by necessity impact their corporate social responsibilities. In countries like Norway much of the dilemma is solved by allowing some use of market mechanisms for non-serious ailments and illnesses, but allocating the serious ones to the public hospitals or making their treatment fully covered by public funding. While there are many public hospitals in most Indian states, in practice the private hospitals have to make the ability to pay to constitute an important consideration for access. Ideally they would then shoulder larger responsibilities than hospital operating in richer public health systems.
30. Here Katz (2007) may overestimate the importance of the public regulation. Even if the purchasers suspect low or uneven quality in the

health care markets due to lack of, or sloppy public regulation, the nature of the services involved and the fact that demand may not be postponed, uncertain quality of health services and medicines is likely to have less negative effect on its demand than such uncertainty will have for the demand for used cars although the information is even more asymmetrically distributed and the consumers may carry strong suspicions about the suppliers.

31. The discussion follows a common way to classify goods according to their informational attributes is to distinguish between 'search goods', 'experience goods' and 'credence goods' (Katz, 2007: 13). In the case of search goods the consumer may determine the quality of the good before the purchase while in the case of experience goods the quality may only be determined afterwards when the consumer have used the good or experienced the effects of the service during a period. In the case of credence goods the quality may not be ascertained at all without specialist investigations. Many ordinary goods - like almost any food – have credence attributes. You may not determine from eating it that this particular can of tuna fish contains harmful metals, but in the case of medical goods and services the credence attributes are likely to dominate.
32. Hence it is no surprise that alcohol and opiates once were popular as remedies for a lot of ailments in different parts of the world. In a comic series popular in my childhood where the plots took place in the Wild West a 'Dr.' Salasso suggested whisky for everything, although most of his medicine disappeared in his and his companion, Windy's, throat. In this exceptional case the medicine was like a used car also in the sense that it could be kept away from the market by the potential supplier and still be of use.
33. New York Times (July 2, 2012) surveys a number of such cases from US where the leading global pharmaceutical companies had to pay large penalties for such inappropriate expansion of patients where the drugs could be used. The largest was paid by GlaxoSmithKline for aggressively promoting (among doctors) its anti- depressive drug Paxil on children for which it was inappropriate. It had also helped to publish a medical journal article that misreported data from a clinical trial. The company guilty on criminal charges and agreed to pay US$3bn in fines for this and several other fraudulent promotion of other drugs. Due to its important role in Indian drug policy we may also not that Novartis has accepted a fine of US$429mn for promotion of an anti-epileptic drug (Trileptal) on psychiatric patients using kickback incentives in the process. (United States Department of Justice, Office of Public Affairs, September 30, 2010). The number of such cases are too many to be coincidental.
34. The condition for when such expansion is legal or not is disputed, but in the US approval by the key regulatory agency of the industry, FDA, US Food and Drug Administration, is normally the decisive one for deciding legality. FDA has in practice an important global role and may also be considered as part of the Indian regulatory system for its pharmaceutical industry.

35. Behavioural economists have studied the effects of minor gift too small to be of any economic consequence for the receiving doctor, but they have nevertheless shown to have significant effect in the for a company desirable direction (Dana and Loewenstein, 2003).
36. Given that the persuasion techniques are rooted in the characteristics of medical goods and services themselves, it is not surprising that we find similar phenomena in India as demonstrated for the Indian states Assam and Chhattisgarh (Sengupta, 2011).
37. These estimates are obviously disputable. For example, the companies may avoid some taxes in other ways.
38. The R&D process in the pharmaceutical industry does not have to be organised this way. Even today part of the research is performed at public universities and not paid by the industry, while the forms of cooperation may have significant impact on the rate of discovery. One hypothesis for the explanation of a seeming slowdown in the discovery rate of new drugs has been sought in the incentives created for the universities to try to patent discoveries themselves that may have disrupted the information flows between them and the companies to a disadvantage to both. While not often practiced, there are some advantages by making clinical trials organised and financed by public organisations as part of the monitoring of the private pharmaceutical companies. They have strong economic interests in manipulating the outcomes (vide Le Carré's fictional horror story about frauds in a private company's clinical trials where they hided dangerous side effects of a drug).
39. Gagnon (2009: 262-265, 369-37) have collected some empirical indications of more extensive cooperation between the pharmaceutical MNCs not in the sense of price fixing cartels but through a number of licensing and marketing agreements, joint ventures, mergers and acquisitions. And, more informally we argue, through joint lobbying in a number of countries and international organisations. In India Novartis has sought to challenge India's stricter interpretation of what would constitute an invention while Bayer challenged an Indian attempt of active use of forced licensing as an instrument against monopoly pricing.
40. Note the observation made in the preceding footnote that a number of the cooperation agreements between the MNCs are marketing
41. Note that it is the costs involved in keeping a stock of patents (through making new inventions) that make it so difficult to enter this high price, oligopolistic end of the market.
42. Ward, H., 'Public Sector Roles in Strengthening Corporate Social Responsibility: Taking Stock', IFC (World Bank), 2004, USA
43. http://www.mca.gov.in/Ministry/latestnews/CSR_Voluntary_Guidelines_24dec2009.pdf
44. NVGs can be downloaded from: http://www.mca.gov.in/Ministry/latestnews/National_Voluntary_Guidelines_2011_12jul2011.pdf

45. IICA: IICA was established in mid-2009 with the objective of honing technical skills of public and private sector representatives on various elements of corporate governance, to create a breed of young professionals who are committed to the cause of 'corporate responsibility'.
46. Guidelines Drafting Committee (GDC), which was chaired by Bharat Wakhlu, Director, Tata Group, India and included CSR experts, scholars, industry representatives, NGOs and civil servants
47. Draft Companies Bill, 2011 can be downloaded from: http://www.prsindia.org/uploads/media//Company/companies%20bill%202011.pdf
48. Indian Rupees
49. SEBI circular (CIR/CFD/DIL/8/2012), dated August 13th, 2012 is available at: http://www.sebi.gov.in/cms/sebi_data/attachdocs/1344915990072.pdf

Empirical Evidence & Analysis from India

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2
Regulatory Architecture in Pharmaceutical and Private Healthcare: Implications for Business Behaviour

The pharmaceutical and healthcare industries play a vital role in contributing towards health and well-being of a society. Given the critical linkage of these sectors with the socio-economic development of a country, these industries tend to resist the pressures of economic cycles across the world. Therefore, the business responsibility aspects of these two sectors require a more critical investigation. In countries like India where the access to affordable healthcare is a severe problem, the need for both the government and the private sector to fulfil the ethical obligations in a social responsible manner is important.

In this section, an overview of the policy and regulatory framework in the Indian pharmaceuticals and healthcare sector has been undertaken. It outlines the key purpose of the regulation in the pharmaceutical and private healthcare sector, links the legislations and their enforcement mechanism at the central and the state levels and then examines the gap between the intent and the actual enforcement of the regulation.

As has been emphasised earlier, the BRCC project provides a unique opportunity to frame corporate conduct within the regulatory context of the sector. This will provide a deeper insight in to understanding the structure of the institutions and whether they enable or disable responsible business behaviour of the sector specific players. The focus of the study is on understanding the regulatory aspects on two critical areas, namely a) the environmental impact, and b) the marketing and distribution aspects and its impact on the consumer.

Pharmaceutical Sector

The phenomenal growth of the Indian pharmaceutical sector as a key export sector and contract manufacturer to the world pharmaceutical industry is well documented. The US$12bn valued pharmaceutical industry in India is expected to grow to US$55bn by 2020. The industry spends around 18 percent of its revenue on research and development (R&D).[1] India is expected to join the league of top 10 global pharmaceutical markets in terms of sales by 2020 with the total value reaching US$55bn.

The Indian pharmaceutical industry is classified under "chemical industry" in the manufacturing sector. The "organised" sector consists of about 300 companies, which account for 70 percent of the total market share, with the top 10 firms contributing nearly 30 percent.[2] However, the total sector is estimated at nearly 20,000 businesses, some of which are extremely small. There are about 8000 small scale units, which form the core of the supply chain of the pharmaceutical industry in India (including five Central Public Sector Units).[3]

Pharmaceutical companies in India manufacture bulk drugs in several therapeutic categories and the industry manufactures various types of dosage and in different formats namely capsule, tablets, injectables, orals, and liquids. Of the 400 bulk drugs in the Indian market, it is estimated that 300 are domestically produced. According to estimates, the proportions of formulations and bulk drugs is in the order of 75:25. There are believed to be over 60,000 formulations manufactured in India in more than 60 therapeutic segments. More than 85 percent of the formulations produced are sold in domestic market. India is largely self-sufficient in case of formulations, though some life-saving and new innovative drugs and formulations continue to be imported. Moreover, India is emerging as the most favoured destination for collaborative R&D, bioinformatics, contract research and manufacturing and clinical research as a result of growing compliance with internationally harmonised standards such as Good Laboratory Practices (GLP), current Good Manufacturing Practices (cGMP) and Good Clinical Practices (GCP).

The industry has several business and trade collectives/associations representing different stakeholders groups – the Organisation of Pharmaceutical Producers of India (OPPI) representing the big companies with R&D base; Indian Pharmaceutical Association (IPA) a professional association of pharmacists; Indian Pharmaceutical Alliance representing leading domestic pharmaceutical firms, Confederation of Indian Pharmaceutical Industry (CIPA) which is the apex body of small scale manufacturers of drugs and pharma and Bulk Drug Manufacturers

Association (BDMA), an all India body representing all the bulk drug manufacturers of India. Apart from these there are several smaller sector associations/collectives at the state level.

The pharmaceutical industry is a highly regulated sector, globally. In India also, the sector has several regulations related to price, quality control, Intellectual Property Rights (IPRs) protection, drug procurement, manufacturing practices, environment and safety, drug promotion and advertising.

It is important to note that pharmaceutical policy in India is perceived as industrial policy rather than health policy. The formulation of pharmaceutical policy, therefore, has traditionally been the responsibility of the Department of Petrochemicals in the Central Ministry of Chemicals and Fertilizers, with only limited inputs provided by the Ministry of Health.

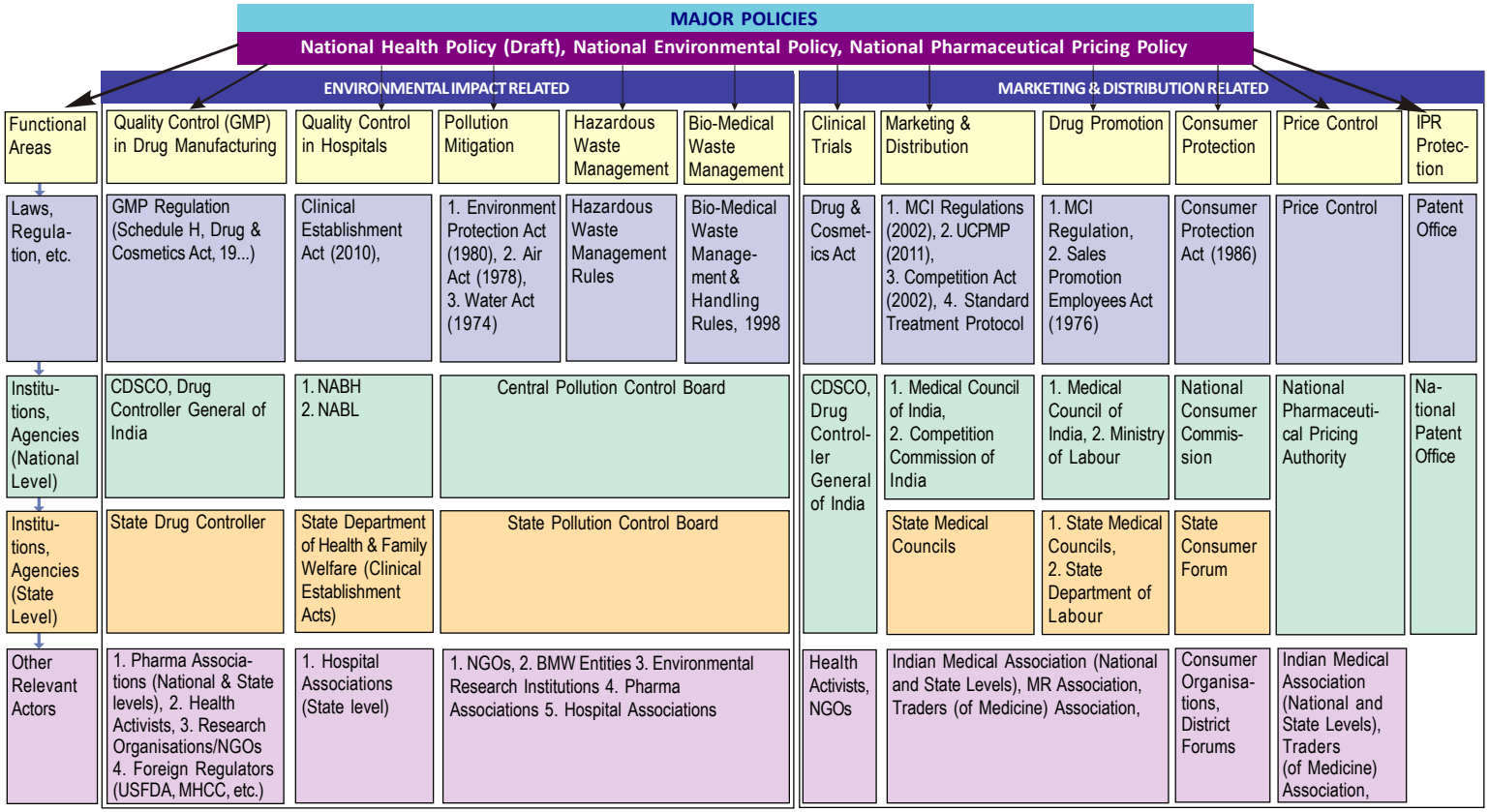
Private Healthcare

The healthcare industry forms the backbone of any nation's well-being and can be broadly divided into five segments namely hospitals, pharmaceuticals, diagnostics, medical equipment and supplies and medical insurance.

The Indian healthcare sector is expected to reach US$100bn by 2015 from the current US$65bn, growing 20 percent on year-on-year basis, as per rating agency Fitch. The industry aims to touch US$79bn in 2012-13 and US$280bn by 2020, supported by increasing demand for specialised and quality healthcare facilities. Further, the hospital services market, which represents one of the most important segments of the Indian healthcare industry, is expected to be worth US$81.2bn by 2015.[4]

Indian healthcare industry operates in both the private and public sectors. Healthcare spending in India accounts for over five percent of the country's GDP. Out of this, the public spending is just over one percent. The presence of public healthcare is not only weak but also under-utilised and inefficient. Meanwhile, private sector is quite dominant in the healthcare. Around 80 percent of total spending on healthcare comes from the private sector. Inadequate public investment in health infrastructure has given an opportunity to private sector to capture a larger share of the market. The private healthcare system in India has grown vastly over the years and is well established and flourishing. At the time of Independence, the private health sector accounted for only 5 to 10 percent of the total patient care. In 2004, the share of private sector in

Figure 2.1: Regulatory Framework of the Pharmaceutical and Private Healthcare Sectors in India



total hospitalised treatment was estimated at 58.3 percent in the rural areas and 61.8 percent in the urban areas. In the case of non-hospitalised treatment, government sources account for only 22 percent in the rural areas and 19 percent in the urban areas (Planning Commission, 2008: 68-69).

Data from the National Family Health Survey (NFHS) III also confirms that the private medical sector remains the primary source of healthcare for the majority of households in urban (70 percent) as well as rural areas (63 percent). Private doctors or clinics are the main source of care in the private sector, catering to 46 percent of the urban and 36 percent of the rural households (IIPS and Macro International, 2007: 436). The focus of the present study is the private healthcare sector.

Purpose of Regulation, Regulatory Framework, Delivery & Impact

Figure 2.1 provides a comprehensive overview of the regulatory context in which both the pharmaceutical and healthcare sectors in India are located. As has already been mentioned, while the pharmaceutical sector is largely governed by the Ministry of Chemicals, the healthcare sector is governed by both the Ministry of Chemicals and Ministry of Health. The National Health Policy, the National Pharmaceutical Pricing Policy and the National Environmental Policy shape the contours of responsible business practices in the context of environment and marketing and distribution in the two sectors.

We have focussed on the key *regulatory purposes* on three dimensions, namely, product/process quality pertaining to the manufacturing practices, environmental pollution and consumer related behaviour across both the sectors. The following sub sections describe each of these dimensions:

i. Product/services quality in pharmaceutical manufacturing and private healthcare services.
ii. Environmental pollution in pharmaceutical and private healthcare.
iii. Consumer as a stakeholder in the marketing and distribution of product and services in the two sectors.

Product/Services Quality in Pharmaceutical Manufacturing

One of the key aspects of responsible business behaviour in the pharmaceutical industry in India is the Good Manufacturing Practices (GMP) which ensures that the quality of the drug manufactured conforms to the required standards. The Food and Drug Control Administration (FDCA) and the Drugs Controller General of India have laid down

minimum GMP requirements to qualify for a drug manufacturing licence. These requirements are far less stringent than international GMP guidelines, including those recommended by the World Health Organisation (WHO).

Governing Policies

The Drugs and Cosmetics Act, 1940 is the law which regulates the import, manufacture, distribution and sale of drugs and cosmetics in the country. The Drugs and Cosmetics Act, 1940 and Drug and Cosmetic Rules, 1945 have elaborate provisions to check the production of spurious and substandard drugs. The Act provides definitions of the terms 'spurious, adulterated and misbranded drugs' for the purpose of taking penal action against the offenders. The Drugs and Cosmetics Act, 1940, has been recently amended under the Drugs and Cosmetics (Amendment) Act, 2008 providing very strict penalties for manufacture of spurious and adulterated drugs.

Schedule M to the Drugs and Cosmetics Rules of 1945, outlines the requirements for GMPs and it is mandatory for the manufacturers of drugs to comply with the requirements of this Schedule for quality control. It specifies in detail the requirements of premises, surroundings, personnel, sanitation, and storage of raw materials, documentation, records and quality control systems.

Central and State level Regulatory Mechanism

India has a dual drug regulatory control at Central and State levels. The main regulatory body at the central level is the **Central Drug Standard Control Organisation** (**CDSCO**) under the Ministry of Health and Family Welfare which regulates drugs belonging to various systems of medicine (allopathy, homoeopathy, ayurveda, siddha and unani). The arrangement of the regulatory framework in the pharmaceutical sector (and distribution of legislative power according to the Indian Constitution), is such that powers related to the drugs (pharmaceutical) sector is provided in the 'concurrent list'. This implies that Central Government (through the Parliament) and the State Legislatures have powers to make laws related to the pharmaceutical sector in the country. The States implement the national legislations by putting in place the desired enforcement mechanisms.

The role of the CDSCO is three fold: (1) to approve new drugs based on safety and efficacy studies at both the Central and State level, licensing and monitoring of manufacturing facilities and distribution channels; (2) to define the standards and measures for ensuring the safety, efficacy and

Table 2.1: Specific Functions of the State Government	
Duties of the State Drug Controller	**Applicable Legislation**
• Enforcement of GMP norms set by the CDSCO, to regulate drug manufacturing, storage and distribution in a state	Drugs & Cosmetics Act, 1940
• Monitoring sale of essential drugs in the state in respect of the prices fixed by the NPPA	Drugs Prices Control Order, 1995
• Provision of license for (i) manufacturing and for (ii) sale of drugs in the state – investigation and prosecution in case of infringement of the law	Drugs and Magic Remedies (Objectionable Advertising) Act, 1954

quality of drugs, cosmetics, diagnostics and devices in the country and regulate the market authorisation of new drugs and clinical trials standards; and (3) to determine whether the rules and laws pertaining to drug control are being implemented effectively in the interest of patients and resort to drug recalls, post-trial tests, etc. CDSCO is presided over by the Drug Controller General of India (DCGI).

The drug manufacturers, however, are expected to not only adhere to the standards imposed by the DCGI, but also standards set by the Drug Regulators of the countries to which the product is being exported. The compliance regime with global standards is becoming stronger as regulators are under mounting consumer pressure especially pertaining to patient safety and security.

State Drug Control Organisation

The State Drug Control Organisation, i.e. the FDCA was set up to implement the provisions of the Drugs and Cosmetics Act, 1940, Drugs Prices Control Order, 1995 and the Drugs and Magic Remedies (Objectionable Advertising) Act, 1954 at the state level. The following specific functions are shouldered by the state government in relation to the above-mentioned legislations:

The regulation in the pharmaceutical sector occurs at the Central and State level. The key agency to formulate the policy and the rules, to set standards and ensure enforcement of the same and finally to monitor and take punitive action for misconduct rests with the CDSCO. The FDCA with its enforcement mandate supports the CDSCO in executing its mandate.

Services Quality Control in Private Healthcare Service Delivery

As has already been mentioned, private sector dominates the healthcare delivery market in India due to their ubiquitous presence and growing inadequacies in the public health system.

Policy and Regulatory Mechanism

The mechanisms to regulate the quality of services in the healthcare market are not as clear as those of the pharmaceutical industry. It appears that there are several institutions which together are expected to be responsible for quality healthcare. They include the Medical Council of India, the Departments of Health in individual states, Indian Medical Association, an association of doctors, and the judicial system that allows consumers to approach a consumer court to seek justice for medical negligence.

Medical Council of India (MCI)

The MCI is a statutory body with the responsibility of maintaining high standards of medical education and to protect and promote the health and safety of the public by ensuring proper standards in the practice of medicine. It is the governing organisation that controls medical education, registration, licensing and ethics of all medical professionals in India. A medical person is not permitted to practice medicine without a valid license from the MCI. It regulates the professional conduct, etiquette and ethics in the medical field.

Department of Health & Family Welfare

The state department of health is responsible for the quality control of healthcare providers in the states. Besides, the department is responsible for implementation of various central and state level health schemes in India.

Consumer Protection Act (COPRA)

COPRA often becomes the only way for affected consumers to protect their interests. COPRA, promulgated in 1986 to protect rights and interests of consumers, recognises medical misconduct as an offence.

The Clinical Establishments (Registration and Regulation) Act, 2010

The basic objective of this legislation is to provide for registration and regulation of 'Clinical Establishments' in the country. The Act comes in the series of attempts by the Central Government Health agencies to codify and manage the healthcare medical services sector in the country. This Act aims at bringing concerns of quality through minimum standards of infrastructure, quality, bio medical waste management related aspects.

Box 2.1: Environmental Problems

The Padra taluka in Gujarat's Vadodara district is famous for borewells that spew reddish brown water. These are referred to as 'Thumbs Up borewells'. Laboratory tests by the Gujarat Pollution Control Board in 2011, showed that nearly half the borewells in the area were contaminated by effluents produced by the neighbouring pharmaceutical industries.

(Source: www.downtoearth.org.in/content/polluters-get-away-making-ad-hoc-payment-farmers)

The pollution caused by the pharmaceutical industry in Ankleshwar, Gujarat has become almost legendary. A household joke–if all the sick people of the world are brought to Ankleshwar, all of them shall become alright, as the entire atmosphere is full of medicine (effluents from pharma units).

(Source: www.articles.timesofindia.indiatimes.com/2010-10-15/surat/28219861_1_ankleshwar-falguni-pathak-garba-venue)

The Patancheru-Bollaram cluster in Andhra Pradesh is another critically polluted area. Residents of the Patancheru area silently suffer from a variety of respiratory problems.

(Source: www.deccanchronicle.com/channels/cities/hyderabad/pollution-chokes-patancheru-974)

Central Pollution Control Board (CPCB) in its report in June, 2011 came up with alarming levels of critical volatile organic compounds in the industrial area of Baddi-Barotiwala-Nalagarh, including cancer emitting carcinogens, enhancing the risk of locals acquiring cancer. The pharmaceutical industry is a very significant contributor to the pollution in this region.

(Source: http://www.tribuneindia.com/2011/20110615/himplus.htm#1)

Vapi in Valsad district, another pharma-hub in Gujarat was declared to be the 4th most polluted place in the world by the TIME magazine in its 2007 survey. The levels of mercury in the city's ground water were found to be disastrously high, upto the tune of 96 times higher than WHO safety levels.

(Source: http://www.time.com/time/specials/2007/article/0,28804,1661031_1661028_1661019,00.html)

Box 2.2: Health Hazards Associated with Poor Management of Bio-Medical Waste

(i) Injury from sharps to staff and waste handlers associated with the healthcare establishment.
(ii) Hospital Acquired Infection (HAI) (Nosocomial) of patients due to spread of infection.
(iii) Risk of infection outside the hospital for waste handlers/scavengers and eventually general public.
(iv) Occupational risk associated with hazardous chemicals, drugs etc.
(v) Unauthorised repackaging and sale of disposable items and unused/ date expired drugs.

In summary, it can be said that the regulatory framework for the healthcare services sector is sparse and relatively unclear. There are several agencies which are expected to provide the framework, but in the absence of clarity of the roles of the various agencies and a weak regulatory framework, the ethical behaviour of corporate conduct is likely to be weak.

Environmental Pollution in Pharma Manufacturing Sector

In the international ranking of the most hazardous countries in terms of environment, India ranks as the 7th worst country with *per capita* carbon dioxide emission at roughly 3000 pounds (year 2007). In 2005, an Environmental Sustainability Index placed India at 101st position among 146 countries[5]. In 2010, Gujarat was declared the most polluted state (Financial Express) in the country. Like most chemical industries, the pharma industry also has environment and hazard management issues, especially in the manufacturing of Active Pharmaceuticals Ingredients (API's or bulk drugs). The noted hazard from the pharmaceutical sector include contamination due to spillage, corrosion due to usage of chemicals, exposure to toxic gases which may cause fires, improper storage of raw materials may result in spillages and accidents, hazards during transportation, generation and disposal of untreated waste streams such as liquids and solids.

Environmental Pollution in Private Healthcare

In India, there are around a million hospital beds and around 15000 hospitals, nursing homes and countless number of registered and unregistered diagnostic clinics[6]. The waste generated is often chemically hazardous, infectious and contains radioactive substances. Such waste because of inappropriate disposal/treatment strategies contribute to serious health hazards in the community. The exponential growth of Healthcare Units (HCU) such as hospitals and dispensaries in India has generated

Box 2.3: After Quacks, Hospitals Under Fire for Dumping Biomedical Waste

Following the detection of first hepatitis-B case in Bharuch, district authorities are on an alert. On Saturday, Gujarat Pollution Control Board (GPCB) conducted raids and issued show-cause notices to six hospitals, including Bharuch Civil Hospital, after finding that they had dumped biomedical waste in a haphazard manner. Fourteen-year-old son of a migrant labourer was confirmed to be infected with hepatitis-B on Friday. Doctors in the district have been directed to test every patient for the deadly virus.

(Source: The Times of India, February, 2009)

large quantum of waste resulting in an alarming situation for local governments. It has been observed very commonly that there is a lack of segregation practices and mixing of hospital wastes with general waste which makes whole waste stream hazardous. Open burning of waste has been a practice among smaller clinics, dispensaries and some hospitals which lead to release of dioxin in the atmosphere

Policy and Regulatory Environment

The environmental issues in both the sectors are governed by the CPCB in India. The production process in the manufacture of drugs generates effluents which pollute water bodies and land. One of the challenges in the pharmaceutical sector is the diversity of manufacturing processes, raw material used and therefore, the differences in the characteristics of wastewater generated from the industry. This is further compounded by the frequent changes in processes and products necessitated by fluctuating market conditions and the chemical composition of the products.

Central Pollution Control Board (CPCB) – The CPCB was established to set up the environmental standards at a national level. To deliver on this mandate CPCB was intended to be supported by the Pollution Control Boards (PCBs) and Pollution Control Committees (PCCs) at state-level. The CPCB was established in 1977 under the Water (Prevention & Pollution Control) Act, 1974. It functions as a multi-disciplinary technical organisation of Ministry of Environment & Forest (MoEF) and plays the role of an adviser and coordinator of the State Pollution Control Boards.

State Pollution Control Boards (SPCB) – The SPCBs were established following the State Legislatures' adoption of the Water Act of 1974 and

the Air Act of 1981. At the State level, the SPCBs are attached either to the Environment Department, or to the Forest and Wildlife Department. In general, SPCBs perform the activities of the CPCB at the state level.

Minimum National Standards (MINAS) for Pharma Manufacturing and Formulation Industry

The Minimal National Standards (MINAS) for effluent discharged from drug and pharmaceutical industries has been developed by taking in to consideration the different categories of pollution, the pollutants, the nature of treatment they require and the best pollution control technologies that are available in the country and globally. The objective of MINAS has been to arrive at a general approach for minimisation of pollution and good water quality management by the existing technology. General standards are prescribed irrespective of products and processes of manufacture. It also include provision of location-specific standards prescribed by State Boards

Bio Medical Waste (BMW): One of the key roles of the Central and the State level pollution control boards is the disposal of BMW as prescribed by the Biomedical Wastes (Management & Handling) Rules, 1998. The genesis of this regulation was through a Public Interest Litigation filed by an NGO on the prevailing unsanitary conditions, practices and risks from BMW handling practices. The Supreme Court of India ordered the CPCB to identify safer and hygienic methods of dealing with bio-medical waste. One of the outcomes of this process was the development of the BMW Rules and its adoption in the country in 1998. These rules were amended in 2003. In 2011, the MoEF notified the Draft Bio-Medical (Management and Handling) Rules, 2011 with a view to make the legislation more stringent.

Biomedical Waste (Management & Handling) Rules, 1998

This is the very first standard on the subject established by the Bureau of Indian Standards (BIS), IS 12625: 1989, entitled 'Solid Wastes- Hospitals-Guidelines for Management'. The notification of the 'Biomedical Waste (Management & Handling) Rules, 1998' assumes great significance, since it was able to introduce the standard as a rule of compliance. These rules apply to all sectors that generate, collect, receive, store, transport, treat, dispose or handle bio-medical waste in any form. According to the rules, it shall be the duty of every occupier of an institution generating bio-medical waste, which includes hospitals, nursing homes, clinics, dispensaries, veterinary institutions, animal houses, pathology laboratories, blood banks etc., to take all steps to ensure that such wastes are handled without any adverse effect to human health and the environment. They

have to either set up their own facility within the time frame (Schedule VI) or ensure requisite treatment at a common waste treatment facility or any other waste treatment facility.

In accordance with the provisions of this legislation, state governments devise their own management and handling procedures. Some state health departments have provided assistance to government hospitals for management of their bio-medical waste in the form of training, bio-medical waste auditing, preparation of hospital specific plans, procurement of materials and supplies, etc. However, private hospitals have had to comply with the requirements of the BMW Rules 1998 using their own resources.[7] There are wide differences between bio-medical waste management practices across states in the country.

The private sector has emerged as an important player in collection, treatment and ultimate disposal of biomedical waste in the states. The process involves door-to-door collection of BMW from various hospitals by a private entity, followed by its treatment in a Common Waste Treatment Facility (CWTF) and finally its safe disposal. Andhra Pradesh was a pioneer in establishing CWTFs in the country using a public-private-partnership (PPP) model where the government facilitated the process for a private enterprise to start a CWTF. This model was replicated later in other states like Karnataka, Maharashtra, Rajasthan, Punjab, etc.

According to a recent report prepared by Indian Institute of Management (IIM), Lucknow, approximately 42, 0461 kg per day or approximately 155 thousand MT per year bio-medical waste is generated in India. "Presently, 50-55 percent of bio-medical waste is collected, segregated and treated as per Bio-medical Waste Management Rules. The rest is dumped with municipal solid wastes," the report says. Out of 84,809 hospitals, only 48,183 are either using common bio-medical waste treatment facilities (which are 170 in number) or have engaged other private agencies.[8]

Studies show that, there is lack of *in-situ* segregation practices and mixing of hospital waste with municipal solid waste is common. Further, independent assessments of the state of hospital/bio-medical waste management across Indian states depict a gloomy picture, especially in terms of:

- Adherence to the BMW Rules, 1998 (amended 2003)
- Lack of segregation of BMW in hospitals
- *In-situ* infrastructure (e.g., autoclave, incinerators) not properly maintained

- Mixing of BMW with municipal solid waste
- Prevalence of inappropriate practices that can have serious public health implications (e.g. salvaging and recycling of BMW waste, burning of BMW waste, discharge of wastewater from hospitals without treatment, etc.)

Turf battles between SPCBs and local administration (municipalities) in dealing with BMW seem to accentuate the problem.

Consumer as a Stakeholder in the Marketing and Distribution of Product and Service in the Two Sectors

Both pharmaceutical and healthcare sector in India have a common goal to provide accessible, quality and affordable healthcare as a part of their business responsibility. As has already been mentioned in the first section, the consumer in this case is the patient. The sectors have inbuilt characteristics of expertise and knowledge associated with a few key stakeholders like doctors, pharmacists and hospitals. Patients often are at a vulnerable stage of their life when they interact with the stakeholders in the sector. There is a power and information asymmetry concerning the consumer and experts. Therefore, several ethical aspects pertaining to the conduct of the stakeholder has become highly critical.

The Economic and Social Research Council (ESRC) in the UK has funded a large study thematically tangential to this project. This study has produced a series of useful and informative literature reviews that address challenges in the regulation of pharmaceuticals both from an international[9] and from India and South-Asia specific angles. Providing an account of the many Commissions and other public initiatives set up to address regulation of the pharmaceutical industry between 1995 and 2006, Jeffery and Santhosh (2009) also describe, in considerable detail, the division of responsibilities between different public bodies.[10]

As Jeffery and Santosh (2009) also point out, some very strong claims have been made about the order of magnitude of the spurious or counterfeit drugs problem within India and India's contribution to the international market in such products.[11] In the international market, the dominance of certain drugs (e.g. Viagra), the fact that Switzerland also ranks high on the list of origin countries and the lack of systematic and credible evidence, makes it hard to evaluate how serious this problem actually is. Within India it would not be surprising if considerable inter-state variation in the presence of drugs with non-active ingredients that could adversely and disproportionately affect poor consumers prevailed. Among the issues Jeffery and Santosh identify as problematic in the Indian setting and which

disproportionately affect consumers without knowledge of English language is the lack of drug labelling and consumer information in vernacular languages.

Unethical Practices in Marketing and Promotion of Drugs

The WHO defines drug promotion as 'all informational and persuasive activities by manufacturers and distributors to induce/influence the sale and use of medicinal drugs'. Drug promotion has an important bearing on the rational use of drugs; on drug price-control mechanisms, the manufacture, availability and use of essential drugs, on equity of drug distribution and the cost of healthcare — all making it a central public health issue. Thousands of Indian companies produce 70,000 brands of various drug formulations compared to WHO's list of 250 essential drugs. Drugs are sold through chemists and stockists who make a margin on the sale. The private sector represents 80 percent of the health expenditure, making a doctor in private practice an influential prescriber.

Consumers are largely unaware of how their drug consumption choices are being shaped by the various stakeholders. The drug-companies interact with doctors in order to promote their medical products. The doctors are encouraged to prescribe the products through samples provided to them. The pharma companies are also known to support medical conferences and fund the doctors' travel to the conference as an opportunity for enhancing their knowledge. While both the samples and conference travel are opportunities for doctors to try newer and more effective ways of treating illnesses, it is evident that what constitutes ethical and unethical promotion is questionable. Given that the vast majority of the patients are uneducated and uninformed, the issue of conflict of interest becomes even greater in India.

The issue of ethical promotion and drugs marketing both in terms of campaigns targeting intermediaries (chemists and doctors) and consumers is important and one where more solid evidence is urgently required (see Ecks and Basu 2009). Are 'distortions' in promotion campaigns and the incentive packages offered to doctors (and chemists) more unethical in areas with less educated (and poorer) consumers as some anecdotal evidence appears to suggest? Is there also a higher prevalence of promotion of harmful drugs in such areas?

Earlier studies undertaken by CUTS have also established the predominance of a nexus between the various providers of healthcare services[12] While such arrangements between pharmaceutical companies and doctors help companies achieve their sales targets; doctors suggesting

Box 2.4: Ethical Concerns Regarding Clinical Trials in India

In 2010, one year after enactment of compulsory registration of clinical trials in Clinical Trial Registry - India (CTRI), there was a shocking incident in Khammam district (Andhra Pradesh) and Vadodra (Gujarat) where a HPV vaccine clinical trial was conducted on nearly 23,500 girls in the 10-14 year age group. Most of their informed consents were signed by a headmaster, as the 'guardian'. Moreover, the justification given by them was ridiculous: the parents were not easily accessible! Reporting of a death was delayed for five months, while two deaths in Khammam district were not reported. Ironically, while measuring and reporting the adverse events after vaccinations which were the "primary end points of the study," the principal and co-principal investigators failed to report all such events to the sponsor within a day, as required under the Drugs and Cosmetics Rules 1940.

Source: http://theclinicaltrialsguru.com/blog1/2012/10/

a patient to undergo diagnostic tests at specific diagnostic clinics are rewarded through 'cuts and commissions' by these clinics. Considerable information asymmetry affects the ability of the consumer (patient, or person seeking medical services) to make a choice and accept what is offered.

Clinical Trial and Research

India has been and continues to be a favourable destination for clinical trials over the years. A tremendous increase in the clinical trials market from US$70mn in 2002 to US$485mn in 2011, displays India's strong value proposition in skilled medical professionals, low-cost services, diverse genetic pool and world-class hospitals to undertake such trials. In addition, India's huge patient base in a plethora of diseases ranging from tropical to nutritional and lifestyle related, has been enticing for many pharmaceutical companies, Contract Research Organisations (CROs) to evaluate efficacy and safety of new molecules, also safety and suitability of existing drugs before marketing them in India. As per the recent Frost & Sullivan report, the domestic CRO market is set to reach US$1bn by 2016.

The manner in which such trials are conducted in India has become a subject of public debate recently with several media reports highlighting the issues concerning these trials. The two issues being debated relate to the required standards to be followed while conducting trials and also

the right to informed consent and the extent to which the education and literacy levels of the people in India allow them to provide informed consent.

Policy and Regulatory Environment

The Drugs and Cosmetics Act of 1940 is the key agency for monitoring clinical trials, import of drugs and monitoring the manufacturing, distribution and sale of drugs. From a consumer perspective, the Drugs and Cosmetics Act, 1940 and Drug and Cosmetic Rules, 1945 have elaborate provisions to check the production of spurious and substandard drugs in the country. The Act provides elaborate definitions of the term spurious, adulterated and misbranded drugs for the purpose of taking penal action against the offenders. The Drugs and Cosmetics Act, 1940, has been recently amended under the Drugs and Cosmetics (Amendment) Act, 2008 providing very strict penalties for manufacture of spurious and adulterated drugs.

Clinical Establishment Act: The Clinical Establishments (Registration and Regulation) Act (CEA) has been passed to achieve the mandate of Article 47 of the Constitution for improvement in public health. The Act also focuses to protect interest of consumers and has set up standards, such as those pertaining to minimum requirement of staff numbers to attend to the patient needs, the general medical and emergency facilities requirements to stabilise the medical condition of a patient in case of a life threatening condition, maintenance of records which would keep the data current and real time for the authorities, etc.

The Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002: When the patient comes to a doctor, he/she is in no position to judge the quality of care due to inherent complexity of healthcare and his lack of requisite information. There exists a high information asymmetry between the care provider and patient. Further, the care provider who gives the advice in many cases is also providing the diagnostic services, leading to a possibility of provider-induced demand for services.

The code of ethics, as laid down under The Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002, serves as an institutional response to safeguard the interest of patients and to enforce a moral and professional obligation on providers to live up to a set of values and standards voluntarily adopted by the fraternity.

Medical Council of India (MCI) is the regulatory body for upholding this code and ensuring its enforcement. But unfortunately, the enforcement mechanisms are not well articulated and very few punitive measures have been taken against unethical practices by healthcare professionals.

Uniform Code for Pharmaceutical Marketing Practices (UCPMP): The Department of Pharmaceuticals (DoP) issued a Uniform Code of Pharmaceuticals Marketing Practices (UCPMP) in 2011, targeting to curb unethical marketing practices among pharma companies. The code is voluntary in nature and the government will review the outcome of the implementation of the UCPMP after six months.

According to the proposed rule, the people qualified to supply pharmaceutical products would not be given any type of additional financial advantage, special benefits or gifts to perform their job. The code also makes it mandatory for all pharma association to have UCPMP uploaded on their official websites, and there will be a 'Committee for Pharma Marketing Practices' to handle all bribing cases. The Committee will have power to take action against the companies found guilty of breaching the code. The DoP has asked pharma companies and other stakeholders to submit their views regarding the proposed code. However, even after the expiry of the 'leniency period' of six month nothing substantive has happened on the ground as the UCPMP is still being talked about for its mandatory implementation.

Consumer Protection Act (COPRA), 1986: Professional organisations such as the Medical Council of India and local medical associations have remained ineffective in influencing the behaviour of private providers. The decision to bring private medical practice under the Consumer Protection Act (COPRA) 1986 is considered an important step towards regulating the private medical sector. COPRA is effective in minimising malpractice and negligent behaviour, but it does have adverse consequences such as an increase in fees charged by doctors, an increase in the prescription of medicines and diagnostics, an unfavourable impact on emergency care, etc.

The medical associations have also argued that the introduction of COPRA is a step towards expensive, daunting and needless litigation. A number of other concerns have been raised by consumer forums which focus on the lack of standards for private practice, the uncertainty and risks of medicines, the effectiveness of the judiciary system, and the responsibility of proving negligence.

(Source: Economic Times, July 10, 2012)

The Drugs and Magic Remedies (Objectionable Advertisement) Act, 1954: This Act provides to control the advertisements regarding drugs and prohibits the advertising of remedies alleged to possess magic qualities.

Political Economy Aspects *vis-a-vis* the Regulatory Framework

In India the National Health Policy falls short of specific and well defined objectives. Health is a state subject in India, and with different states in the country at different stages of economic development, the spending on upgrading the health system to make it accessible and affordable for the poor is not uniform. Apart from this, the poor coordination between the centre and the state governments and failure to align healthcare services with broader socio-economic developmental agenda accentuates the problem.

The accountability for the healthcare lies with two central ministries: Health and Chemicals & Fertilisers. The Health Ministry's mandate is affordable healthcare, but the Ministry of Chemicals and Fertilisers essentially deals with the sector as another industry within its responsibility, with little or no focus on improvement of health. Within these ministries, there are different entities which look at different aspects of drug regulation; and since each entity essentially works in a silo, there is no systemic perspective on health.

The above 'picture' captures the complexity in the institutions engaged in regulating both the sectors. Various ministries are involved in the regulation of healthcare and pharmaceutical sector on several different aspects. This sometime leads to jurisdiction overlaps and presents a classic case of unsynchronised regulation.

The drug prices in India are controlled under the *Drugs Prices Control Order (DPCO)*. The National Pharmaceutical Pricing Authority (NPPA) is entrusted with the task of recovering amounts overcharged by manufacturers for the controlled drugs from the consumers. It also monitors the prices of decontrolled drugs in order to keep them at reasonable levels. The NPPA comes under the Department of Pharmaceuticals, however, time and again the experts in the industry as well as the Planning Commission of India proposed that NPPA be placed under the Ministry of Health and Family Welfare.

Conclusion

From the discussion above it is evident that the quality of manufacturing/ service provision, environmental pollution and marketing and distribution constitute the most critical aspects which require a deeper understanding from a regulatory perspective. The pharmaceutical industry is identified as one of the 17 categories of grossly polluting industries in India by the CPCB.

A large part of the manufacturing occurs in the small and medium segment, where enforcement of legislation is particularly weak. A more critical understanding of the environment with particular reference to pollution and safe manufacturing practices is necessary. On manufacturing, an Indian version of WHO GMP was incorporated in the Drugs and Cosmetics Act at an early stage. One of the important areas to investigate is the extent to which manufacturing malpractices[13] occur despite the prevalence of GMP in pharma production.

Bio-medical waste and its management has become an increasingly important area in private healthcare. It is estimated that annually about 0.33 million tonnes of hospital waste is generated in India and, the waste generation rate ranges from 0.5 to 2.0 kg per bed per day.[14] The exponential growth of Healthcare Units (such as hospitals, dispensaries, polyclinics, diagnostic centres, pathological labs, etc.) in India has generated massive healthcare wastes creating an alarming situation for local governments. In spite of existing legislation (and an implementation mechanism) on bio-medical waste, often bio-medical waste gets mingled with municipal solid waste thus creating large-scale public health hazards. State governments have been implementing the bio-medical waste management in cooperation with the private sector (using a PPP model). Private operators are licensed by the state to collect, transport and dispose bio-medical waste from private hospitals. However, the issue of managing such waste remains a challenge and there is a need to increase attention to this problem.

Finally, the issue of ethical promotion and drugs marketing both in terms of campaigns targeting intermediaries (chemists and doctors) and consumers is important and one where more solid evidence is urgently required. Earlier studies undertaken by CUTS have also established the predominance of a nexus between various providers of healthcare services.[15] While such arrangements between pharmaceutical companies and doctors help companies achieve their sales targets; doctors suggesting to a patient to undergo diagnostic tests in specific diagnostic clinics are rewarded through 'cuts and commissions' by these clinics. Considerable information asymmetry affects the ability of the consumer (patient, or person seeking medical services) to make a choice and accept what is offered.

It is evident from the above section that several institutional, structural and procedural aspects of regulation in the two sectors need to be comprehensively understood and implemented to facilitate positive corporate conduct in the sector. Within this, it appears that the healthcare

regulations still seem to be evolving, are nascent and require strong implementing institutions to make them effective.

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3
Research Design, Methodology and Fieldwork in States

As has already been mentioned, the pharmaceutical and private healthcare sector in India offer interesting opportunities to examine how regulations determine/influence business (or corporate) conduct of firms in these sectors. Of particular significance is the fact that both the sectors pose stern challenges to regulators and legislators, especially since public interests associated with various aspects of the business conduct is high.

Based on CUTS prior experience in the sector and the feedback gathered through the 'research dialogues' and 'round table meetings' conducted under the BRCC project, it was decided to focus on two key issues in the sectors – the environmental issues in the healthcare and pharmaceutical sector; and the ethical aspects in distribution and marketing chains between the pharmaceuticals companies, chemists and doctors of private hospitals.

The **objectives** of the study were to:

a. Understand the role of the different actors in the healthcare and pharmaceutical sectors with respect to the regulation and the corporate conduct pertaining to environment and marketing and distribution of products and services.
b. Identify the key challenges and conflicts faced by the actors in managing the interaction between regulation and their conduct.
c. Identify key gaps between the intent of the regulation and its implementation to strengthen the regulation, policy and the procedures both at the centre and state level.

The following research questions informed our exploratory research on searching for the relationship between business regulation and the manner in which the devolution of the regulation happens in practice across the stakeholders. While CUTS realises there are other issues from a 'business

responsibility', perspective in these two sectors, the following 'critical issues' were arrived at following internal brainstorming and external discussions with experts.

Research Questions for the Pharmaceutical Sector

Environmental Performance Related

The following questions were posed to the key respondents in the pharmaceutical sector:

What is the nature and extent of environmental impact (especially in terms of pollution) by the pharmaceutical companies? How do the existing regulatory safeguards[1] operate? What are the factors that make enforcement of the existing regulations weak? What has been the experience of the various stakeholders with the agencies (both state and centre) that regulate the sector? What has been the experience of the agencies (state and centre) in dealing with other stakeholders toward building responsible conduct? What are the available mechanisms which strengthen or weaken the interdependence across different actors? What needs to be done to strengthen the existing regulations making their implementation easy for all the stakeholders to achieve positive environmental outcomes?

Marketing and Distribution Related

The following research questions were explored with the stakeholders in the pharmaceutical industry:

What are the marketing and distribution challenges in promoting responsible corporate conduct? How do the marketing and distribution incentives of the large companies operate? Do these incentives impact the 'Rational Use of Drugs'? How do the existing regulatory safeguards prevent or perpetuate the marketing activities of the firms? What kind of practices do companies follow to maintain standards of ethical behaviour in the marketing and distribution chain?

Research Questions for the Healthcare Sector

Environmental Performance Related

What is the current status of Bio-medical Waste (BMW) management practices being followed by hospitals and diagnostic service providers in the state? What are the regulatory safeguards available in this sector? How do these safeguards get implemented? How do the different stakeholders who are responsible for effective delivery of the various

safeguards work together to achieve the outcomes of responsible behaviour? What are the current areas that weaken the safeguards and how can they be remedied?

Marketing and Distribution Related

What is the nature of the relationship between the hospital doctors and the pharma company representatives? What is the nature of relationship between the hospitals and the diagnostic service providers? Is there a common understanding of the standard treatment protocol among the private healthcare institutions? If there are deviations, what could be the possible reasons? How are hospitals promoting alignment with standard treatment protocols? Are there adequate measures undertaken by the healthcare providers to respect the diagnosis and treatment related queries of consumers (patients)?

The choice of methodology was guided by the exploratory nature of the of the research questions of the project.

Methodology

The case study method is appropriate when:

(1) the research is exploratory and the 'how' or the 'why' questions and the processual aspect of the phenomenon are investigated ; and
(2) when the research is studying a real-life phenomenon embedded in the context.

Case studies involve rich, thick and detailed descriptions of a particular phenomenon, and may involve a variety of data sources including primary data collection methods like in- depth interviews, observations, and so on as well as secondary data sources such as articles, reports and other printed or electronic sources (Yin, 2003). It was decided to treat the four states (where the BRCC research would be undertaken) as four case studies.

The research design of the project posed several challenges and has been emergent and iterative as the project evolved. In the first phase of the project, it was decided to arrive at the choice of the states based on an analysis of the economic performance of the states using data from the ease of doing business index. The shortlisting of the sectors was done based on the percentage growth in revenues in the sector and its contribution to state-level GDP. A matrix (as presented in Table 3.1) was thus created using the rankings of states based on the economic freedom index (EFI[2]) on the one axis and percentage of manufacturing and services contribution to state-GDP on the other.

Table 3.1: Manufacturing + Services Share in Net State Domestic Product			
		High	**Low**
EFI (Regulation of Business and Labour) Rank	**High**	**(High, High)** Maharashtra, TN, Gujarat, Haryana, Karnataka	**(High, Low)** Orissa
	Low	**(Low, High)** Andhra Pradesh, Kerala, Jharkhand	**(Low, Low)** UP, West Bengal, Rajasthan, MP, Punjab, Bihar

The above categorisation of states and sectors was shared with scholars and practitioners at two regional dialogues organised in *Jaipur* and *Bangalore* in July 2011. There was unanimity across the participants that given the objective of the study, the choice of the sectors should precede the selection of the states. This meant a significant change in the design since, the key discussions in the dialogue focussed on sectors that have greater environmental and social impacts than certain other sectors.

After examining several sectors like financial services, automobile, pharma, mining and retail, it was decided (at a Research Strategy Dialogue held at New Delhi in November 2011) that the *pharmaceutical* sector and the *private healthcare* sectors should be chosen for the research representing the manufacturing and services sector respectively. The overwhelming arguments for the choice of the sectors were that they were engaged in providing public goods and services; their impact at the societal level is significantly high and finally, the growth of the private firms in these two sectors has been significant in the last two decades. The sectors were also defined by CUTS' prior expertise and experience in them and familiarity with issues that had bearing on responsible conduct of firms operating in these sectors.

Once the sectors were identified, a detailed analysis of the firms/private hospitals in the sector was conducted. The five states with a high concentration of firms in the two sectors were Gujarat, Andhra Pradesh, West Bengal, Maharashtra and Madhya Pradesh. At a meeting in January 2012 to define the scope and methodology of the project, it was decided that apart from these five states, a few 'pristine' (relatively new and emerging hubs of pharmaceutical industry) should also be chosen. Himachal Pradesh and Sikkim are the two states which are emerging as pharmaceutical hubs. It was felt that having one 'pristine' state and one state with 'fairly long history' of the presence of the sector, would provide

an understanding on how the growth trajectory of the sector could impact the business responsibility related outcomes over a period of time. CUTS devised the analytical framework for undertaking research in sectors juxtaposing the NVG framework (Principles & Core Elements) on various components of the sector as presented in Annexure 1.

At this stage, given the scope of the research problem to be investigated and the nature of the study being exploratory, it was decided that four states would be chosen after a reconnaissance visit (referred to as a fact finding visit) was undertaken by CUTS. It was also decided that partners who had a deep understanding of the context at the state level would be chosen to assist CUTS in primary data collection and stakeholder discussions/meetings at the state level. The role of the fact finding visit was for the research team to familiarise themselves with the contextual aspects at the state level (nature of the sector, key actors, regulatory institutions, individual researchers, NGOs, etc.) in the two sectors. It also provided an opportunity for CUTS to identify possible state level partner organisations that could support the research in each of the four states. Finally, the following four states were identified:

- **Andhra Pradesh**
- **Gujarat**
- **Himachal Pradesh**
- **West Bengal**

Further, CUTS identified the following partner organisations in the four states to engage with in undertaking state-level research, dialogue and outreach. In undertaking field-work and also for other tasks, each of the partner organisations was asked to engage sectoral experts/institutions.

Table 3.2: Partner Organisations Engaged in Research, Dialogue and Outreach

State	Partner Organisation
Andhra Pradesh	Centre for Climate Change, ESCI
Gujarat	Raman Development Consultants Pvt Ltd
Himachal Pradesh	Gunjan Organisation for Community Development
West Bengal	CUTS Calcutta Resource Centre

A detailed note – ***Guidance Note for Field-work*** (**Annexure II**) was prepared and discussed with each state level partner to develop a shared understanding of the methodology and the design of the field-work, and to enable them to gather data/information pertaining to these two sectors from the states. The field work in all the states was undertaken between

Table 3.3: Key Respondents

Key Respondent Groups (State)

Government	Business	Stakeholders
• Pollution Control Board • Department of Environment • Food and Drugs Controller • Department of Health • Department of Industry	• Pharma Firms • Pharma Collectives • Industry Collectives • Medical Representatives and their Collectives • Chemist Associations	• CSOs • Media • Academia • Community residing in proximity of Pharma Manufacturing Units

May and September 2012. State level partners were asked to collate their findings into state-level reports (one each for the pharmaceutical and private healthcare sectors). The methodology would be useful for those interested in building a multi-state multi-stakeholder research design in the future, for other sectors as well.

A brief overview of the key respondent groups and sample size across the various stakeholders from the four states is given in Table 3.3 and Table 3.4 respectively.

Questionnaires were developed for each of the above respondent groups to gather the information from the key respondents (14 different state and non-state actor categories within each state). The questionnaires used for undertaking interviews are available at: http://www.cuts-ccier.org/BRCC/Questionnaires.htm. Apart from primary data collection based on the questionnaire, each partner was also required to gather and analyse secondary information pertaining to the two sectors in each state and present the same (along with the primary data) in the state level reports.

A mixed method design was adopted to ensure that the data collected was reliable and valid. Apart from in-depth interviews which were done across all key actors, prescription analysis was also undertaken. Prescriptions were gathered from some of the private hospitals covered

Table 3.4: Key State 'Actors' Interviewed During Fieldwork				
Key State-level Actors, Institutions	**Andhra Pradesh**	**Gujarat**	**Himachal Pradesh**	**West Bengal**
Pharmaceutical firms	95	100	49	51
Private hospitals	72	100	40	50
Medical representatives	61	35	55	40
Bio-medical waste entities	1	1	1	1
Hospital associations	1	-	1	1
Pharma association(s)	1	1	-	1
MR association(s)	1	1	3	1
Chemists' association(s)	1	1	1	2
IMA state and local branches		1	-	1
State and local industry collectives	1	1	-	-
State Food & Drug Control Authority	1	1	1	1
State Pollution Control Board	1	1	1	-
State Department of Environment	1	1	1	1
State Department of Health & Family	1	1	1	1

under the field survey to complement the information gathered from the interviews. An analysis of the website and the key documents pertaining to the actions of the various actors was also done. The entire field research in the states was undertaken in three phases as presented in Table 3.5.

To summarise, the methodology on the project comprised of a mixed multi-method research design. While secondary data was used extensively to identify the problems, a combination of in-depth interviews, questionnaires, insights from the four investigation partners in each of the states who had prior nuanced understanding of the context along with a prescription analysis provided a comprehensive framework to capture both the objective and the perceptual data from four states. In the next section, an overview of the two sectors, the state wise contextual aspects and the analysis of data from key respondents across the various stakeholders are presented.

Table 3.5: Three Phased Field Research (States)					
Phase-I		**Phase-II**		**Phase-III**	
Respondents	**Research Tool**	**Respondents**	**Research Tool**	**Respondents**	**Research Tool**
Pharmaceutical firms	Questionnaire	Pharma association(s)	Questionnaire	State Department of Env & Forests	Questionnaire
Private hospitals	Questionnaire	Hospital association(s)	Questionnaire	State Department of Health & Family Welfare	Questionnaire
Consumer feedback	Prescription analysis	MR association(s)	Questionnaire	State Drug Controller	Questionnaire
Medical representatives	Focus Group Discussion	BMW Management entities	Questionnaire	State Pollution Control Board	Questionnaire

Endnotes

1. Environmental Regulations – e.g., Water Act, Air Act, EIA Notification, Environmental Protection Act, etc.; and standards stipulated for compliance monitoring
2. EFI (Economic Freedom Index) is a measure of economic freedom. More economic freedom is indeed associated with greater wealth, higher growth, and improvements in the whole range of human development indicators. The figures in this table were used from the Economic Freedom of India States report 2011 prepared by the CATO Institute and Indicus Analytics. The report is available at: http://www.cato.org/economic-freedom-india/EconomicFreedomIndia-2011.pdf

4
Analysis and Findings from the States

This chapter is divided into two sub-sections. The first sub-section highlights the different aspects of environmental responsibility of firms in the two sectors as observed across the four states. The second sub-section consists of findings pertaining to responsibility of firms in marketing and distribution of pharmaceutical products and services (healthcare services) in the same four states.

The findings have been presented in this chapter according to the below-mentioned scheme:

I. Responsibility towards the Environment

(a) Pharma Sector
- Internal Factors
- External Factors

(b) Private Healthcare Sector
- Internal Factors
- External Factors

II. Responsibility in Marketing and Distribution Practices

(c) Pharma Sector
- Internal Factors
- External Factors

(d) Private Healthcare Sector
- Internal Factors
- External Factors

Responsibility towards the Environment in Pharmaceutical and Private Healthcare

In this section we present findings from the analysis of data gathered from the four states (Andhra Pradesh, Gujarat, Himachal Pradesh & West Bengal), describing the various internal and external factors that have implications on the environmental performance of pharmaceutical firms and private healthcare in these states.

Pharma Sector

The data collection was done in the four states and covered a total of **295 pharmaceutical firms.** The number of firms surveyed from each of the states is presented below:

Table 4.1: Number of Surveyed Pharma Firms

States	Total pharma firms surveyed	Pharma SMEs surveyed
Andhra Pradesh	95	74
Gujarat	100	74
Himachal Pradesh	49	38
West Bengal	51	51
TOTAL	**295**	**237**

Pharmaceutical manufacturing is one of the 17 most polluting industries identified by the Central Pollution Control Board (2010), and the environmental impacts of the sector are very pronounced. The Central Pollution Control Board in consultation with State Pollution Control Boards has identified 24 areas in the country as 'critically polluted' areas.[1] The survey also covered the following "critical areas" across the four states, viz.:

(i) Ankhleshwar and Vapi in Gujarat
(ii) Kala Amb in Himachal Pradesh
(iii) Patancheru-Bollaram and Vishakapatnam in Andhra Pradesh
(iv) Durgapur-Howrah in West Bengal.

Key Environmental Impacts of Pharma Units

The respondents were asked to rank the key environmental impacts of the pharmaceutical industry. It is evident from the figures that firms from Gujarat, Andhra Pradesh and Himachal Pradesh felt that water, air and land pollution together with hazardous wastes were the main environment related concerns in their operations. The levels of importance they assigned to each of these types of environmental impacts were more or less similar across firms from these three states with slight variations.

Figure 4.1: Predominant Environmental Impacts from Pharma Units (Andhra Pradesh)

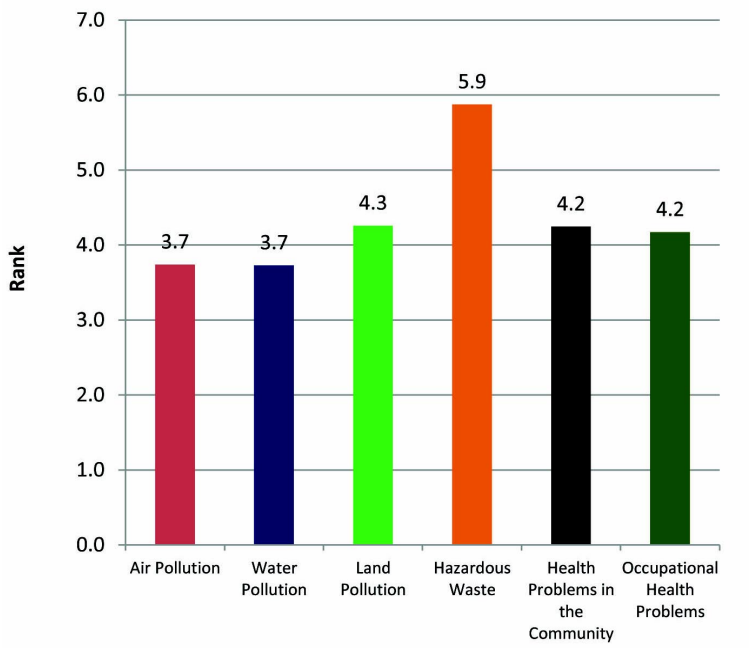


Figure 4.2: Predominant Environmental Impacts from Pharma Units (Gujarat)

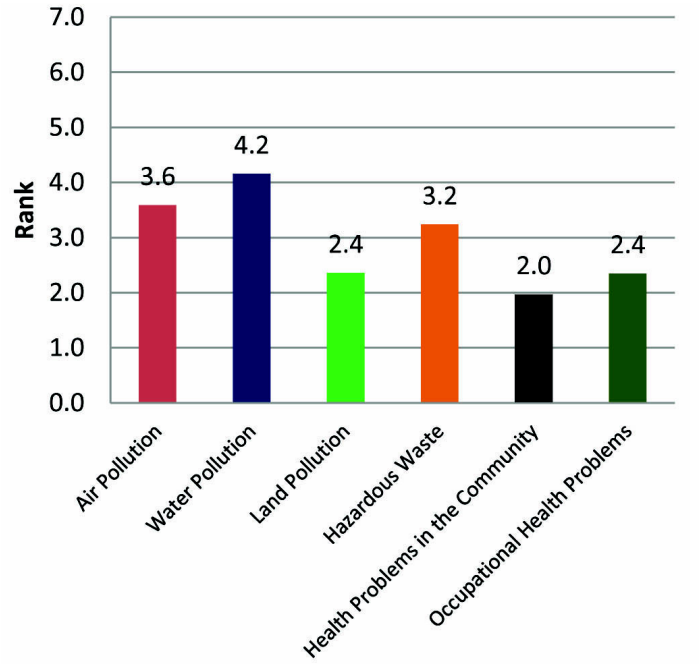


Figure 4.3: Predominant Environmental Impacts from Pharma Units (Himachal Pradesh)

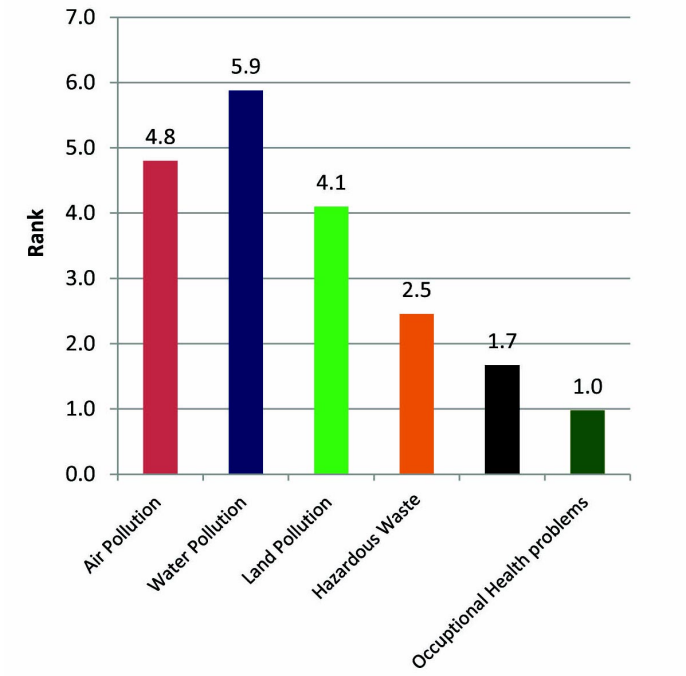
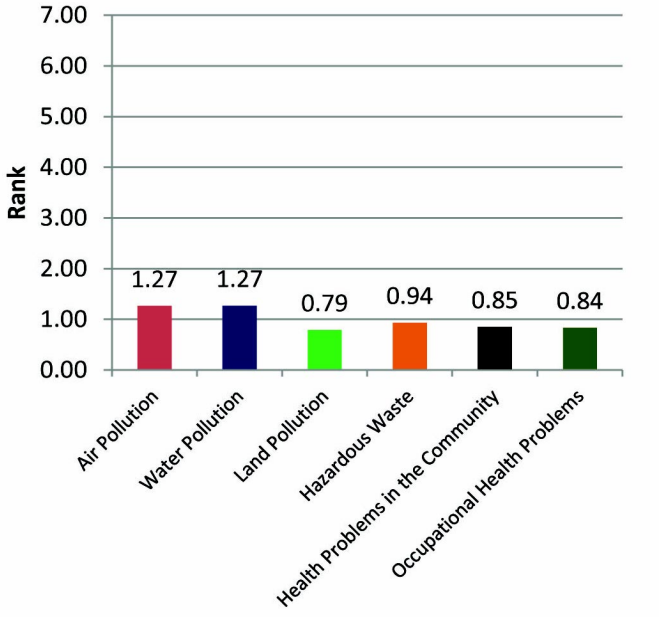


Figure 4.4: Predominant Environmental Impacts from Pharma Units (West Bengal)



However, firms from West Bengal did not seem to consider that there were considerable environmental implications of their operations in the state – as is presented in the Figure 4.1.

Internal Factors

Firm-level resources to mitigate environmental impacts

According to the Environmental Protection Act, as amended in 1991, it is mandatory for firms to treat effluents and spent gases to bring down pollutants within permissible/tolerable limits before they are released into the environment. The standards are specified by the Pollution Control Board. The respondents were asked about the availability of infrastructure within the firms to be legally compliant with the Act.

Table 4.2: Firm-Level Resources to Handle Environmental Impacts

Sl No	States	No. of Firms surveyed in the State	Existence of Environment Management Infrastructure (%)	Firms with Environment Management Department (%)
1	Andhra Pradesh	95	83	69
2	Gujarat	100	80	40
3	Himachal Pradesh	49	87	71
4	West Bengal	51	55	10

There are significant differences across the states in the infrastructure available at the firm level to manage environmental impacts. Most of the firms surveyed in Andhra Pradesh, Gujarat and Himachal Pradesh reported that they possessed *infrastructure to manage environmental impacts*. However, only half of the firms in West Bengal reported having such facilities in place. The absence of such infrastructure among firms could pose significant hazards to the local environment in and around these pharmaceutical units in West Bengal. In order to understand the situation better, the results were disaggregated for the SMEs in the four states as presented in Table 4.3.

It is interesting to note that over three fourths of the SMEs' reported having such infrastructure in place in Andhra Pradesh (81 percent), Gujarat (74 percent) and Himachal Pradesh (74 percent). In contrast, only 55 percent of the SME's surveyed in West Bengal reported possessing such infrastructure.

Table 4.3: Resources to Handle Environmental Impacts in SMEs					
Sl No	States	Total Firms Surveyed	No of SMEs Surveyed	Existence of Environment Management Infrastructure (%)	Firms with Environment Management Department (%)
1	Andhra Pradesh	95	74	81	67
2	Gujarat	100	74	74	26
3	Himachal Pradesh	49	38	74	45
4	West Bengal	51	51	55	10

One explanation can be that these small-scale units in West Bengal are unable to afford the installation of such infrastructure on their own. However, it should be borne in mind that any violation of the environmental standards cannot be tolerated even if firms are small in scale.

One of the often cited reasons for lack of infrastructure is the affordability. However, since several small scale units are often suppliers for large companies, there is a need to investigate the responsibility of large companies to ensure that their suppliers carry out their manufacturing practices in a responsible manner.

Awareness about Good Manufacturing Practices (GMP)

It is well recognised that GMP compliance impacts the extent of environmental pollution dramatically. The questionnaire contained items pertaining to awareness of GMP compliance, the extent of compliance and the factors that result in non-compliance. It is evident from the Table 4.4 that there is a fairly high level of awareness about GMP guidelines among the respondents across all the four states. However, the variation in adherence by the firms to GMP guidelines, especially those aimed at minimising adverse impacts on the environment, across the four states is significantly different.

Table 4.4: GMP Compliance (Environmental Aspects) All Firms in States			
Sl No	States	Awareness about GMP requirements (% firms)	Compliance with GMP requirements (environmental impacts) (% firms)
1	Andhra Pradesh	98	93
2	Gujarat	95	80
3	Himachal Pradesh	100	37
4	West Bengal	96	43

Further analysis to check for differences in compliance between SMEs and large enterprises across the four states, did not show any differences. It appears that compliance in general appears to be weak in Himachal Pradesh and West Bengal.

Figure 4.5: Environmental Infrastructure and Level of Compliance in Pharma Firms

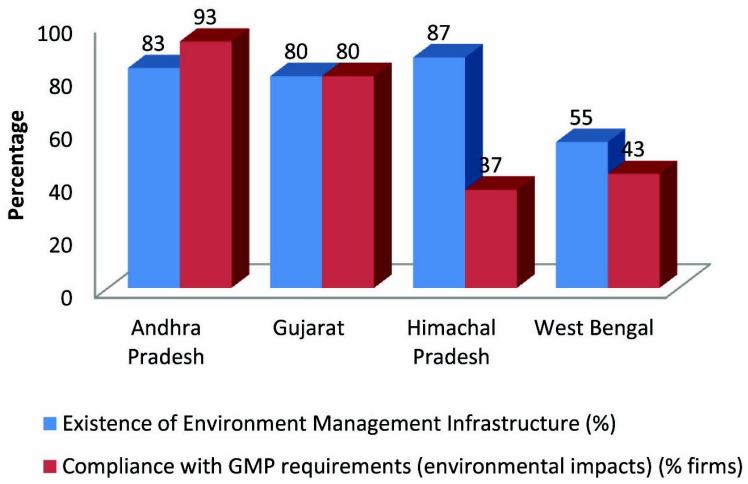


Figure 4.5 compares the extent of environmental infrastructure present in firms and the level of their compliance.

The situation is interesting in the case of Himachal Pradesh, where in spite of the fact that most firms reported to have made investments in the infrastructure to deal with environmental impacts, only about a third of the firms surveyed indicated that they were in compliance with all the GMP requirements. It appears that weak enforcement of the GMP requirements could be a major reason for this discrepancy.

During the last decade, the Government of Himachal Pradesh has made considerable efforts to boost economic development with support and incentives to industries (including tax holidays). Therefore, it is likely that the investment in the environmental infrastructure might not have had a significant financial implication for the firms, as the government provided incentives and 'tax reliefs' for establishing pharma units in the state. With Himachal Pradesh emerging as the 'new' hub of pharmaceutical manufacturing in the country, the strict enforcement of the GMP requirements might not have been considered as a priority.

Interviews with key respondents from the Himachal Pradesh Pollution Control Board (HPPCB), indicate that while they have been stringent in dealing with polluting firms including issue of orders to state electricity board (SEB) to disconnect electricity supply to firms that are chronic defaulters on environmental performance, the law does not empower the state pollution control boards to impose fines. Actions commonly taken by the HPPCB and indeed other state pollution control boards are to cut off electricity and water supply for such firms violating environmental standards for a period of 15 days. Such action is initiated by the state pollution control board with support of the SEBs.

The Gujarat Pollution Control Board (GPCB) has also resorted to similar actions (of cutting electricity supply) for delinquent firms. Any enforcement of environmental legislations by state pollution control boards requires co-ordination across different departments within the state government. In the absence of such concerted co-operation across different departments, defaulters go without punishment. There is also a need to strengthen the position of the state pollution control board by empowering them to penalise firms that violate environmental standards.

How can firms handle the environmental effects proactively?
An interesting finding was that many firms across the four states felt that environmental impacts of their businesses can be best addressed by bringing it to the attention of their senior management and in board-room discussions. In Himachal Pradesh and Gujarat, several respondents believed that the government and/or state pollution control boards were well equipped to handle these issues, and hence engaged proactively with the state machinery to deal with this issue. In Andhra Pradesh and West Bengal, only a few firms engaged with the state government/state pollution control board, which reflects a poor level of cooperation between the business community and the state government on environmental issues.

In Himachal Pradesh, a number of firms thought that the industry associations can also play a key role in handling issues related to their impacts on the environment. One of the reasons for high expectations of pharmaceutical firms in Himachal Pradesh is the support/incentives that the industry has been receiving from the state government. The key question, however, would be how much and how far can the government continue to provide such economic incentives? Firms in Andhra Pradesh and West Bengal have had a much longer history of engagement with their respective government agencies, and it appears that their confidence in possible interventions by state government agencies for improving environmental performance is rather low.

Table 4.5: Improving Environmental Performance (All Firms)				
States	Responses by Firms (%)			
	Inclusion in board-level discussions	Interacting with other firms	Raising it with the pharma associations	Engaging with the Govt/SPCB
Andhra Pradesh	38	24	15	17
Gujarat	54	18	26	42
Himachal Pradesh	61	45	41	51
West Bengal	69	43	23	29
Note: Firms provided multiple answers to this question				

In Gujarat, a state with a fairly long history of industrial development, a continued belief in the ability of the government to support the firms is an indicator of congenial state-business relations. Evidence suggests that the attitude of the state government towards industry in the state of Gujarat has been quite supportive. The approach has been to try and find solutions together. It is also interesting to note that not many firms in Andhra Pradesh, Gujarat and West Bengal believed that environmental issues should be included in the agenda of state pharma associations.

In case of SMEs there seem to be a clear inclination towards improving self-regulation, as was also found in the mixed population of all firms across the four states. However, there was a much higher tendency of SMEs to learn from each other and cooperate with each other for achieving the desired environmental performance.

Tables 4.5 and 4.6 raise two interesting questions – is there a need to engage the owners/senior managers of the firms in the sector more actively in both the compliance and voluntary environmental compliance aspects?

Table 4.6: Improving Environmental Performance (SMEs)				
States	Responses by SMEs (%)			
	Inclusion in board-level discussions	Interacting with other firms	Raising it with the pharma associations	Engaging with the Govt/SPCB
Andhra Pradesh	53	57	47	16
Gujarat	47	16	19	35
Himachal Pradesh	58	39	34	42
West Bengal	69	43	23	29
Note: Firms provided multiple answers to this question				

What is the nature of economic incentives that require to be structured to continue to maintain responsible behaviour at a firm level?

To summarise, it can be inferred that while environmental infrastructure exists (largely) across all the states, their compliance with the environmental regulation is weak. The expectation from the firms is that the govenrment will continue to provide financial support and incentives. However, the state level differences on the expectations from the government and the regulation is significant. Such differences across states throw some important questions on the manner in which enforcement of the law has to be done. There is also a need to invest more significantly in the education of the firms – both at the senior management /owner and board level to further the agenda on corporate conduct.

External Factors

Nature of support received from government

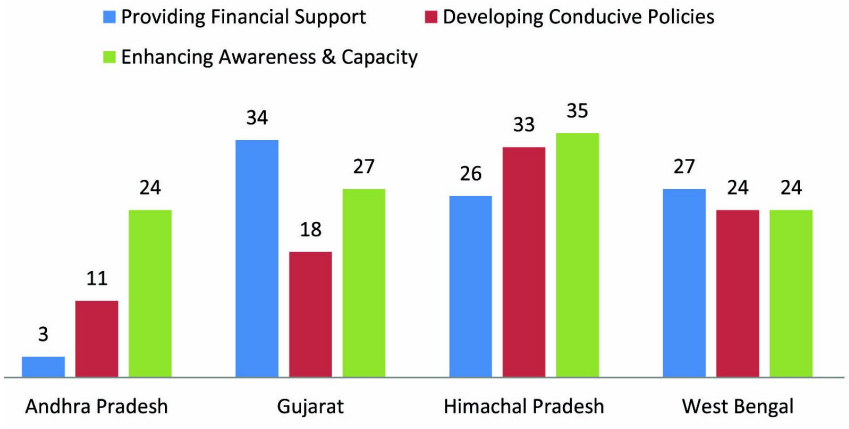
Nearly three-fourths of the firms surveyed in Himachal Pradesh (73 percent) received technical support from the government for managing the environmental infrastructure they had installed. The level of support in other states was fairly low. Most of the firms (80 percent) in Gujarat reported that they had not received as much assistance as they hoped for from the government. Two in every third firm surveyed (67 percent) in West Bengal reported that they did not get government's assistance in dealing with the pollution related issues. Consequently, it was found that while many firms in Himachal Pradesh (51 percent) were keen to engage with the government, only a few (17 percent) in West Bengal were inclined in doing so. It is evident that the expectation from the government in the field of support on environmental infrastructure continues to be high, while the actual support is really low.

When asked about the role that the governments could play for promoting better environmental compliance in the states, an interesting trend emerged. Most of the firms across the four states expected the government to provide technical assistance through capacity building programmes (to

Table 4.7: Analysis of Surveyed Firms

Sl No	States	Lack of Govt support (%)	Keenness to engage with Govt (%)
1	Andhra Pradesh	45	14
2	Gujarat	80	42
3	Himachal Pradesh	8	51
4	West Bengal	67	17

Figure 4.6: Support Expected from the Government (Firms)



Note: Not all firms provided answers to this question

raise awareness about existing rules, etc.). This was followed by a number of firms expressing the need for increased financial support from the government to meet their environmental responsibilities. The third expectation was the number of firms which expected government to play the role of an 'enabler' or 'facilitator' of the industry in the state. What does this role of enabler/facilitator involve requires further investigation.

What type of regulation can deal better with environmental impacts?
One of the key aspects of the BRCC project is to assess the extent of confidence that exists for various kinds of regulations (public regulation, co-regulation and self-regulation) in controlling environmental impacts of pharmaceutical units across the four states.

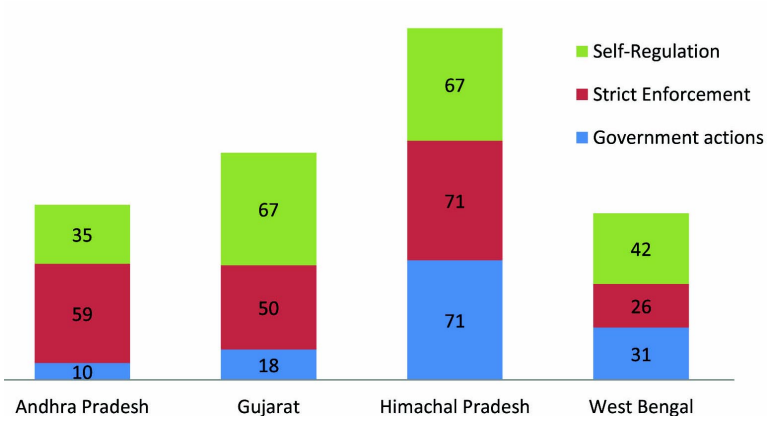
Table 4.8: Firm Confidence in Types of Regulation (%)

States	Government Actions	Strict Enforcement	Self-regulation
Andhra Pradesh	10	**59**	35
Gujarat	18	50	**67**
Himachal Pradesh	**71**	**71**	67
West Bengal	31	26	**42**

Note: Firms provided multiple answers to this question

In Gujarat and Himachal Pradesh, a majority of the firms surveyed thought that self-regulation was the way forward for dealing with their environmental responsibilities. In West Bengal, however, there was no clear direction on the most effective method of regulation. Nearly a third

Figure 4.7: Confidence in Regulation (Firm Responses, in %)



of the surveyed firms were in favour of some government actions. However, in Himachal and Andhra Pradesh firms were in favour of strict enforcement of rules and regulations. Firms in Himachal Pradesh were the only ones to have a very strong affinity for government action to help them improve their environmental responsibilities. The feedback from Himachal Pradesh firms continues to point towards the high level of expectation the firms have from the government. In Gujarat, there was a strong inclination towards self-regulation.

The GPCB has changed its strategy of regulation over the last 5-7 years and acts mainly as a 'mentor' (they call themselves *doctors*, which is different from their earlier role of being *police*) by helping firms improve their internal environmental compliance standards themselves. This is different from GPCB's erstwhile *avatar* of being a strict and ruthless regulator, strongly penalising firms for polluting the environment. The current approach of GPCB seems to be giving positive results. In Andhra Pradesh, strict enforcement clearly seems to be the suggested way forward.

Determinants of firm behaviour vis-à-vis regulatory actions

One of the key aspects that the present study examined was to highlight factors that determined firm's approach/behaviour towards dealing with their environmental impacts. Firms were asked to respond if their behaviour in dealing with environmental performance was determined by: financial losses, reputational losses or government actions against them.

Almost half of the firms surveyed in West Bengal were afraid of having to face financial losses as a result of regulatory actions by the West Bengal Pollution Control Board – which would hurt the SME dominated

Table 4.9: Feedback about Impact of Regulatory Actions (%)			
States	Financial loss	Reputational loss	Government actions
Andhra Pradesh	39	**71**	64
Gujarat	**39**	25	18
Himachal Pradesh	**59**	**59**	53
West Bengal	**48**	18	30
Note: Firms provided multiple answers to this question			

pharmaceutical sector in the state badly. Most firms in Andhra Pradesh were worried about reputational losses as a result of such actions, since several of them were a part of the global supply chains in the export markets in Europe and North America. In Himachal Pradesh, many firms expected to face both financial and reputational losses as a result of actions taken by the state pollution control boards. Such a feedback from the business community is understandable given the enthusiasm of the state government and the business community to attract more investments, which might be affected due to regulatory actions.

In Gujarat, firms were neither worried about reputational losses nor financial losses too much as a result of regulatory actions. Only half of them believed that strict enforcement was the way forward. The responses received from firms in Gujarat convey an interesting element about entrepreneurship in the state. It is evident that the firms are focussed only on doing business in the state. The business community has received considerable support and cooperation from the state government over the years, and have such expectation the in future as well.

Such an attitude (expecting the state machinery to be an enabler/facilitator of business) is demonstrated by them even when they have to deal with strict regulators like the GPCB. Such behaviour by firms forced the GPCB also to change their own approach and strategy of interacting with firms in the state. Pharmaceutical firms from West Bengal had little confidence in regulatory actions helping improve their environmental responsibility.

Variation in application of regulation

A large majority of firms in West Bengal, Andhra Pradesh and Gujarat advocated for the need to apply environmental regulations differently depending on the size of the firms. Less than half of the firms in Himachal were in favour of any such arrangement for differential enforcement of environmental regulations depending on the size of the firms.

Table 4.10: Application of Regulation				
Sl No	**States**	**Firms In favour (%)**	**Firm not in favour (%)**	**Firms not sure (%)**
1	Andhra Pradesh	76	24	0
2	Gujarat	72	24	4
3	Himachal Pradesh	43	37	20
4	West Bengal	84	6	2

Interaction between regulator and firms:
The BRCC project partners with their nuanced understanding of the context in their respective states, provided overarching insights which were more holistic and systemic. Such assessments (which included personal interviews and discussions) go beyond the objective and quantitative analyses to provide subjective and qualitative information related to the interplay between regulation in the pharmaceutical and behaviour of firms at the state-level. An attempt has been made through Table 4.11 to capture the institutional contexts in the four states and also provide a brief discussion of the unique aspects. This section also informs the emerging conclusions presented and discussed in Chapter 5.

It was observed by the GPCB officials that the environmental performance of the pharmaceutical firms in the state had improved substantially over the last 10 years. The reasons that were cited by them were:

- implementation of dedicated pollution monitoring programmes (e.g., Comprehensive Environmental Pollution Index) in pollution hot-spots in the state like Vapi, Ankhleshwar and Ahmedabad;
- improvement in the environment management infrastructure in the state;
- strengthening the nature and degree of communication with pharma units and their associations in the state; and
- change in the attitude of dealing with environmental problems in the state. The GPCB has transformed its attitude to that of a 'doctor' from that of a 'policeman' in dealing with the pharmaceutical units (and/or other industries in the state). This implies that GPCB officials try to understand/diagnose problems being faced by industries to meet the requirements under the environmental legislations, and assist them accordingly – rather than cracking down on them if their environmental performance is not up to the mark.

In Andhra Pradesh, interviews with the respondents in the Andhra Pradesh Pollution Control Board (APPCB) revealed that the agency had adopted a number of measures to stimulate good practices among the firms.

Table 4.11: Institutional Contexts in Four States	
States	**Some Elements of Government-Business Interaction**
Gujarat	- Long history of the pharmaceutical industry - Sector seen as critical in economic development not only of the state but also its contribution to the country - Installation and operation of pollution mitigation infrastructure has often happened through state government support - Strong compliance with the law with penalties - Facilitating role played by the regulator to enable industry
West Bengal	- Ambiguous signalling on the importance of the sector to the state - Very weak (often absent) infrastructure for pollution mitigation - State Government support to create the infrastructure not apparent - SME's (including a large number of small-scale units) constitute a large part of the pharma sector in the state - Regulator (WBPCB) not perceived as an effective entity by the industry - Ministry of MSME (Government of India) under its Cluster Development Programme can become an institutional actor in the state
Andhra Pradesh	- Existence of large firms and export orientation very high - Regulator (APPCB) decisions not consistent - Regulator criticised by both industry and the environmentalists - Pharma company owners would like the regulator to demonstrate higher and consistent compliance
Himachal Pradesh	- Late entrant to the industry - incentives have been provided to boost the industry/state economy - High expectation from the regulator for a strict regulatory oversight, given the nature of the state - HPPCB role critical given the geo-diversity of the state/ region - Evolving institutional structures at the state has implications for businesses

However, the dominant focus has been one of a 'carrot and stick' principle. Some of the recent decisions pertaining to the pharmaceutical industry in the state have been quite controversial. In July 2012 APPCB ordered closure of 12 pharmaceutical companies in Ranga Reddy and Medak districts,

since these violated the environmental legislations and accused them of producing drugs in excess of quantities for which they had received permission. This enraged the bulk drug manufacturing association, which filed a case with the appellate authority. The tribunal of the APPCB subsequently lifted the ban in October 2012 providing relief to the industry, a decision that was not welcomed by the stakeholders concerned with the environmental impacts of industries in the state.

In November 2012, it was rumoured that the APPCB was planning to quash a 15-year moratorium imposed on the expansion of bulk drug industries in Patancheru-Bollaram, one of the 24 most critically polluted areas in India. This news drew strong reactions from environmental activists and academics in the state. In December 2012, it was reported that the APPCB was likely to order closure of as many as 50 pharma and chemical units that have been reported to be repeatedly flouting the environmental standards. However, evidence also suggested that certain 'good practices' have been initiated by the pharma industry to address possible adverse environmental impacts as under:

- improved solvent recovery systems;
- efforts made towards zero liquid discharge systems;
- recovery of by-products;
- segregation and sending high calorific wastes to cement plants for co-processing.

It is evident that there have been several incidences leading to tensions between the regulator and industry in Andhra Pradesh.

In the case of Himachal Pradesh, since the pollution had reached alarming levels in the Baddi-Barotiwala-Nalagarh Industrial Area (BBIA), the Supreme Court intervened and ordered the state government to draw up a plan for addressing environmental problems in the area. Consequently, a Common Effluent Treatment Plant was recently installed. The HPPCB has a regional office in the BBIA area to monitor the environmental performance of the firms in the region. However, it appears that lack adequate human resources is preventing effective execution of the environmental issues in the area.

West Bengal Pollution Control Board (WBPCB) categorises Bulk Drug & Pharmaceutical industry under 'red category', which implies that these units cannot be established in the Kolkata Metropolitan area. The state industrial policy (developed under the aegis of the West Bengal State Industrial Development Corporation), considers the pharmaceutical industry as an important industry in the state, and hence the state pollution

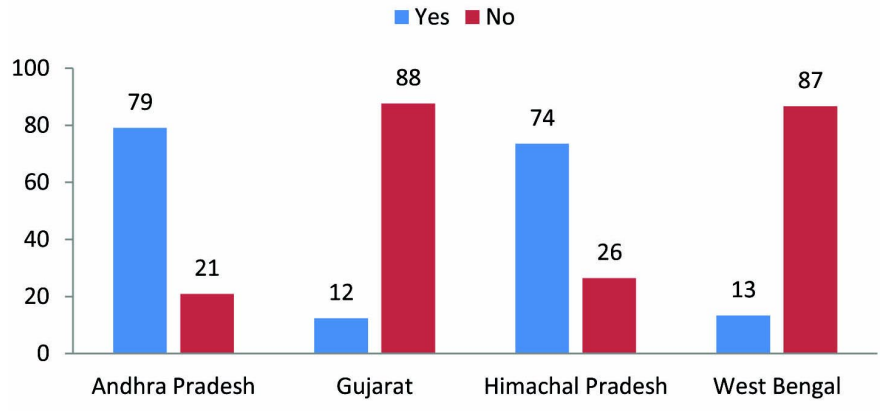
control board has often been considered to be a bit lenient in its approach towards these units in the state. This explains why there has not been much action in spite of the fact that many of the (small) pharma units in the state have operated without pollution abatement infrastructure.

On the basis of the information gathered from the four states, the need to adopt different approaches to regulation under different conditions/ circumstances becomes clear. One size fits all approach of regulation is not applicable across all actors. Therefore, it would be worthwhile exploring if state level regulatory regimes (dealing with environmental issues in pharma sector) can be so designed that they are flexible enough to accommodate *in-situ* regulatory improvisations.

Role & functions of pharma associations

The interviews with the respondents from the industry associations across the four states show significant differences. The pharma associations in Andhra Pradesh and Himachal Pradesh have been active in helping the pharma units to address their environmental impacts. Firms in Gujarat and West Bengal on the other hand did not get much assistance from their associations. An analysis of the clauses in the Memorandum of Association reveals that monitoring the conduct of their member companies is not mentioned as a role of the association.

Figure 4.8: Assistance Received by Firms from Associations



Engagement with relevant government departments/agencies

While the respondents from the associations across the states mentioned that they often interacted with the relevant government departments/ agencies, it was clear that these interactions were largely 'reactive' rather than being 'pro-active' or 'consultative'.

The respondents mentioned the following aspects of their interaction with the Government:

- Notices: Regulators issue notices to control/curb unwarranted actions of pharma firms/associations;
- Litigation: In many instances interactions between the pharma association and government departments/entities happened mostly during litigation (e.g., BDMA vs APPCB case in Andhra Pradesh);
- Outreach programmes: State governments have used the pharma association as a platform for propagating information, news (e.g., in Gujarat there is some evidence of such programmes having been undertaken).

There was no evidence of any institutionalised process of interaction between the pharma associations and relevant government departments/ agencies in any of the state pertaining to addressing the issue of environmental pollution.

To summarise, there is clear evidence that the size of the sector and its importance to the economy of the state have an impact on the nature of engagement between the regulator and the firms (and the structure and function of the regulatory apparatus designed by the state). It is interesting to note that the role of the regulator (in terms of their definition of their roles and the industry's perception of the regulator) has been varied. While the industry expects the regulator to enforce strict compliance across the four states, the regulators themselves have played varied roles across the states, depending on various circumstantial, historic and cultural factors. This was witnessed in the approach adopted by the different state pollution control boards covered under the project. Some of them have introduced a certain degree of flexibility in their approach in dealing with business in an attempt to play the role of a facilitator. Others have maintained a very rigid approach when it comes to dealing with businesses. However, in both the cases incentives have worked equally well – irrespective of the attitude of the regulators towards the business.

There is a need to understand more deeply the changing role of the regulator in the four states. One of the interesting and positive aspects of the study is the conviction of the respondents across the four states that if environmental management became a board level agenda in the firms it is likely to be addressed better. This offers an opportunity to explore the role of incentives and voluntary self-regulation by firms. Finally, it appears that the industry associations have played an insignificant role in aspects pertaining to environment in the pharma industry. While this is a source

of concern, it also provides an opportunity to engage in a discussion on the role of co-regulation for the sector through the industry association.

Private Healthcare

The private healthcare sector in India contributes significantly to the healthcare delivery system in the country. As a part of the BRCC project, the study covered **262 private hospitals** across the four states. The number of hospitals surveyed from each of the states is presented in Table 4.12.

Table 4.12: Number of Private Hospitals Surveyed

States	Total private hospitals surveyed
Andhra Pradesh	72
Gujarat	100
Himachal Pradesh	40
West Bengal	50
TOTAL	**262**

The Central Government implemented the Bio-Medical Waste Management and Handling Rules in the year 1998. The responsibility of the implementation of these rules was allocated to the state governments, and each state was expected to devise its own strategy for the management, handling and disposal of bio-medical waste (BMW).

Effective management of BMW by private hospitals comprise the most important element of environmental responsibility of the private healthcare sector.

This section of the report present analyses of information pertaining to various elements of bio-medical waste management gathered from respondents/stakeholders of private healthcare from the four project states. Proper handling, management and disposal of bio-medical waste is considered as a critical component of the social and environmental responsibility of private hospitals.

Internal Factors

BMW management methods

Data from the respondents from the private hospitals across the four states shows that in all these states, private facilities play a critical role in the disposal of BMW. In Gujarat the hospitals had agreements with private companies to manage BMW. There are 14 different private companies

Box 4.1: AMC, GPCB Lock Horns Over 'Missing' Biomedical Waste

The Ahmedabad Municipal Corporation (AMC) and Gujarat Pollution Control Board (GPCB) are playing a blame game over the biomedical waste (BMW) that has mysteriously gone missing from the sealed scrap warehouses.

On April 4, when the GPCB officials visited the sealed warehouses - AMC had earlier conducted raids on places trading in biomedical waste - they found that the waste material was missing. AMC's medical officer SP Kulkarni said, "GPCB is responsible for delayed action. Why blame the AMC?"

Sources in GPCB are however blaming AMC officials, saying they handed over the warehouse keys to dealers who shifted the biomedical waste. But AMC has a different story to tell. They say they had sealed nine godowns in February after these were found trading in the biomedical scrap. The civic body then intimated the GPCB about it on March 03, asking them to dispose the waste since they were the licenced authority for it.

A source in the AMC says, "GPCB told us that once we open the seals of the warehouse, the waste will be disposed in five days." Following this, on March 24, the corporation opened the seals of all warehouses and had scrap dealers sign on stamp papers stating they will not deal in biomedical waste. GPCB was also intimated about it. "But they took no action. We reminded them again on March 30. But they made a visit to the warehouses on April 4. It is GPCB that gave them more than 10 days. Isn't that time enough for the scrap to go 'missing'?" said another AMC official. Regional officer of GPCB K C Mistry was unavailable for comment.

(Source: Ahmedabad Mirror, April 08,2009)

across Gujarat that collect, treat and dispose bio-medical waste from hospitals in the state. About half of the private hospitals covered in the other three states also had agreements with private providers. In these three states, private hospitals also relied on common facilities for disposing their bio-medical wastes.

Awareness of and adherence to BMW Rules

As far as responses pertaining to awareness of the BMW Rules are concerned, it was noted that almost all the private hospitals covered in the survey from Gujarat and West Bengal were aware about this legislation. However, the level of awareness was moderate both in Himachal Pradesh (69 percent) and Andhra Pradesh (62 percent).

Figure 4.9: Resources Available to Deal with BMW, % (Andhra Pradesh)

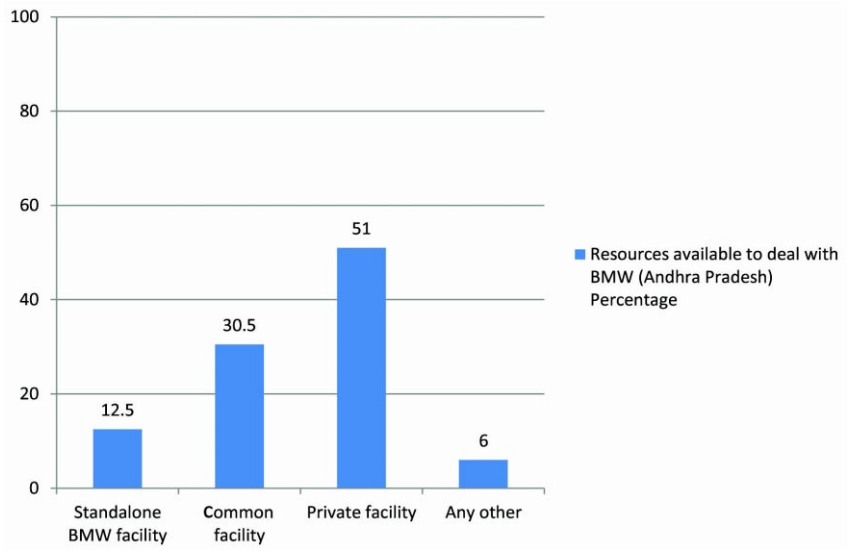


Figure 4.10: Resources Available to Deal with BMW, % (Gujarat)

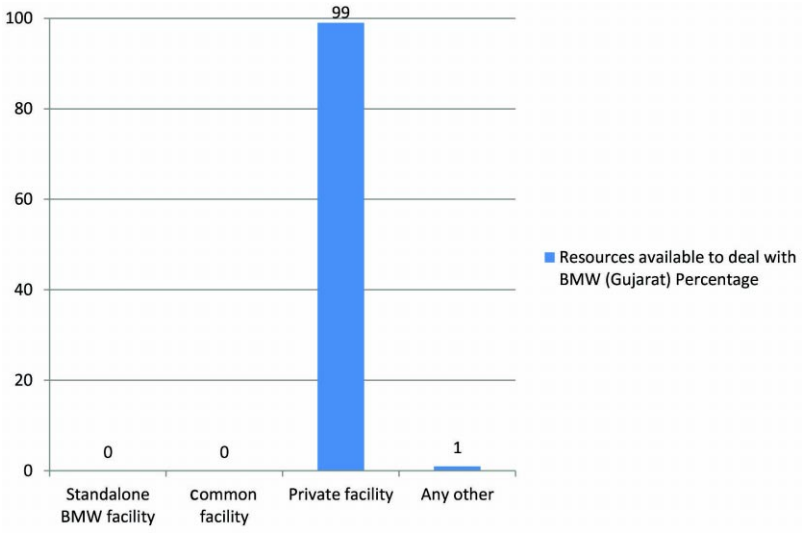


Figure 4.11: Resources Available to Deal with BMW, % (Himachal Pradesh)

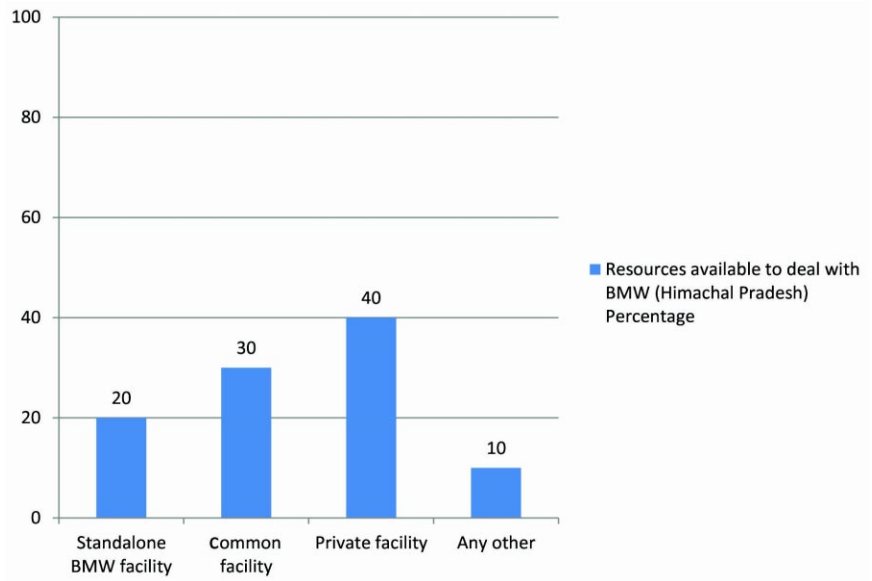
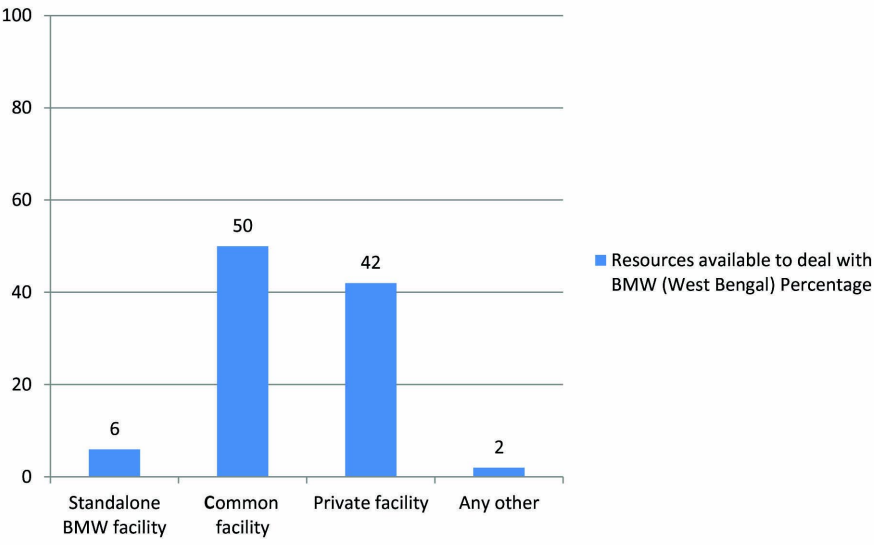
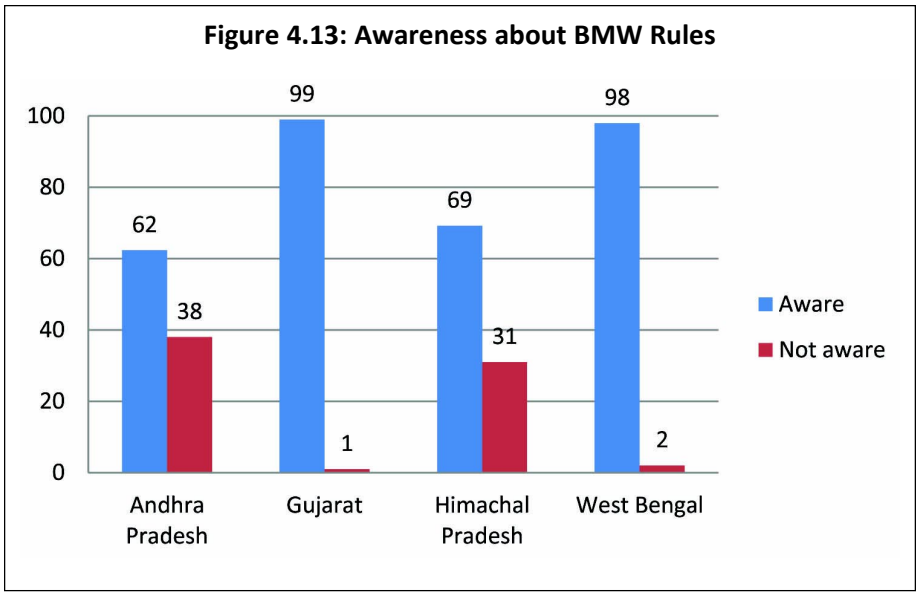


Figure 4.12: Resources Available to Deal with BMW, % (West Bengal)



Reporting on BMW

According to the Section 10 of the BMW Rules it is necessary that, "Every occupier/operator shall submit an annual report to the prescribed authority on Form 11 by 31 January every year, to include information about the



categories and quantities of bio-medical wastes handled during the preceding year". Respondents were asked whether they submitted reports as per the BMW rules. The variations across the four states were quite significant.

Most of the private hospitals which indicated submitting reports regularly in West Bengal (96 percent) and Gujarat (90 percent), did so to the respective State Pollution Control Boards. In Andhra Pradesh, while 75 percent of the surveyed hospitals submitted these reports to the Andhra Pradesh State Pollution Control Board (APPBC), about a fifth of them (20 percent) shared these reports with other state government departments. Similarly in Himachal Pradesh nearly a third of the hospitals (28 percent) shared their report with state departments, while a majority of them (63 percent) shared these reports with the HPPCB. However, it seems that a large number of hospitals in Gujarat were not submitting these annual reports to the state pollution control board.

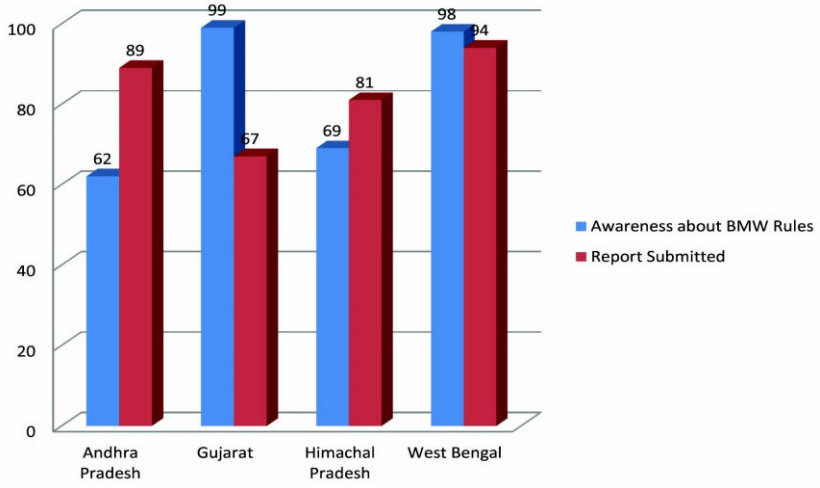
When asked whether they submitted any periodical report to government department/regulatory authorities, most of the surveyed hospitals in West Bengal (94 percent) and Andhra Pradesh (89 percent) indicated they did. Nearly a fifth of the hospitals (19 percent) surveyed in Himachal Pradesh indicated that they did not. In the case of Gujarat, a third of the surveyed hospitals (33 percent) did not submit such periodic reports to the relevant authorities.

This gap in the case of Gujarat is particularly significant. Through interviews with key respondents, attempts were made to understand the gap. Interviews revealed that a small team of staff dedicated to BMW management within the GPCB, seem to have invested a great deal of effort in promoting awareness about the rules among private hospitals. However, their effectiveness in developing background information about the state of BMW in the state is weak because of lack of strong tracking mechanisms.

Table 4.13: Interviews with Key Respondents

Sl. No.	States	Awareness about BMW Rules (%)		Submission of compliance reports (%)	
		Aware	Not Aware	Report Submitted	No Report Submitted
1	Andhra Pradesh	62	38	89	11
2	Gujarat	99	1	67	33
3	Himachal Pradesh	69	31	81	19
4	West Bengal	98	2	94	6

Figure 4.14: Awareness of Rules vs Submission of Report



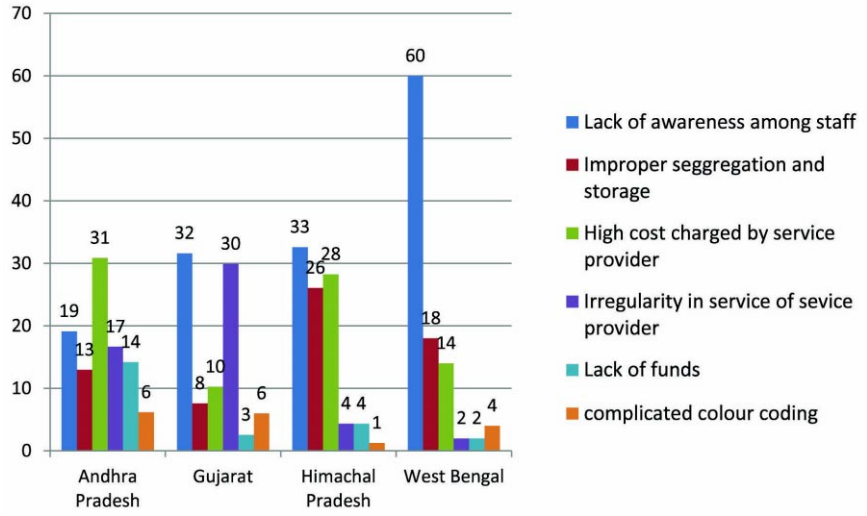
Challenges/difficulties faced by hospitals

It is evident from Table 4.14 that the low level of awareness among the hospital staff was the biggest concern in Gujarat, Himachal Pradesh and West Bengal. In Andhra Pradesh, high charges by service provider emerged as a constraint faced by hospitals. In Himachal Pradesh a large section of the surveyed hospitals also listed high cost of the service as a constraint.

In Gujarat, irregularity of the service provider was also mentioned by a third of the hospitals surveyed.

It is very interesting to observe that there are mixed challenges mentioned by hospitals surveyed in the four states in dealing with the BMW. The significant among those are lack of awareness and training regarding handling of bio medical waste among the hospital staff and high cost per bed charged by the private BMW management entity. Only a sizeable section of hospitals in Himachal Pradesh mentioned improper segregation and storage of waste as a challenge.

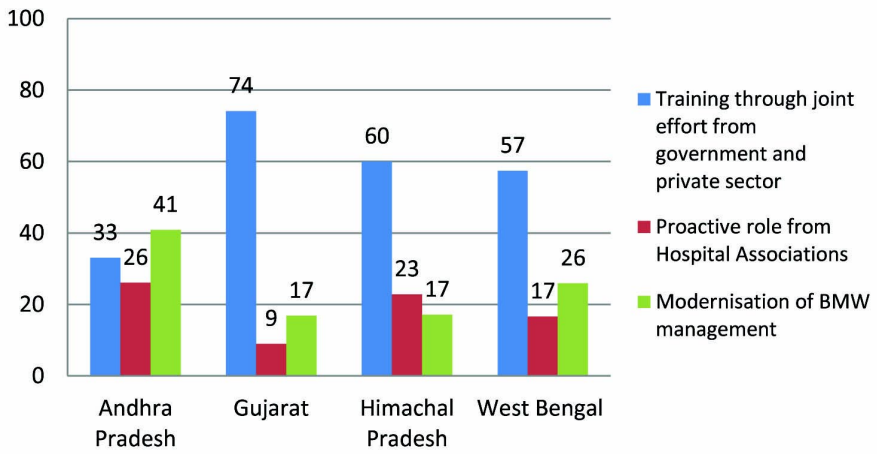
Figure 4.15: Challenges in Dealing with BMW



Feedback from Private Hospitals

When asked about suggestions/recommendation to overcome these challenges, most hospitals from Gujarat, Himachal Pradesh and West Bengal stressed on the need for the state governments to provide training/ capacity building support for managing BMW, as the state governments did in case of the public hospitals. In AP, however, over 40 percent of the respondents suggested modernisation of the existing system of collection and disposal of the bio-medical waste. The private hospitals had little confidence in the ability of hospital associations to provide assistance in dealing with biomedical waste management issues. In Gujarat the reason is understandable, given the absence of any registered private hospital association there. However, in the other states too – only about a fifth of the hospitals covered in the survey thought that the association could play any part in this matter.

Figure 4.16: Suggestion for Addressing Challenges



Feedback from BMW service provider

In-depth interviews with the BMW service providers provided some insights. The following salient points emerged on analysing the feedback of BMW service providers from the four states:

- Hospital administration across all states was well aware of the BMW Rules, there is need for its proper enforcement by SPCBs.
- Performance of the four states state pollution control boards can be ranked as below:

Table 4.14: Performance of SPCB (Feedback from BMW entities)

States	Excellent	Good	Fair	Poor
Andhra Pradesh			▯	
Gujarat		▯		
Himachal Pradesh	▯			
West Bengal	▯			

- Lack of proper segregation of waste at the source was one of the biggest challenge, and state health departments need to extend training and capacity building support to private hospitals as well.
- Lack of awareness and proper training of hospital staff hampered effective management of wastes in the hospitals.

External Factors

Policies to promote BMW management services

There is a great diversity in the level of engagement of private agencies in the process of collection, segregation and treatment of BMW (referred to as Common Bio-Medical Waste Treatment Facilities, or CBWTF) in the four states according to the data available from the Central Pollution Control Board.[2] Different states have adopted different policies/strategies for this sector.

While in Andhra Pradesh there were 11 different private players, in Gujarat there were 12 providing this service.[3] In West Bengal, only 2 private entities were involved in providing such services, whereas in Himachal Pradesh there was only one. Availability of BMW treatment and disposal infrastructure and provision of incentives for service providers to take up such work can help in achieving 'zero residual waste' status in the states as far as BMW is concerned.

Even in Andhra Pradesh with such a large number of providers, the APPCB indicated that 30 percent of the BMW still gets mingled with the municipal waste that can have grave public health implications. According to a survey done by DISHA in 2003, only a third of the BMW was actually collected and underwent treatment and disposal in the state.

Given that private healthcare sector across the country is sprawling, this is a market (i.e., BMW management services) that needs to be developed further, and state governments need to strategise accordingly. Exchanges between states that have successfully introduced private participation and those which have not done that so far, could be beneficial and can be pursued.

Table 4.15: Private Hospitals vs BMW Agencies (states)

States	No of Private Hospitals	No of Private BMW Agencies
Andhra Pradesh	759	11
Gujarat	523	12
Himachal Pradesh	52	1
West Bengal	302	2

Role of SPCBs

State pollution control boards have been alert and strict in dealing with BMW. APPCB has been quite active in this area over the years given the state is considered as the medical capital in the country. APPCB issued show-cause notices to 119 private hospitals for flouting the BMW Rules

in January 2012.[4] GPCB has also taken some serious action (May 2012) on 13 hospitals in Palanpur. Earlier the GPPCB had issued notices to f over 500 private healthcare institutions for not renewing their authorisation for disposal of BMW (as per the BMW Rules).

A senior official at GPCB has been given exclusive duties of BMW monitoring and management in the state. While the WBPCB has conducted studies and taken cognisance of the matter, information about actions taken by the agency in recent times was not publicly available. Not much information about actions taken by HPPCB on hospitals was publicly available.

In Gujarat the BMW agencies indicated that they formally engaged on a monthly basis with the state pollution control boards. In West Bengal, such interaction only happened once every six months. BMW entities in Andhra Pradesh and West Bengal reported interacting regularly with the SPCBs, but did not indicate the frequency of such interactions. Efforts to institutionalise such interactions should also involve state hospital associations.

Role of the State Government

The role of the state governments in developing strategies for dealing with BMW is critical. State governments have been found to provide direct training and technical support to public hospitals to deal with their BMW, but don't seem to have any such programme for private hospitals. Private hospitals are expected to manage their own BMW, by securing the service of private agencies.

Through the local administration, the state governments make provisions for Common Bio-Medical Waste Treatment Facilities (CBWTFs) by providing land and also developing the infrastructure, often through a public-private-partnership model. The private entities providing such infrastructure and management support are also accorded the responsibility to provide BMW management services. This involves collection of BMWs from hospitals and their treatment and final disposal at these CBWTF.

The state pollution control boards are given the responsibility to monitor the services provided by these entities to ensure that BMW is regularly collected and disposed according to the set norms. The state pollution control boards thus have a huge responsibility to ensure that BMW (often containing infectious matter) does not get mingled with municipal solid waste and create public health emergencies. State governments still have

to cover considerable ground when it comes to effective management of BMW. This sector needs greater attention both from the state and national government. It also offers considerable scope for private entrepreneurs to start providing these services.

In some states strong political undercurrents and interference were observed in the activities of the state pollution control board. This can impact the autonomy and can affect their independent functioning. While support from the government is necessary in strategic matters to strengthen resources for capacity building and strengthening of regulatory institutions, unnecessary interference is bound to cause negative effects on their functioning. State governments should also encourage development of private hospital associations in the state, like in Gujarat, as that would help them engage more meaningfully with the sector as a whole.

Responsibility in Marketing and Distribution of Pharmaceutical and Private Healthcare

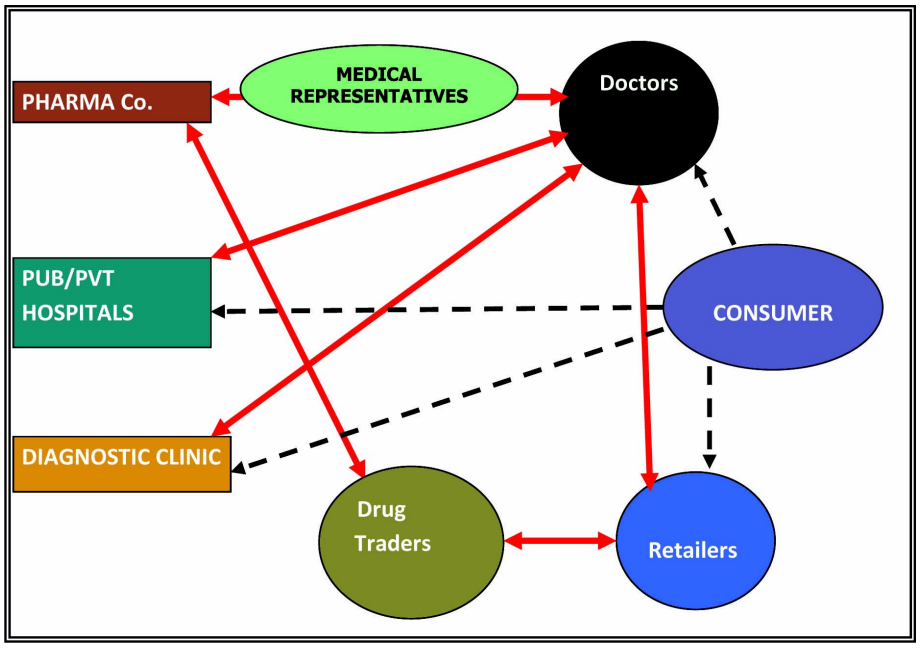
Pharma Sector

Drugs reach consumers from the manufacturing unit after passing through a number of stages and various players, as is presented in a simple flow diagram in Figure 4.17. Interactions among the various players influence the quality and timeliness of drugs reaching the consumers and the cost they pay for it.

The drug marketing and distribution chain in the pharmaceutical industry has been studied extensively in the last decade, both globally and in India. The marketing strategies adopted by the pharmaceutical industry, like incentives to doctors and pharmacists through medical sales representatives, the employment conditions of the sales representatives (steep sales target, long working hours, etc.) have an impact on the quality of drugs and the prices that consumer pay for the same.

Given the nature of complex inter-relationships across the various actors, the BRCC project collected data from the four states.[5]

Figure 4.17: Drug Marketing and Distribution Chain



Internal Factors

Methods adopted by Firms for marketing drugs

The data analysis from the pharmaceutical firms regarding the methods adopted for marketing drugs revealed that sponsoring of events (e.g., meetings, seminars, dinners, etc.) for doctors was a fairly common practice. Nearly half of the firms surveyed in both Gujarat (43 percent) and West Bengal (49 percent) indicated that they periodically undertook such activities. However, in Himachal Pradesh (76 percent) and Andhra Pradesh (85 percent) this practice was widely prevalent.

Further analysis of the data on whether the practice was more prevalent in large companies revealed that a large proportion of SMEs surveyed were also sponsoring events for doctors. The percentage was much less in West Bengal (49) and quite low in Gujarat (15). It appears that this

Table 4.16: Percentage of Firms Sponsoring Events for Doctors

State	Firms (%)
Andhra Pradesh	85
Gujarat	43
Himachal Pradesh	76
West Bengal	49

Table 4.17: SMEs Sponsoring Events for Doctors	
State	**SMEs (%)**
Andhra Pradesh	51
Gujarat	15
Himachal Pradesh	60
West Bengal	49

practice is endemic to the industry; while the conflict of interest is apparent, the extent to which the practice has a direct bearing on doctors' willingness to prescribe requires further investigation. If all companies are engaging in the practice, then what is the basis for the doctor to recommend a drug? This would require a deeper understanding of the nature and type of events sponsored.

The *Indian Medical Council (Professional Conduct, Etiquette and Ethics) (Amendment) Regulations, 2009*, clearly specify that, "……A medical practitioner shall not accept any travel facility inside the country or outside, including rail, air, ship, cruise tickets, paid vacations etc. from any pharmaceutical or allied healthcare industry or their representatives for self and family members for vacation or for attending conferences, seminars, workshops, CME programme etc. as a delegate".

Data was collected regarding the number of medical representatives that were employed by the firm. The respondents were asked questions regarding the objectives of the direct marketing efforts undertaken by the Medical Representatives (MR). An analysis of the state wise data shows some interesting similarities and differences:

Andhra Pradesh

Only half the firms surveyed in Andhra Pradesh, provided information about the number of MRs they had working for them. Most firms employed less than 25 MRs and the highest number of MR's in a single firm was 450. A large majority of firms (85 percent) confirmed that they sponsored events for doctors. Direct engagement with doctors seemed to be the most preferred method for marketing their drugs.

A large number of SMEs (51 percent) also used direct marketing to the doctors as their strategy. About 44 percent indicated that the purpose of supporting conferences and other events was to provide doctors information about their products; nearly a third confirmed that such events also helped them meet their sales targets. 25 percent of the surveyed

firms indicated that these events helped doctors meet the Continued Medical Education (or CME) requirements (set by different state government agencies).

Gujarat

Data gathering on the MR's was the most difficult in Gujarat. Less than a third of the firms surveyed provided the data on MRs employed. Out of those which provided the data, the average number of MR's employed by a firm is 75. The highest number of MR's employed by a single firm in our sample was 3000. Firms adopted different channels to market their drugs in Gujarat. Direct marketing efforts were targeted at doctors, hospitals and chemists.

Many firms (43 percent) indicated having organised events for doctors, while a majority (57 percent) denied having ever sponsored any such events. Only a small section (15 percent) of the SMEs sponsored events for doctors. It is interesting to note that only 50 percent of the respondents in Gujarat answered the question on the benefits that accrued to them by sponsoring events. When this aspect was explored in the interviews, it was apparent that the firms were not comfortable talking about the issue. Over a third (38 percent) of those who responded indicated that providing information about products was the main objectives of these events. Another third (32 percent) of these firms mentioned that these events helped meeting their sales targets. Just over a fourth of them (26 percent) indicated that these events helped doctors in their professional development.

Himachal Pradesh

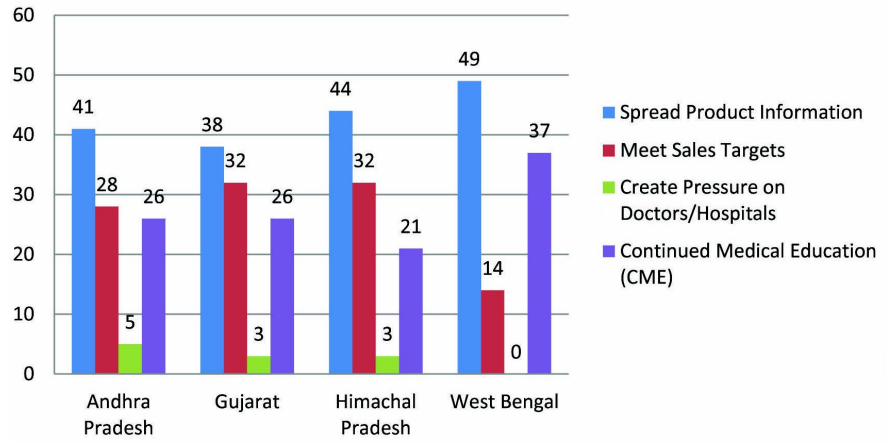
Two-third of the firms surveyed in Himachal Pradesh provided information about the number of MRs they employ. The number of MR's employed by them ranged from 25 – 1600. Direct marketing efforts were targeted at doctors, hospitals and chemists.

Over three-fourth (76 percent) of the firms surveyed indicated having sponsored events for doctors. 60 percent of SMEs indicated sponsoring such events for doctors. Firms were quite open to talk about benefits that they derived from these events. The key benefit as perceived by the respondents was providing information about products (44 percent). A third of them indicated that these events helped in meeting targets.

West Bengal

All the firms shared data on the number of MR's by them. As was mentioned earlier in the chapter, West Bengal had the largest number of

Figure 4.18: Benefits to Firms from Sponsoring Events



SME's in the sample. The number of MR's employed by the firms ranged from 50-400. All firms were using a direct marketing to doctors, chemists and hospitals.

Nearly half of the surveyed firms (49 percent) confirmed having sponsored events for doctors, while half of them denied ever having done so. Only a fraction of them (14 percent) indicated that these events helped firms meet their targets. Over a third of them (37 percent) indicated that such events helped doctors fulfil their CME requirements as per the state norms.

Awareness about relevant regulations

One of the objectives of the study was to understand to what extent the pharma firms were aware of the ethical aspects of the relevant regulations that govern the marketing and distribution activities in the sector. Clause 6.8 of the Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002 developed under the auspices of the Medical Council of India (MCI) specifies that a doctor (or association of doctors) shall maintain professional autonomy and not accept the following favours from a pharmaceutical or allied healthcare company:

- any gifts;
- any travel facilities (for business or professional education/research);
- any hospitality, for example, accommodation in a hotel; and
- any cash or monetary grants.

The data from the pharma companies across the four states revealed (see Table 4.18) that, while many firms were aware of the regulations, but

Table 4.18: Awareness about MCI Regulations 2002 & Compliance (all firms)						
States	Awareness about MCI Regulation			Compliance with MCI Regulation, 2002		
	Yes (%)	No (%)	No response (%)	Yes (%)	No (%)	No response (%)
Andhra Pradesh	58	15	27	12	55	33
Gujarat	35	20	45	9	29	62
Himachal Pradesh	27	51	22	10	43	47
West Bengal	37	41	22	12	35	53

very few had initiated any concrete actions to abide and promote them within their organisations. Lack of awareness about this regulation was fairly high in Himachal Pradesh followed by West Bengal. Firms in Andhra Pradesh were most aware about this regulation.

Awareness of Uniform Code of Pharmaceutical Marketing Practices
In August 2011, the Department of Pharmaceuticals (Government of India) introduced a voluntary code entitled, *Uniform Code of Pharmaceutical Marketing Practices* (UCPMP) to encourage pharmaceutical companies to market their products without indulging in any misconduct. This was in response to the growing concern about the malpractices that pharmaceutical companies often indulge in for pushing their products into the market and eventually to the consumers/patients. The government also announced that the UCPMP would be transformed into a statutory code, if pharma companies are found not to abide by its requirements.

From the responses received across the four states, it emerged that only in Andhra Pradesh is there a fairly good level of awareness about the UCPMP, 2011 (even half of the SMEs are aware of this). In the other three states only about a fifth of the respondents were aware about this code (this was irrespective of whether they were large, medium or small firms).

Table 4.19: Awareness about UCPMP, 2011						
States	Awareness (all firms)			Awareness (SMEs)		
	Yes (%)	No (%)	No response (%)	Yes (%)	No (%)	No response (%)
Andhra Pradesh	61	13	26	52	15	33
Gujarat	21	41	38	16	46	38
Himachal Pradesh	22	55	23	24	71	5
West Bengal	18	61	21	18	61	21

External Factors

Gift seeking behaviour

Since Clause 6.8 of the Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002 specifies that a doctor (or association of doctors) shall maintain professional autonomy and not accept gifts or favours from a pharmaceutical or allied healthcare company, it was decided in the study to ask the pharmaceutical companies whether they gave away gifts to the doctors.

In Gujarat and Andhra Pradesh most of the respondents from the firms mentioned that the doctors sought gifts from the MR's. In West Bengal, less than half of the firms indicated such gift seeking behaviour. In Himachal Pradesh, the prevalence of gift seeking behaviour among doctors as reported by firms was negligible.

Table 4.20: Gift-seeking Behaviour of Doctors (opinion of pharma companies)

States	Doctors seeking gifts	
	Yes (%)	No (%)
Andhra Pradesh	67	33
Gujarat	77	23
Himachal Pradesh	6	**94**
West Bengal	43	57

Since comparable data was not collected from the doctors, we are unsure if there is both a gift seeking and gift giving behaviour. Drawing on the data presented in the tables on marketing strategies, awareness of the regulation and gift seeking behaviour, one could argue that firms in both the states (Andhra Pradesh and Gujarat) seem to have more entrenched relationships through gifts and support to doctors and other channels when compared with the other two states. This could also be due to the maturity of the pharmaceutical industry in these two states. This aspect of the study requires further investigation and the incentives and disincentives for such behaviour need to be examined further.

It emerges from the analysis of firm's opinion that in the case of Andhra Pradesh and Gujarat, firms had to invest in both sponsoring events and providing gifts to remain in the good books of doctors. One of the reasons could be the size of the sector in both the states and cut-throat competition among firms. One could also deduce from the responses received from firms that different firms in these two states relied on different routes for marketing their products; though deeper investigation of this phenomenon

is required. There is a possibility that while some of the firms engaged more closely with the doctors; others seem to engage more closely with the hospitals. A third group engaged directly with chemists. It might be worth investigating if such allocation of marketing methods was being deliberately done by pharmaceutical companies. Firms in Himachal Pradesh seem to be achieving their targets in the state by sponsoring events and don't really need to provide other incentives to doctors.

In West Bengal, some firms (though lesser than Andhra Pradesh and Gujarat) had to rely more on providing gifts to the doctors than sponsoring events. This may be due to their size/turn-over as it is cheaper to provide gifts than to sponsor personal/professional events for doctors. A large number (57 percent) of the firms denied having to provide any gifts to the doctors.

The above analysis would have been well-complemented if the survey could have also gathered opinion from some doctors in the four states about gift-giving tendency of pharmaceutical companies. However, due to various operational reasons this could not be done.

Salary structure of MR's and marketing efforts

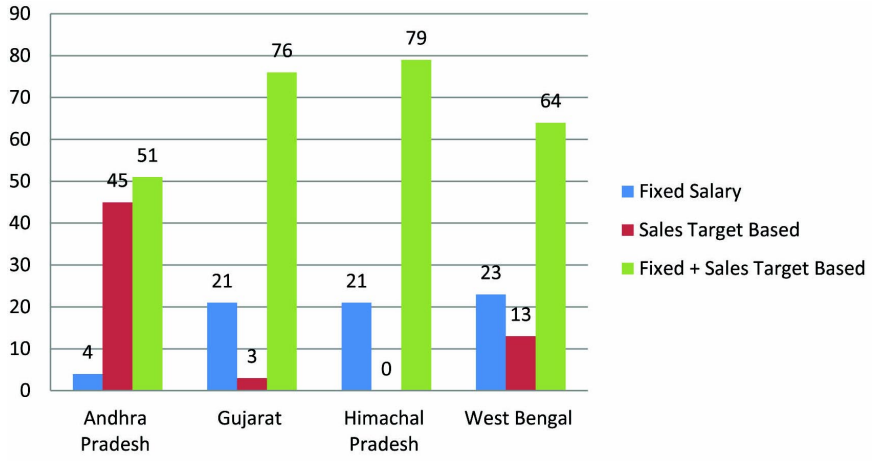
The Sales Promotion Employees (Condition of Services) Act came into being in 1976 on account of efforts made by the Federation of Medical Representatives Association of India (FMRAI), including submitting a petition to the Committee on Petitions in the Parliament of India (Rajya Sabha). It was thought necessary to have a separate legislation to protect the interests of sales promotion employees (including Medical Sales Representatives or MRs as they are popularly referred to), who were not covered under the Industrial Disputes Act, 1947. As a part of the project, data was collected from the firms on the salary structure of the MR's.

The salary structure of the MRs, is 'fixed salary plus target based commission' across all firms in the states. A fifth of the firms surveyed in Gujarat, Himachal Pradesh and West Bengal indicated that they offered fixed remuneration to their MRs. In Andhra Pradesh, 50 percent of the firms followed a system where the salary was based on the 'sales targets achieved in a month. The remaining half of the MRs followed a fixed and variable compensation.

Further, majority of the firms (71 percent in Gujarat and 90 percent in Himachal Pradesh) were not keen on fixing their base salaries. It is evident that converting a fixed salary cost in to a variable cost improves the margins for the firms. However, the overall social security related philosophy of

Table 4.21: Salary Structure of MRs					
States	Salary structure of MRs (%)			Willingness to fix salary of MRs (%)	
	Fixed salary	Sales target based	Fixed + based sales target	Willing	Not willing
Andhra Pradesh	4	45	51	20	80
Gujarat	21	3	76	29	71
Himachal Pradesh	21	0	79	10	90
West Bengal	23	13	64	19	81

Figure 4.19: Salary Structure of MRs in States



the regulation has not yielded the intended effect. The activities of MRs and the regulation of their functions have significant implications on the ultimate availability (and quality) of medicines for consumers. There are not many studies available that have examined this profession in India, and it emerges from the BRCC project that there is a need for the same. Greater overall attention to this profession and its regulation is required.

Private Healthcare

Internal Factors

Awareness about MCI guidelines

A fairly high level of awareness about the MCI Regulations, i.e. Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations 2002 was noted among most of the private healthcare institutions surveyed

Figure 4.20: Awareness about MCI Regulations, 2002

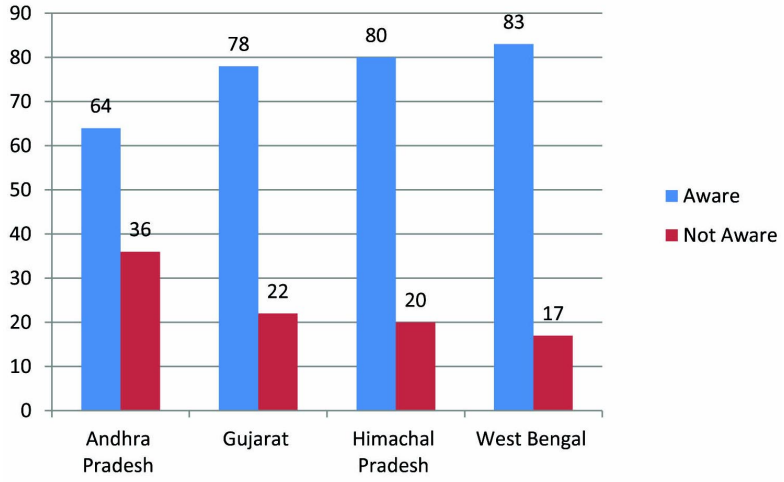
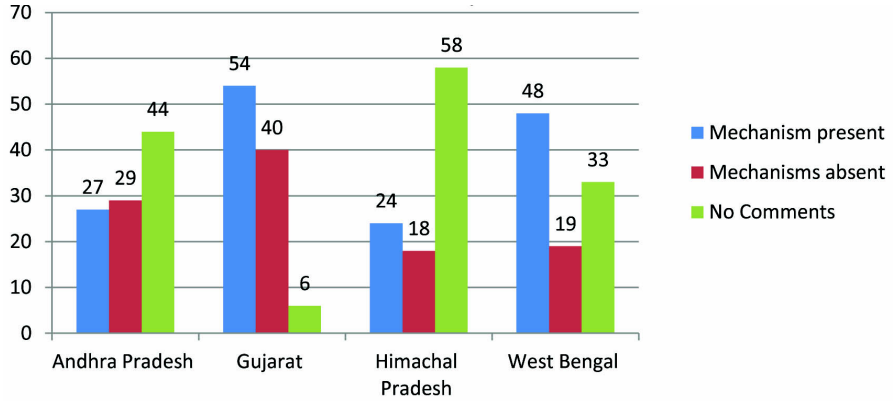


Figure 4.21: Mechanism for Monitoring of Doctors behaviour in Hospitals



in West Bengal (83 percent), Himachal Pradesh (80 percent) and Gujarat (78 percent). However, the level of awareness about this regulation was lower in Andhra Pradesh. More than a third of the private hospitals surveyed in the state were unaware of this regulation. Therefore, only about a quarter (27 percent) of the surveyed hospitals in Andhra Pradesh indicated having any mechanism in place to monitor whether in-house/ visiting doctors were abiding by these regulations.

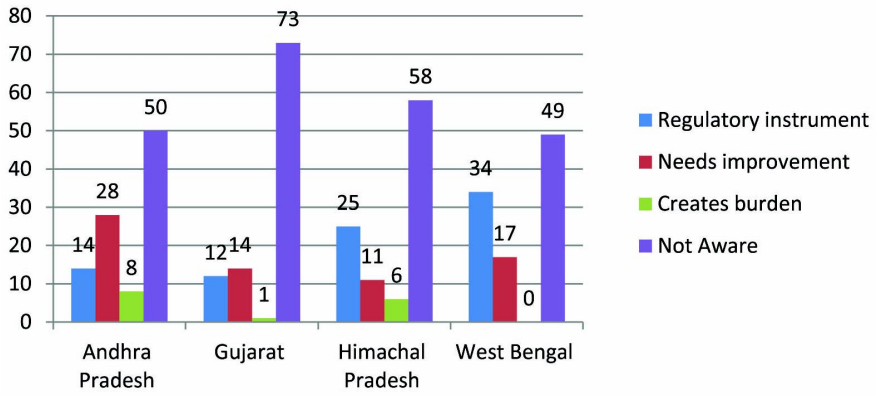
In Gujarat, West Bengal and Himachal Pradesh, while the awareness of the regulation was very high, the mechanisms to regulate the behaviour were not as widely prevalent. What is however interesting is the fact that

a large number of those surveyed did not respond to the question. This is the only question in the survey for which there were a high number of non-responses.

Awareness on UCPMP

There was a considerable lack of awareness among private healthcare institutions about the 'Universal Code of Pharmaceutical Marketing Practices' (UCPMP, 2011) which is a voluntary code of conduct.

Figure 4.22: Views on the UCPMP, 2011

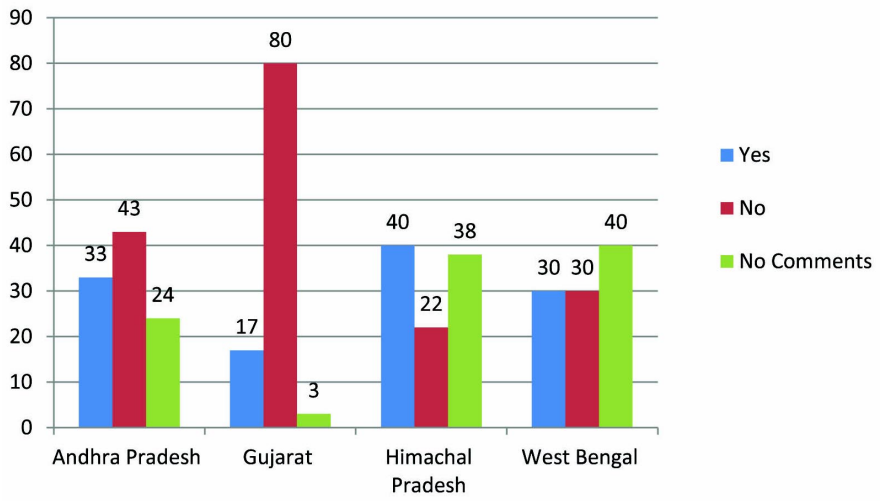


Guidelines for prescription

Irrational use of medicines is a major problem worldwide. There have been efforts both at the international level and to some extent at the national level as well, to ensure that medical professionals practice 'rational use of drugs' (RuD). The World Health Organisation (WHO) estimates that more than half of all medicines are prescribed, dispensed or sold inappropriately and that half of all the patients fail to take them correctly. The overuse, underuse or misuse of medicines results in wastage of scarce resources and widespread health hazards. Examples of irrational use of medicines include: use of too many medicines per patient ("poly-pharmacy"); inappropriate use of antimicrobials, often in inadequate dosage, for non-bacterial infections; over-use of injections when oral formulations would be more appropriate; failure to prescribe in accordance with clinical guidelines; inappropriate self-medication, often of prescription-only medicines; non-adherence to dosing regimes.[6]

Most hospitals in Gujarat (80 percent) indicated that they did not have any in-house guidelines for doctors to prescribe medicines in a certain manner. Large percentage of hospitals in West Bengal and Himachal

Figure 4.23: Guidelines for Monitoring Prescription Pattern



Pradesh were not comfortable responding to this query. 30 and 40 percent respectively of those who responded in these two states indicated having such guidelines in place. In Andhra Pradesh, a third of the hospitals had these guidelines, while nearly a half of them did not have any such guideline.

Awareness on Rational Use of Drugs

According to the World Health Organisation (WHO, 1985) rational use of drugs requires that "patients receive medications appropriate to their clinical needs, in doses that meet their own individual requirements, for an adequate period of time, and at the lowest cost to them and their community".[7] With assistance from the WHO, promotion of rational use of drugs has been undertaken in India under the National Rural Health Mission (NRHM). The MCI Regulations, 2002 indicate that "every physician should, as far as possible, prescribe drugs with generic names and he/she shall ensure that there is rational prescription and use of drugs".

An analysis of the responses from the private hospitals reveals that less than half of them had in-house guidelines on RuD.

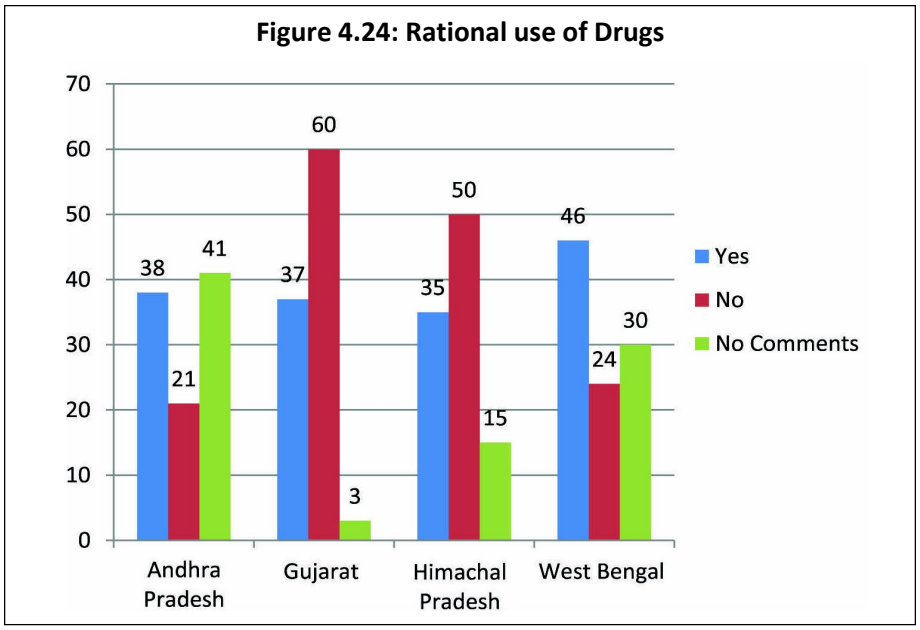
Views on prescription audit as mandatory

One of the elements of the Antibiotic Policy being pursued by the Ministry of Health and Family Welfare is to make 'prescription audit' necessary across healthcare institutions. Although, the proposal poses operational challenges, yet it has the potential to curb irrational prescription – if

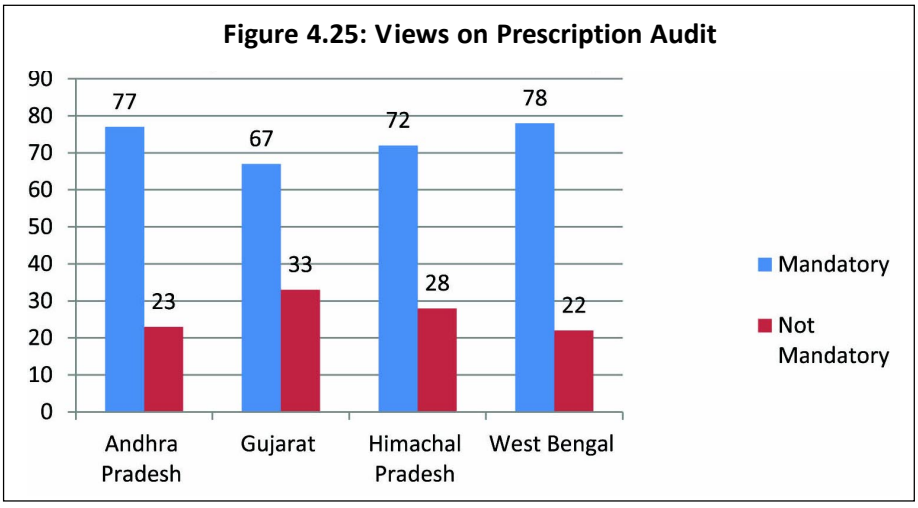
Box 4.2: Reasons for Irrational Drugs in India

1. ***Lack of information:*** Unlike many developed countries we do not have regular facilities, which provide us with up to date, unbiased information on the currently used drugs. The majority of our practitioners rely on medical representatives. There are differences between pharmaceutical concern and the drug regulatory authorities in the interpretation of the data related to indications and safety of drugs.
2. ***Faulty and inadequate training and education of medical graduates:*** Lack of proper clinical training regarding writing a prescription during training period, dependency on diagnostic aid, rather than clinical diagnosis, is increasing day by day in doctors.
3. ***Poor communication between health professionals and patients:*** Medical practitioners and other health professionals giving less time to the patient and not explaining some basic information about the use of drugs
4. ***Lack of diagnostic facilities/uncertainty of diagnosis:*** Correct diagnosis is an important step toward rational drug therapy. Doctors posted in remote areas have to face a lot of difficulty in reaching a precise diagnosis due to non-availability of diagnostic facilities. This promotes poly-pharmacy.
5. ***Demand from the patient:*** To satisfy the patient expectations and demands of quick relief, clinicians prescribe drugs for every single complaint. Also, there is a belief that "every ill has a pill" All these increase the tendency of polypharmacy.
6. ***Defective drug supply system and ineffective drug regulation:*** Absence of a well-organised drug regulatory authority and presence of a large numbers of drugs in the market leads to irrational use of drugs.
7. ***Promotional activities of pharmaceutical industries:*** The lucrative promotional programmes of the various pharmaceutical industries influence the drug prescribing.

Source: *D. Brahma , M. Marak, J. Wahlang: Rational Use of Drugs and Irrational Drug Combinations. The Internet Journal of Pharmacology. 2012 Volume 10 Number 1*



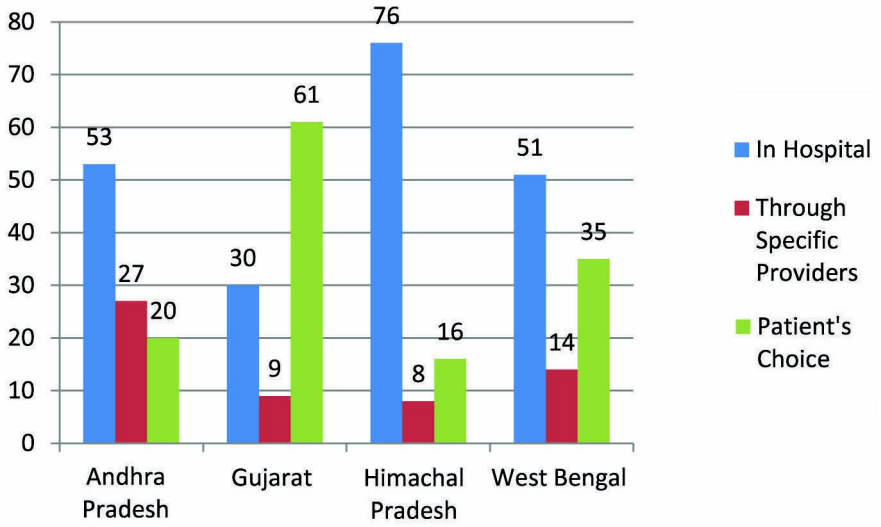
properly implemented. As a part of the project, it was felt that views on such initiatives need to be gathered from relevant stakeholders. As is evident from the graph below, it appears that the respondents from hospitals across the states felt that prescription audit should be made mandatory.



Should diagnostic tests be done through specific providers or within hospitals?

The respondents in Himachal Pradesh, West Bengal and Andhra Pradesh mentioned that most of their hospitals had their patients undertake diagnostic tests inside the hospital. Only in Gujarat, a sizeable section (61 percent) of private hospitals indicated leaving the choice of getting diagnostic tests done to the patients. A number of private healthcare institutions in Andhra Pradesh asked their patients to get diagnostic tests done through specific diagnostic clinics.

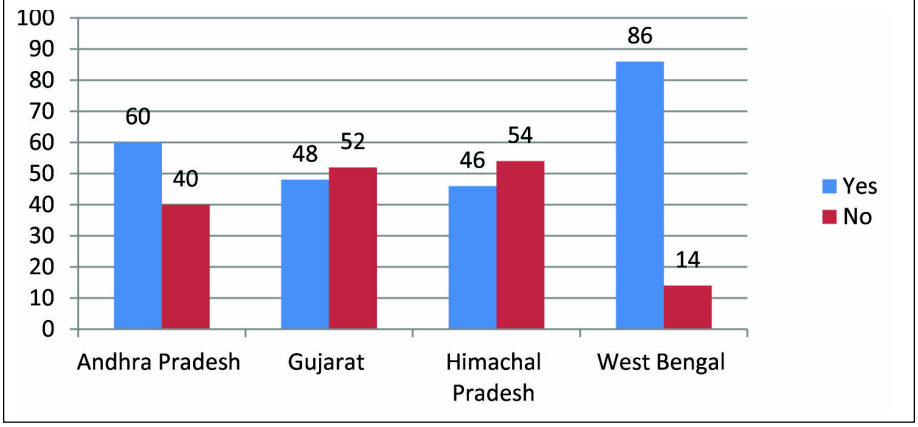
Figure 4.26: Pattern of Prescription for Diagnosis



Existence of Standard Treatment Protocol (STP)

Most (80 percent) private healthcare institutions in West Bengal seem to have a focus on promoting 'STP's. One of the possible reasons was that the Government of West Bengal developed a STP for implementation in public hospitals, and has included STP promotion as a key element of its state drug policy (2004). Many private healthcare institutions in Andhra Pradesh (60 percent) mentioned that they have an in-house STP policy. In the other two states, this was observed in less than half of the private hospitals.

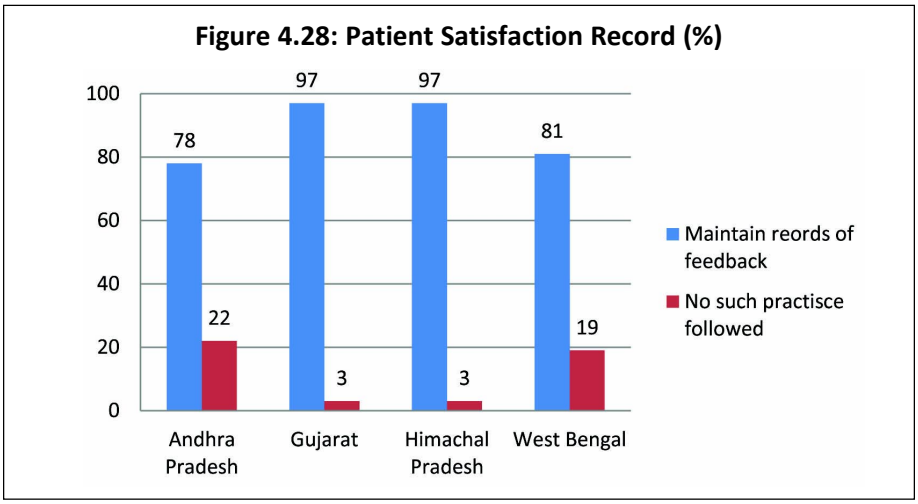
Figure 4.27: Existence of in-house STP Policy



Patient satisfaction record

Most private hospitals across the state already seem to be maintaining such records, although analysis of such reports are not available in the public domain - and were not provided to the researchers. These institutions felt that maintenance of such records should be mandatory for private hospitals – both for internal analysis and regulatory purposes.

Figure 4.28: Patient Satisfaction Record (%)



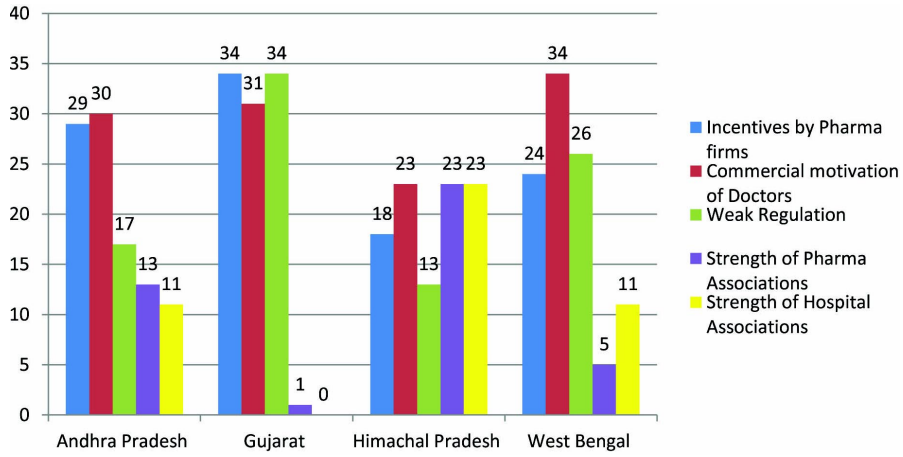
Major determinants of unethical practices in private healthcare

An overarching generic question was posed to the respondent on what they believed were the reasons for such a high prevalence of unethical behaviour in the healthcare. Commercial motivation of doctors was the reason mentioned by respondents from - West Bengal (34 percent), Andhra Pradesh (30 percent) and Himachal Pradesh (23 percent). However, incentives by pharma firms emerged as the most significant determinant in Gujarat (34 percent) and Andhra Pradesh (29 percent).

Table 4.22: Major Determinants of Unethical Practices in Private Healthcare		
States	**Major determinants of unethical practices in private healthcare**	**Responses (%)**
Andhra Pradesh	Commercial motivation of doctors	30
	Incentives by pharma firms	29
Gujarat	Incentives by pharma firms	34
	Weak regulation	34
Himachal Pradesh	Commercial motivation of doctors	23
	Strength of pharma associations	23
West Bengal	Commercial motivation of doctors	34
	Weak regulation	26

Figure 4.29 provides a more comprehensive view of all the other determinants of unethical behaviour in private healthcare as recorded in the four states.

Figure 4.29: Determinants of Unethical Behaviour in Private Healthcare



How do the hospitals perceive their business responsibility in the sector
It emerged from a synthesis of the feedback received from private hospitals that they considered the following as elements of business responsibility as being relevant and applicable for them:

• Providing good quality healthcare at reasonable costs • Patient (customer) satisfaction	Core Business
• Providing community services • Organising free healthcare and awareness camps	Philanthropy

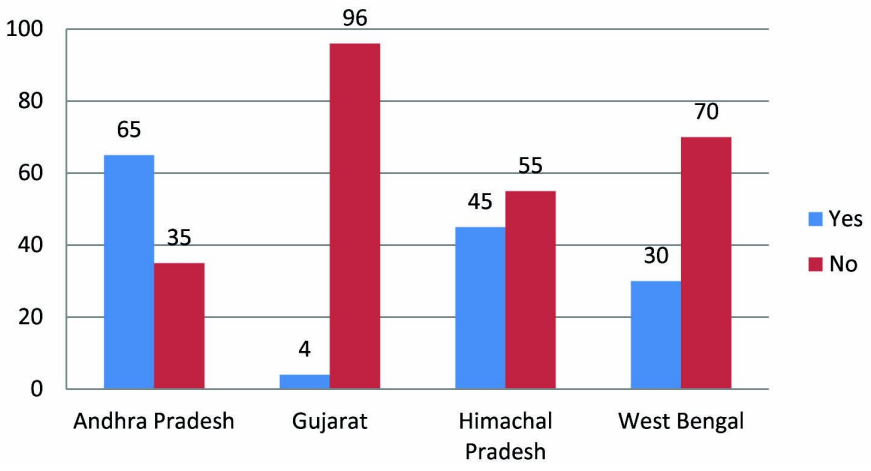
External Factors

Role of hospital associations

During the course of the field-work in the states and the subsequent discussions with the various stakeholders, it emerged that while hospital associations were present in some states and were fairly active (as in case of Andhra Pradesh and West Bengal) in others they were either not present (e.g., in Gujarat) or were fairly weak and had a small membership base (e.g., in Himachal Pradesh).

Even in states where hospital associations existed, like in West Bengal, many hospitals were not members of the association. In Andhra Pradesh, however, the hospital associations were well-structured and systematically governed. It is not only in the interest of the industry players, but also of the state governments to motivate private healthcare institutions to become members of hospital associations. In Gujarat no formal associations were found to exist, in spite of the fact that there were over 500 private hospitals in the state. In Himachal Pradesh the researchers could identify a some hospital associations, which were local.

Figure 4.30: Membership of Hospital Associations



It was observed that the main function of hospital associations (in states like Andhra Pradesh and West Bengal – where they were comparatively strong) was to engage with the government on policy related issues. The associations did not have any role in monitoring the behaviour of its members. The associations in Andhra Pradesh offer good case studies for other states to emulate, *vis-à-vis* its organisation and management.

Associations discussed a variety of issues in their meetings. Biomedical waste management emerged as one of the most discussed issues in association meetings. STP emerged as the other most commonly discussed issue. On certain occasions, hospital associations in Andhra, Himachal Pradesh and West Bengal had included RuD in their agenda for discussions.

Endnotes

1. List available in the CPCB website at: www.cpcb.in
2. Number of state-wise operators (in 2008) listed in: http://cpcb.nic.in/wast/bioimedicalwast/CBWTF-STATUS.pdf
3. According to the information obtained during the field survey there were a total of 18 providers in Gujarat
4. http://www.downtoearth.org.in/content/andhra-hospitals-flout-bio-medical-rules
5. Sengupta, R., 'Unholy Alliance in Healthcare Services', CUTS, 2011
6. http://www.who.int/medicines/areas/rational_use/en/
7. http://www.who.int/medicines/areas/rational_use/en/

5
Emerging Conclusions

From the preceding discussions, it is clear that promotion of responsible business practices in the pharmaceutical and private healthcare sectors in India (and indeed in other such key sectors) depends not only on certain key internal factors (innate to the sectors), but also on a number of external factors pertaining to the environment within which these sectors operate in society. Keeping this in mind, this chapter presents emerging conclusions from the study under two broad perspectives pertaining to: (i) external environment and (ii) internal elements.

External Environment

It includes certain factors pertaining to those aspects in the policy and institutional environment that impact business regulation and responsible corporate conduct. Some of these aspects have been acknowledged and documented in several reports by stakeholders, including CUTS. Key issues pertaining to the external environment have been highlighted here to provide thrust to the issue, since they form an integral part of the findings of the study:

Relationship between level of economic development and compliance in states

There is no direct relationship between the level of economic development of a state and levels of compliance witnessed in industries therein. The research has clearly demonstrated that there is an overwhelming propensity to flout the laws among firms even in the states that are economically well developed in a sector and where firms are highly profitable. It appears that more thought needs to be given to structure tax subsidies for investments in a manner that promote responsible conduct.

Coordinated regulatory enforcement

The findings of the study clearly indicate that absence of coordinated enforcement of laws across several agencies provided opportunities for the actors to more easily circumvent the law. Two such aspects are highlighted to demonstrate the impact of the lack of co-ordination in enforcement. Such glaring omissions can be fixed easily and since the pharma industry is a rapid growth industry, the Government would need to be prepared to invest in the monitoring of the sector more effectively.

(I) MCI Regulations, 2002: It empowers the State Medical Councils to penalise doctors who seek gifts and other commercial benefits from pharma companies. However, there is lack of any reference to the State Drug Controller when such an offense is detected, so that the State Drug Controller can also take action against pharma companies that resorted to 'providing' such gifts and/or commercial benefits to the doctors. The State Medical Council and State Drug Controller, if empowered, could together enforce the required legislative aspects more effectively and in tandem.

(II) Drug and Cosmetics Act 1940 (Schedule M[1]) – Effective enforcement of Schedule M (Good Manufacturing Practices) calls for cooperation between the State Drug Controller and the State Pollution Control Boards, as per Clause 1.4 of Part-1 of Schedule M of the Act. In reality, however, no evidence of such cooperation between these two regulatory institutions was observed in the four states covered in the project.

Related to this point is the fact that there is not enough involvement of sectoral associations of pharma manufacturers, chemists and doctors with the Government agencies (particularly at the state level) to facilitate and strengthen the compliance and the awareness within the existing regulatory context. Meetings between the associations and the state agencies seem to be more in the nature of seeking benefits for the industry through lobbying rather than a systematic attempt by the state to educate the industry on its responsibilities.

Fragmented Regulation in pharmaceutical and private healthcare sector

The findings of the study clearly reveal the regulatory gaps exist in the field of pharmaceutical and private healthcare service in India and have implications on business behaviour. It is difficult to infer the expectation/ outcome that the government had in mind while developing such a loose

regulatory framework for these two sectors. This is particularly baffling given that the sector is expected to grow at a rapid pace in the next decade. There are differences across states on the adoption of legislations, setting up the infrastructure, investing in resources and finally about clarity on roles and responsibilities of the different agencies.

Different states have reacted differently to the call for adoption of the Clinical Establishment Act 2010. The Clinical Establishment Act 2010 makes provision for minimum standards of facilities, services and minimum requirement of personnel for registration and regulation. While there has been a lot of debate on some of the elements of the Act, however, there is nothing which governs the quality of service or the nature of facilities that the hospitals should invest in. The report argues that such serious lapses in the regulation are likely to be detrimental to the behaviour of firms in the sector, as can be noted from the findings.

Human capital management

Two patterns were observed pertaining to the quality and number of staff needed to enable an effective regulatory context. The ratio of the staff to the degree of compliance needed has to be studied further. As both the sectors continue to grow, the current staff strength across regulatory agencies is insufficient. The second aspect is the quality of the staff needed to educate, create awareness and enforce the regulations in the sectors.

For example, the BMW (Management & Handling) Rules 1998 require the state governments to provide technical assistance and capacity building support to public hospitals to help them handle their bio-medical waste. However, private hospitals are expected to manage these wastes with their own resources. Given the growth of private hospitals, the state governments should be able to provide such assistance for the private sector too. These could of course be partly paid for the private sector or alternate business models could be developed for the same. The research team observed this phenomenon of lack of knowledgeable staff in the case of State Drug Controllers, the Pollution Control Board and all other regulatory agencies mentioned above.

BMW management and disposal services is an emerging sector; and state governments should design appropriate incentive schemes to promote greater private participation in providing such services. With the manner in which the healthcare industry is expected to grow in the next decade,

there is an urgent need to find sustainable solutions to manage bio-medical wastes, and the public sector would not be able to manage it on its own. PPP models have been explored by some states like Andhra Pradesh and Gujarat. Both the states have been able to stimulate considerable private participation in this sector and develop the market well enough. This should be a lesson for states like West Bengal and others, where private participation has been much less in this market.

Ambiguity in role of regulator

Related to the phenomena above is the ambiguity in the structures especially where there is a conflict of interest involved. For example, the state drug controller has the responsibility of providing licences while at the same time is responsible for regulating and enforcement. On a related note, there is similar ambiguity in the functioning of state pollution control boards especially in states where a particular sector(s) enjoys considerable importance from an economic development perspective. Some agencies have tried to balance this duality of role – but it is not easy and can lead to uncertainty of regulatory purpose.

Information exchange across state regulators

Finally, even where commendable actions have been taken and there has been significant improvement in the regulatory outcome, the information dissemination seems to be very poor and erratic (if at all present). It was observed in the project that several initiatives undertaken in one state were not known to the respondents in other states. There is a need to share and promote 'good practices' in state level regulation in the country. Such good practices should be recognised and promoted through a proper strategy – for example a centralised database of successful state-level regulatory actions/improvisations. Some examples of 'good practices' in regulation as witnessed during the field work in the four states are presented here:

(i) Use of ICT tools (e-governance) has proved quite useful for the FDCA, Gujarat in monitoring the activities of the drug inspectors in the state. This is probably the way to go in the future and a lesson for other state governments (especially in states ready access to ICT services, like Andhra Pradesh and West Bengal).

(ii) The Pollution Control Boards have a crucial role to play in ensuring that firms comply with the relevant environmental regulations. Different approaches have been employed by different state pollution control boards to carry out their functions in different states. In Gujarat, for example there was a change in the approach taken by

the GPCB as it transformed itself into a 'doctor' rather than a 'policeman'. They opted to provide guidance to firms unable to meet standards and diagnose the reasons behind them, so that relevant interventions could be made. The results have been fairly positive so far.

(iii) The Himachal Pradesh Government has adopted the Clinical Establishment Act and initiated the process of implementing the same. The state government seem to have realised the gap that existed in effective enforcement and monitoring of regulations/legislations pertaining to healthcare in the state and therefore created a dedicated Directorate of Health Safety and Regulation in the year 2009. This directorate (department) is entrusted with the responsibility to implement and monitor enforcement of various regulations/legislations at the state level including the Bio-Medical Waste (Management & Handling) Rules 1998, Drugs & Cosmetic Act 1940 (and Rules 1945), etc.

Internal Elements

These refer to the manner in which the different actors within the system interact with each other in demonstrating compliance to the system while at the same time engaging in responsible conduct. Based on the findings of the study, three key conclusions emerge:

Role of associations as platforms

Findings of the study indicate that there is a strong case for strengthening the associations in both the sectors. In a diverse country like India with the regulatory institutions at different stages of maturity, there is a need to build collective networks that can facilitate "co-regulation". Some of the interesting findings include the pharmaceutical associations. The pharma associations are established at the national level (headquarters) and have branches across many states. However, the state branches do not have any independence/autonomy and have to depend heavily on the national associations to carry out their functions at the state level. In the study, the pharma associations across different states exhibited varying degrees of strength and capabilities *vis-a-vis* their membership. The level of interaction between national pharma associations and their state-level branches is also considerably varied.

In contrast, hospital associations were mostly constituted at the state-level. In some states, hospital associations seem to be either absent or

loosely constituted and managed (e.g., in Gujarat, the project team did not come across a registered hospital association). Most of the hospital associations covered in the project had a certain degree of coverage/ membership base within the state. It was not mandatory for hospitals to be a member of one hospital association or the other in the states, where these associations existed. The project clearly sees a void in the associations across states in both the sectors.

Incentives and disincentives for firms

In the case of the pharmaceutical sector, awareness of pharmaceutical firms *vis-à-vis* environmental regulations was found to be fairly high across all four states. However, such awareness does not seem to be translated into improved environmental performance. One of the main reasons for this is the cost of compliance (that reflects in the company's balance sheet under the 'operations and maintenance' head). Even if initial investments are made in pollution abatement infrastructure/devices to get clearances, the nature and magnitude of recurring 'operation and maintenance costs' seem to deter companies from incurring these costs, especially in environments (states) characterised by weak monitoring and enforcement by the regulator (state pollution control board).

Yet, in the study it was found that several companies had better compliance where they had access to foreign markets. Many developed economies in Europe and the US import large volumes of drugs from India and the firms have to demonstrate compliance to the regulators from these jurisdictions (e.g., USFDA, UKMHRCC, etc.). Thus, the incentive of getting better access to foreign markets (where there is comparatively less competition than in India), drives many 'exporting' pharmaceutical companies to abide by regulatory and compliance requirements. Almost at the same time when this report was being finalised, a big Indian pharma company was penalised in the US for supplying bad quality drugs and in the EU for anti-competitive practices. It is clear, therefore, that even large MNCs cannot get away with such practices in developed markets – as they could in developing countries like India.

The findings indicate that many private hospitals do not have any mechanisms to monitor the behaviour of doctors in terms of their prescription pattern *vis-à-vis* Rational Usage of Drugs (RUD) norms as per Section 1.5 Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002. Such absence of accountability (that obviates the possibility of punitive measures or other means of control)

can hamper adoption of industry wide standards to achieve compliance. In case of the Uniform Code of Pharmaceutical Marketing Practices (UCPMP, 2011), the awareness was very low and this in turn impacts compliance. It should, however, be borne in mind that ignorance of a law/regulation cannot be taken as an excuse for not complying with a legislation.

Ethical practices in marketing

This is an area where evidence gathering on the project has been the most difficult and least comprehensive. There are two sensitive areas which require to be highlighted: the role of medical representatives (MRs) and the role of the firms themselves. The findings *per se* do not provide empirical evidence to sufficiently make a compelling argument on this issue. The role of the MRs as "employees" of the pharma companies and their relationship with the doctors/pharmacists in their professional capacity has revealed some interesting insights.

The interviews with the MR's revealed that their awareness of most clauses in the Act pertaining to marketing and distribution was very poor. They mentioned the "stiff targets" and incentives that they received and did not indicate any ethical conflict in their interactions with the doctors and with the gifts and sponsorships that were being offered to the doctors. Giving gifts, sponsoring conferences was not seen by them as unethical; yet most MR's indicated that doctors asked them for the gifts. A further investigation into the secondary data pertaining to the MCI guidelines prohibiting doctors from accepting gifts revealed no prosecution or even a complaint from either the pharma firm or the MR's.

Another area of concern was the unwillingness of pharma firms to provide data on the number of MR's employed, the basic salary paid to the MR or the salary structure of the MR. All of this calls for more investigation in understanding this relationship better.

Notion of Business Responsibility beyond philanthropy

Business responsibility as a concept is not often properly understood by firms. The dominant orientation is still philanthrophy and community welfare. This appears to be pervasive and the notions of CSR by large companies also seem muddled. In the case of SME's there is no notion that individually each firm is contributing to damaging the environment or not giving value to the customer. The notions of the stakeholder are so beyond the imagination of the average firms in the sector that it offers a

challenge for any policy for positive conduct. One could therefore argue that the recent Indian Government initiative on NVGs would be a significant contributor in this direction. The NVGs has included the SMEs and it is important that adequate investments in educating the SMEs are made to strengthen the system especially given that many sectors of the economy are dominated by SMEs.

Low level of consumer awareness (information asymmetry) is a salient characteristic of both the pharmaceutical and the private healthcare sectors. This leads to very weak consumer bargaining power in these two sectors. Therefore, firms do not have any incentive to enhance consumer awareness or improve access to information. There is an urgent need to demonstrate to senior management and board members of firms the 'business case' argument for responsible conduct. A two pronged strategy has emerged from the study, (i) that an enlightened senior management and board is likely to be the best resort for responsible conduct; and (ii) a compelling evidence of the 'business case' benefit related to the 'competitive advantage' argument. Both of them need thought leadership from the industry.

Endnote

1 See http://cdsco.nic.in/html/gmp/schedulem(gmp).pdf

6

Way Forward

The focus of the BRCC project was to understand the interplay between business regulation and business behaviour in two sectors in India. The intent of the research design was to gain deeper understanding of the perception of the different actors associated with the pharmaceutical and private healthcare sector to better understand this interplay (how regulatory structures and functions in these sectors influence responsible firm behaviour?). The project report has mapped the institutional context of the two sectors, gathered data from different stakeholders to understand the realities and challenges and presented findings on different facets of regulation and implications for business behaviour.

The research design was deliberately kept inclusive to bring more stakeholders to participate in the process. Round table meetings in different states, engagement of four partner organisations (local CSOs) who collected the data at the state level and workshops with key state level actors were attempts to build a community of practitioners who could carry the agenda forward on responsible business behaviour in the states, particularly the sectors. A key conclusion at the end of the project is that given the nature of public good that the two sectors provide and India's poor performance on health care indicators, there is a need for a large scale systemic approach to ensure that the regulations are complied with and businesses conduct themselves responsibly.

It is evident that there are large gaps in the regulatory framework, weak institutional arrangements and ineffective compliance mechanisms with several rules lacking alignment and actually working at cross purposes and therefore, unintentionally strengthening opportunistic behaviour across the value chain. The purpose of the report is not to belabour on the point

of regulation or its enforcement alone. Further, the analysis has also tried to use a broad and more comprehensive connotation of business regulation. Business regulation is often understood in the narrow sense as ***public regulation*** only. However, a more holistic understanding of business regulation from the perspective of business behaviour is important and should comprise – ***self regulation*** and ***co-regulation***.

The findings of the study clearly show that while reforms in the regulatory environment of the two sectors are vital and urgent, other conditions for creating a culture of responsibility are equally important. Therefore, the report does not contain any recommendations; rather the intent is to identify threads/themes that allow for "meaningful conversations" to take place within and across the sectors and stakeholders to foster responsible business behaviour.

Two quotations from the interviews done on the project highlight our intent in this chapter. A doctor who spoke to us about the challenges faced by him when he was scaling a 100 bed hospital to a 600 bed hospital: "Everyone knows that there is a time for band aid; there is a time for surgery. Several band aids do not prevent a surgery. Our sector has worked with band-aids for too long. A surgery requires a longer and more comprehensive planning".

During the course of the study, another respondent mentioned "the word post-mortem is used in everyday life very loosely. Why is post mortem such an integral part of medical training? Post-mortem is a highly specialised procedure that consists of a thorough examination of a corpse to determine the cause and manner of death, and to identify the disease or illness that caused it. The post-mortem helps to identify medical errors but more important to build continuous improvement. Unlike other professions, doctors do not have the luxury of a failure the first time. Post mortem done on a corpse allows us to gain learning and insight so that we do not make mistakes on a living person".

The report identifies ***four broad areas*** which require dialogues in the pharmaceutical and private healthcare sectors in India – both at the state and the central levels.

Examining the sectors from a Complex Adaptive System perspective

It is evident that the pharmaceutical and health care sector is a complex, highly context embedded social system with far reaching impacts on the health of the people of India. There are several interrelated systems in the sectors interacting with each other – the Ministries (Centre and State), the Judiciary (laws and regulations), enforcement agencies (Central and State), the private and public sector pharma firms and hospitals, the diagnostic clinics and device providers, the drug manufacturers, the pharmacists, the drug distributors/traders, the BMW disposal agencies, the quality certification agencies, the global buyers in pharma and finally the consumer.

Rouse (2008) defines healthcare as a Complex Adaptive Systems with the following characteristics:[1]

1. Healthcare systems are *nonlinear and dynamic* and do not inherently reach fixed-equilibrium points. As a result, system behaviours may appear to be random or chaotic.
2. Healthcare systems are composed of *independent agents* whose behaviour is based on physical, psychological, or social rules rather than the demands of system dynamics.
3. Because agents' needs or desires, reflected in their rules, are not homogeneous, their *goals and behaviours are likely to conflict*. In response to these conflicts or competitions, agents tend to adapt to each other's behaviours.
   a. Agents are *intelligent*. As they experiment and gain experience, agents learn and change their behaviours accordingly. Thus overall system behaviour inherently changes over time.
   b. Adaptation and learning tend to result in *self- organisation*. Behaviour patterns emerge rather than being designed into the system. The nature of emergent behaviours may range from valuable innovations to unfortunate accidents.
   c. There is *no single point(s) of control*. System behaviours are often unpredictable and uncontrollable, and no one is "in charge." Consequently, the behaviours of complex adaptive systems can usually be more easily influenced than controlled.

It emerges from the analyses that healthcare systems in India reflect all the characteristics mentioned above. Effective healthcare delivery requires, both the private healthcare and the pharmaceutical sector to engage in a collaborative and mutually reinforcing manner. This presupposes the existence of a shared purpose, well understood norms, well defined codes

of conduct, comprehensive information systems, robust monitoring and feedback processes, comprehensive reporting systems, trust based mechanisms for reconciliation of conflicts and finally incentive structures that breed mutual collaboration. In such systems, rules and regulation define the boundaries of the game and set a level playing field for the actors. The behaviours of other actors needs to managed through leadership, dialogue and peer influence, well-defined measurements based on outcomes rather than outputs and finally, focusing on interdependent gains and collaborative goal setting across the partners in the network.

From this perspective, the study suggests that there is an increased role for two actors in improving business behaviour in the sector: (i) firm themselves (driven either by or a combination of – internal values and quest for a market clinching business case) and (ii) sectoral associations (empowered by the government to monitor their members, and be accountable for their behaviour in the market).

Recognising the plurality of India

Health care delivery systems in India are also highly context specific, and interact closely with the socio-cultural, economic and political environment of the state/community. Several scholars have mentioned that the '*socio-demographic factors, social structure, levels of education, cultural beliefs and practices, gender discrimination, status of women, economic and political systems, environmental conditions, and the disease pattern and the health care system itself*' contribute to the complexity in this sector. In the context of developing countries, longstanding existence of the traditional medical knowledge and folklore has its imprints on the socio-cultural practices of the population, their health seeking behaviour and health system access. The co-existence of multiple traditional systems of medicine with the biomedical system entails an additional layer of complexity in the health systems in India.

One important finding of the study highlight these differences across states in the manner in which the regulations (of similar construct) get interpreted, managed and enforced by similar institutions. While the contrast between states is especially striking in the context of our study, there is also dramatic variation in perceptions both in the quality and the nature of delivery of public goods and in institutional outcomes more generally. The question then is what causes this variation? While a simplistic answer would be the variations in institutional structures, our findings suggest that other factors like the attitude of the entrepreneurs, history

and nature of businesses' interaction with the state machinery, their prior experience with regulation, the cost associated with compliance of the regulation, the extent to which reputation risks are perceived as critical, the advocacy of professional associations of doctors, pharmacists, the role of civil society and the strength of the local media contribute even more significantly to ultimate business behaviour in these sectors across the states. Institutions developed to manage/monitor the behaviour of these sectors need to be well aware of these factors in dealing with firms at the state level. This implies that all such information should be available to these institutions before they initiate actions, etc.

Looking through this lens, it is evident that the regulatory framework conceptualises "a single India" while the enforcement mechanisms show that there are "multiple coexisting India's". The differences in the socio-cultural attitudes and perceptions of the stakeholders in the different states and regions pose challenges for a top down "one size fits all" regulatory regime. Both scholars and practitioners of Indian political economy are aware that political institutions operate more effectively in some parts of the country than in others. More discussion is needed to answer questions such as "What is the minimal level of compliance that should be implemented within the regulatory framework as non-negotiable? How should institutions be strengthened to deliver this outcome? What would be the accountability structures of the different agencies to manage this minimal regulatory requirement across different states? How should the non-regulatory aspects be structured to get the business to go beyond compliance?

Finally, the nature of regulation or the approach (strictness) followed in regulating the players seem to be greatly influenced by the importance of that sector to the state's GDP. Therefore, it is understandable that on a long-term time horizon, variations are noted in the manner of enforcement of regulation (and the approach taken in monitoring firm behaviour) in that state.

Revisiting regulatory structures and functions

The institutional and organisational features of regulatory framework in India can be considered under three broad approaches:[2]

(i) Establishes independent regulatory bodies outside the line ministry (e.g., telecom, electricity, seaports, banking, insurance, capital markets, etc.)

(ii) Places regulatory functions in the line ministry concerned and in specialised agencies with the ministry (e.g., civil aviation, highways, etc.)
(iii) The line ministry performs the multiple tasks of policymaker, service provider and regulator (e.g., railways, etc.)

In the context of the pharmaceutical and private healthcare sector, such a clear approach of the regulatory framework is not evident. Independent regulatory institutions as presented above are developed with the expectation of insulating economic decision-making from political control, ultimately contributing towards a consistent and rational policy environment, providing a level playing field for competition and reducing regulatory uncertainty among the private players. Given the context that both the sectors deliver public goods which contribute directly to the human development in India, a clear approach adopted towards the regulation would be significant.

The health care sector in India, therefore, remains volatile and highly vulnerable from a regulatory perspective. Escalating healthcare costs and technological advancements are compelling governments to continuously re-calibrate regulatory structures. We look at the following key segments of business regulation (co-regulation, self-regulation and public regulation) and their implications for business behaviour in these two sectors in the following section.

Co-regulation

One of the most heartening aspects of the study is the widespread awareness among all stakeholders of the regulations that govern the sectors. Yet, the compliance on the regulation does not seem to go hand in hand with the awareness. One of the mechanisms of ensuring better compliance is through the sectoral associations. Historically, in the Indian context, they have played a strong role in lobbying and advocacy with the Government on behalf of the industry, in particular on tax rebates, incentives and subsidies.

The increased need for co-regulation is emerging as a global discourse. In the Indian context, the loose nature of the regulatory framework in both these sectors and the complexity and plurality across states provides an even more compelling case for co-regulation. An effective co-regulation context requires that the private associations play a constructive regulatory role, and also effectively design their interactions with individual firms

(members) This requires two key aspects: a genuine commitment on the part of the private companies to honour the regulatory purposes and a sufficiently robust governance mechanism that ensures that collective interest is protected.

All of this needs to be understood within framework of "co-regulation". Such a framework requires that the regulator have a clear mandate, maintains a close watch over those quasi-public or private players, receives accurate information about the activities of the players, and has sufficient expertise and capacity to assess the performance of parties concerned. Of course, it can be envisaged that a third party audit of the regulatory performance is carried out periodically. The "Responsible Care Initiative" of the Chemical industry (http://www.icca-chem.org/en/Home/Responsible-care/) provides an interesting model of co-regulation that can be referred to. More investigation is needed to understand how the industry associations could be strengthened to participate in co-regulation to strengthen responsible business conduct.

Self-Regulation

One of the key concerns in the study is the poor understanding of what constitutes responsible conduct among the surveyed firms. Philanthropy is still the dominant mind-set among the surveyed organisations and is seen as CSR. It is obvious that there has been considerable interest in promoting CSR (in the traditional sense of 'philanthropy') by firms and is probably going to dominate the process of enforcement of the new Companies Bill 2012 in the near future.

The notion of Business Responsibility, on the other hand involves business strategies and initiatives adopted voluntarily by firms that go beyond regulatory requirements to manage their social, economic and environmental responsibilities and contribute positively towards societal development. Such an understanding is not very widely prevalent among the firms in these two sectors. Understanding of the 'business case' in self-regulation is not common even among business leaders in the country – and can have implications on how (eligible) firms approach this issue under the new Companies Bill regime. There are two crucial factors required for effective self-regulation – a strong belief and an ethical value system within the organisation which nurtures and supports responsible business conduct or a compelling argument that responsible business practices are a source of competitive advantage to firms. At this stage, in India even among large firms there is a dearth of case studies which

unambiguously highlight the business case argument. In a country where high cynicism on corporate conduct prevails and the study *per se* reaffirms this perception, a more detailed and deeper understanding is critical.

An important next step would be to identify those aspects of the applicable regulation which can be moved in to the domain of self-regulation at the level of individual firms. The recent changes in the reporting requirements under the National Voluntary Guidelines (NVGs) provide a way forward for the firms to improve their compliance voluntarily. The reporting framework (Annual Business Responsibility Report) promoted by the Ministry of Corporate Affairs (and also mandated for top 100 listed companies by the Securities and Exchange Board of India) provide a good starting point for firms if they choose to report on their responsible conduct, or explain reasons for departure/non-compliance.

Public Regulation

Public regulation for these sectors is highly fragmented and the arrangement in enforcing these regulations (national Vs state level) induces variations in the performance of regulators leading to varying outcomes *vis-à-vis* business behaviour. In fact, there is hardly any regulation for private healthcare. After a long drawn effort, the Clinical Establishment Act 2010 was introduced and only a handful of states have adopted the same. There is a need for consolidating the regulatory arrangement in both these sectors not only in the interest of the long-term future of the industry in India, but also in the larger public interest given the nature of these two sectors.

Concluding Message

It is evident globally that as countries progress along a particular (positive) economic growth trajectory, political and economic institutions tend to improve. As people become richer, they demand more from public institutions - better public services, more security and law and order, and greater political participation. More emphasis is placed on building norms and self- motivated codes of conduct that support and reinforce practices in the manner in which different institutions engage with each other. This requires building soft infrastructure of change which rests on voluntary efforts along with supportive regulatory frameworks and a political context to stimulate such changes.

In recent years, the Government of India has initiated several measures towards initiating changes in public systems management. One initiative is the Performance Management Secretariat reporting to the Prime Minister's office with a vision to create a "results driven Government machinery that delivers what it promises". A beginning in this direction could be envisaged by bringing the enforcement of regulations in the pharmaceutical and private healthcare sectors into the Results Framework Document (RFD) prepared jointly by the Ministry of Health & Family Welfare and the Department of Pharmaceuticals (within the Ministry of Chemicals and Fertilisers). This would set the context for change in the sectors. Similarly, the Ministry of Corporate Affairs could bring the NVG implementation among companies in to its RFD process. These little steps can be seen as pathways to a meaningful dialogue across stakeholders in the sector. As Albert Einstein remarked, "The world as we have created it, is a process of our thinking. It cannot be changed without changing our thinking."

Regulating firm behaviour (ensuring that firms behave in a particular manner) *vis-à-vis* responsible business behaviour even in the presence of a common framework (like the NVGs) is not a simple or quick process. It involves managing relations between various components of the regulatory apparatus on the one hand, and relations between the regulatory apparatus and entities in the external environment on the other. However, it is clear that relationship between some of these entities is much better evolved and stronger than the others. Achieving desirable outcomes would depend on how some of these relations are identified and effectively managed.

There is some good news that under the 12th Five Year Plan (2012-17) developed by the Planning Commission (Government of India), considerable emphasis has been given to improving the business regulatory framework in order to attain the targets of inclusive and sustainable development that the government has envisaged. An operational strategy is in place and progress is being made towards achieving it.

Endnotes

1 Rouse, William, B (2008), "Healthcare as a Complex Adaptive System: Implications for Design and Management", National Academics of Engineering, USA

2 Mehta, Pradeep S (eds). (2009), "Creating Regulators is not the end, key in the regulatory process", Serials Publications, New Delhi

Annexure 1

Sectoral Analysis of Corporate Conduct in Pharmaceutical and Healthcare Services

1. Interface with NVG Principles

Table 1: Approach to assessing Corporate Conduct/Business Behaviour in Pharmaceutical sector

SECTOR	GENERAL MANUFACTURING PROCESSES	ENVIRONMENT	STAKEHOLDERS, COMMUNITY	LABOUR	MARKETING	DISTRIBUTION
I. Pharmaceuticals	IPR	Resource Efficiency and Sustainable Production Practices (LCA)	Stakeholder engagement and communication	Complaint and Grievance Redressal	Transparent Marketing Information & Communication	Abuse of Dominant Position (Exclusionary)
	New technologies, R&D	Good Manufacturing Practices (GMP)	Community well-being & inclusion	Equal Opportunity at work	Anti-competitive practices	Corruption (influencing doctors and other providers to sell drugs)
		Reduce, Reuse, Recycle		Child, Bonded and Forced Labour	Consumer Education and Information (product labelling, weights & standards)	Anti-competitive practices
		Periodic Impact Assessment and Disclosure		Occupational Health & Safety	Sustainable Consumption (Rational Use of Drugs)	Lobbying and policy advocacy processes

SECTOR	GENERAL MANUFACTURING PROCESSES	ENVIRONMENT	STAKEHOLDERS, COMMUNITY	LABOUR	MARKETING	DISTRIBUTION
		Pollution Control Measures		Wage Policies	Deceptive Marketing Practices (UTPs)	
		Clean Technology & EMS		Workplace Environment	Freedom of Choice (Consumers)	
		Environmental performance of Value Chain members		Human Rights (bonded labour, sexual harassment, child labour, disabled person)	Consumer Grievances and Handling	

Note: The Numbers represent the corresponding NVG Principles (2011)

Table 2: Approach to assessing Corporate Conduct/Business Behaviour in the Healthcare services sector

SECTOR	GENERAL MANUFACTURING PROCESSES	ENVIRONMENT	STAKEHOLDERS, COMMUNITY	LABOUR	MARKETING	DISTRIBUTION
II. Healthcare Services[1] (Hospitals, Diagnostic Service Centres, Health Insurance providers, Medical Equipment producers)	IPR	Resource Efficiency and Sustainable Production Practices (LCA)	Stakeholder engagement and communication	Complaint and Grievance Redressal	Transparent Marketing Information & Communication	Abuse of Dominant Position (Exclusionary)
				Complaint and Grievance Redressal	Transparent Marketing Information & Communication	Corruption (influencing hospital/providers[2] to sell produts)
	New technologies, R&D	Good Manufacturing Practices (GMP)	Community well-being & inclusion	Equal Opportunity at work	Anti-competitive practices	Corrupt practices in Hospitals
				Child, Bonded and Forced Labour	Transparent Marketing Information & Communication	Corruption ('Commission/ Cuts for Doctors)
		Reduce, Reuse, Recycle	Community well-being & inclusion	Occupational Health & Safety	Consumer Education and Information	Anti-competitive practices
		Periodic Impact Assessment and Disclosure		Occupational Health & Safety	Sustainable Consumption	Lobbying and policy advocacy processes

SECTOR	GENERAL MANUFACTURING PROCESSES	ENVIRONMENT	STAKEHOLDERS, COMMUNITY	LABOUR	MARKETING	DISTRIBUTION
				Wage Policies	Deceptive Marketing Practices (UTPs)	Anti-competitive practices
		Pollution Control Measures		Workplace Environment	Deceptive Marketing Practices (UTPs)	
		Pollution (Hospital Waste) Control Measures		Human Rights (bonded labour, sexual harassment, child labour, disabled person)	Consumer Education and Information	
		Pollution (Pathological Waste) Control Measures			Deceptive Marketing Practices (UTPs)	
		Clean Technology & EMS			Freedom of Choice (Consumers)	
		Clean Technology & EMS			Consumer Grievances and Handling	

SECTOR	GENERAL MANUFACTURING PROCESSES	ENVIRONMENT	STAKEHOLDERS, COMMUNITY	LABOUR	MARKETING	DISTRIBUTION
		Environmental performance of Value Chain members			Consumer Grievances and Handling	
					Consumer Grievances and Handling	

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Issues for Device Manufacturers

Issues for Hospitals

Issues for Diagnostic Service providers

Issues for Insurance providers

2. Methodological Note

This note has two components, which represent the approach to assess corporate conduct in each of the two sectors that have been identified for the BRCC research, viz. pharmaceuticals and healthcare services.

2.1 PHARMACEUTICAL

2.1.1 For the purpose of the assessment of 'Corporate Conduct' in the pharma sector, the following segments of the value-chain would be looked at: (i) Manufacturing; (ii) Marketing and (iii) Distribution

2.1.2 In the **manufacturing** segment, the conduct of the business entities should be analysed in terms of:
(a) general manufacturing process/issues, (b) environmental impacts, (c) stakeholder interactions and (d) labour issues. In **marketing,** issues related to consumer welfare and protection would be looked at; and in case of **distribution**, the market interaction among various entities in the distribution network would be analysed.

2.1.3 This note elucidates the method to be followed for analysing each of the above-mentioned aspects of corporate conduct in the pharmaceutical sector. It provides a detailed guidance about how each of the 'Critical Elements' highlighted above could be looked at, explaining the indicators to be used, type of input data and its source(s). The methodological note for the pharma sector is segregated into the following sub-sections:

- General Manufacturing
- Stakeholder/Community
- Marketing (Consumer Interface)
- Environment
- Labour
- Distribution network

A. General Manufacturing

Corresponding Business Regulations	*Key Question(s)*	*Input Data*	*Data Source*
- The Patents Act, 1970 - Trademarks Act, 1999	To what extent do pharmaceutical manufacturers preserve/ observe/maintain Intellectual Property (IP) Rights in the process of developing new molecules?	Evidence of violations of IP rights cases against companies	- Annual Report of firms - IP Audit reports (by Independent IP Audit Firms) - List of 'Oppositions' filed against firms under the Trademarks Act - Feedback from Rivals - Information about cases filed in High Courts (States) - Information from Law Firms - Information obtained from Patent Office

B. Environment

Corresponding Business Regulations	***Indicators of Corporate Conduct***		
	Key Question(s)	***Input Data***	***Data Source***
- Drugs and Cosmetics (Amendment) Rules, 2001 [Schedule M]	What 'Good Manufacturing Practices' (GMP) are employed by the pharma company? What have been some of the (quantifiable) benefits from the same?	- Accreditation reports - Risk Assessment and Mitigation Methods employed - Process related information, etc.	- Annual Reports - Physical verification - Compliance Reports (for GMP[3] accredited firms) - Risk Assessment and Mitigation report/documentation
- Drugs and Cosmetics (Amendment) Rules, 2001 [Schedule M]	Evidence of Clean Technologies introduced by the company in its manufacturing process, and its effectiveness (INTERNAL)	- Input and/or raw material reduction (efficiency) - Waste reduction/ reuse - Reduction in Energy use - Evidence of recycling	- Reports submitted to (and monitoring undertaken by) the State Pollution Control Boards - Energy Audit reports - EMS (ISO 14001, ISO 14004) reports and processes (implementation) - R&D budget-line (trends) - Physical verification
- Water (Prevention and Control of Pollution) Act, 1974 [Sections: 24, 25, 26] - Air (Prevention and Control of Pollution) Act, 1981 [Section: 17]	Extent to which the business has been polluting the local environment (EXTERNAL)? Adoption of pollution control measures by businesses?	- Status of pollution (air and water) and evidence thereof - Presence of effective pollution abatement measures - Existence of solid and hazardous waste management processes - Impact on air, water sources, land in the vicinity (including local 'Epidemiological' impacts)	- EIA report (prepared by independent sources) for environmental clearance from Central Government[4] - Information available in Environmental Data Bank (of CPCB) - Physical verification in the vicinity/ local community - Pollution monitoring reports[5] (government and non-government organisations) - Physical inspection of solid and hazardous waste disposal measures - Newspaper reports - Reports by local/national NGOs; discussions with CBOs in the vicinity

C. Stakeholders, Community

Corresponding Business Regulations	***Key Question(s)***	***Input Data***	***Data Source***
- Industries (Development and Regulation) Act, 1951 [Sections 6 and 11B] - Public hearing provisions under the EIA Notification 1994 (amended 2002) [Schedule IV] - Schedule Y of the Drugs and Cosmetics Act governs the clinical trials	How have the businesses engaged with stakeholders, especially communities in the vicinity	- Interactions with the community? - Issues discussed and the mechanisms for information sharing - Taxes paid - Impact on community resources	- Discussion with the community representatives (*Gram Sabha/Panchayat*) - Local employment/job opportunities (number and types) - Any documentation of such reports and the issues discussed? - Payment of taxes (timely) to the local/ state level authorities

D. Labour

Corresponding Business Regulations	***Key Question(s)***	***Input Data***	***Data Source***
	Is there an effective complaints receiving and redressal mechanism in place? How effective has it been?	- Existence of such a process, and its effectiveness in grievance redressal - Cases of/information about labour law infringement	- Discussion with current/former Labour Inspectors (in states) - Discussions with labour/trade union leaders - Cases in Labour court - Discussions with State Labour Commissioner's office - Newspaper reports, or other independent sources of information
	Has the business adopted measures to protect occupation health and safety of its workers?	- Occupational health and safety measures employed in workplace/factory - Accidents (frequency and casualty/fatality) - Accreditation (BIS[6] standards, ISO 18001)	- Discussions with current/former Factory Inspectors (in states) - ISO 18001 reports - Discussions with labour/trade union leaders, especially about accidents and deaths - Newspaper reports, or other independent sources of information

E. Marketing (Consumer Interactions)

Corresponding Business Regulations	***Key Question(s)***	***Input Data***	***Data Source***
- The Drugs (Control) Act, 1950 [Section 10] - The Drugs & Cosmetics Act, 1940 [Section 17]	How transparent are the company's marketing and information systems? Is the product properly labelled?	- Consumers' feedback - Information about the composition of a drug and other details - Use of vernacular language on labels	- Survey of consumers - Physical verification for (content, weight, standards, manufacturing and expiry dates, batch no. etc.)
	What has been the business's track record in terms of promoting 'Rational Use of Drugs'	- Efforts undertaken by the business - Information at the consumers' end	- Prescription Analysis - Evidence of company's RuD policies (speech of CEO or board's decisions on Rational use of Drugs) - Discussions with Union of Medical Representatives - Discussions with doctors and their association members - Discussion with Chemists and their association members
The Consumer Protection Act, 1986 [Section 2]	Evidence of deceptive and/or UTPs by the businesses	- Information gathered from consumers - Any other information	- Information gathered from consumer courts[7], and discussions with aggrieved consumers - Discussions with Consumer Organisations in state
The Consumer Protection Act, 1986 [Chapter IV]	What has been the record of the company in dealing with consumer grievances, and addressing them?	- Process of receiving consumer grievances and swiftness in addressing them	- Information gathered from consumer courts, and discussions with aggrieved consumers - Data in State/District Consumer Forum - Discussion with consumer organisations in state

E. Distribution networks

Corresponding Business Regulations	*Key Question(s)*	*Input Data*	*Data Source*
Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002 [Section 6.8]	What is the business track record in terms of influencing doctors and other providers for selling their products?	- Commissions/ gifts[8] provided to doctors - Agreements with Chemists	- Discussions with unions of Medical Representatives - Discussions with doctors and their associations in state - Information about agreements (exclusive agreements) with Chemists – gathered from Chemists Associations in state
Competition Act 2002 [Section 3 & 4]	Has the business engaged in anti-competitive practices while undertaking distribution of its drugs through the network	- Anecdotal evidence of such practices	- Discussions with rivals, association members - Information available with state government departments/agencies

2.2 HEALTHCARE SERVICES

2.2.1 For the purpose of assessing 'Corporate Conduct' in the healthcare services sector, the following sub-sectors could be considered – (i) hospitals, (ii) diagnostic service providers, (iii) medical device manufacturers and (iv) health insurance providers.

2.2.2 It emerges from the approach presented in Table2 that the following aspects of Corporate Conduct could be looked at for each of the above-mentioned sub-sectors of the healthcare sector:

SUB SECTORS	ELEMENTS OF CORPORATE CONDUCT
Hospitals	Environment (hospital waste and EMS), Stakeholders, Marketing, Distribution
Diagnostic service providers	Environment (laboratory/hazardous waste), Marketing, Distribution
Medical device manufacturers	Distribution
Health insurance providers	Marketing, Distribution

2.2.3 This section elucidates the method to be followed for analysing each of the above-mentioned aspects of corporate conduct in these four sub-sectors of the healthcare services sector. It provides a detailed guidance about how each of the 'Critical Elements' highlighted above could be looked at, explaining the indicators to be used, type of input data and its source(s).

I. HOSPITALS

A. Environment

Key Question(s)	***Input Data***	***Data Source***
To what extent do hospitals employ an effective system for collection and proper disposal of hospital waste?	- Hospital waste management processes (collection, segregation at source and proper disposal)	- Hospital waste management strategy and evaluations/reports - Physical verification - Awareness level of staff (especially the ward boys, nurses and other non-technical staff) - EMS reports, if hospitals have adopted such systems (ISO 14001)

B. Stakeholders

Key Question(s)	***Input Data***	***Data Source***
How have hospitals engaged with stakeholders, especially communities in the vicinity?	- Provisions made by the hospitals for the local communities - Employment opportunities created by the hospital for the local population (and type of employment)	- Discussions with the local community leaders (*Gram Sabha, Panchayat* members, etc.) - Newspaper reports - Reports/account gathered from other sources

C. Marketing

Key Question(s)	***Input Data***	***Data Source***
How transparent are hospitals in providing marketing-related information to consumers?	- Information about rates/charges of hospitals - Interaction of staff with consumers	- Hospital websites, brochures and other information materials - Consumer feedback
How effective have hospitals been in handling consumer grievances?	- Information about consumer grievances, and the promptness with which they are handled by the hospitals	- Information available with State/District Consumer Forum - Consumer feedback - Newspaper reports - Report from other independent sources
Have hospitals been engaged in anti-competitive practices and deceptive practices (UTPs)?	- Evidence of UTPs	- Information available with State/District Consumer Forum - Consumer feedback - Newspaper reports - Report from other independent sources

D. Distribution

Key Question(s)	***Input Data***	***Data Source***
What steps have been taken by the hospitals to combat corruption?	- Evidence of measures taken in handling corruption - Information about any corruption charges, or information about corrupt practices in the company	- Annual report of firms - Discussions with senior staff members
Has the hospital engaged in anti-competitive practices?	- Evidence/allegation of ACPs	- Reports, newspaper report or any other evidence available from secondary sources - Discussion with senior staff members

II. DIAGNOSTIC SERVICE PROVIDERS

A. Environment

Key Question(s)	***Input Data***	***Data Source***
To what extent do these labs have an effective system for collection and disposal of waste?	- Waste management processes (collection and proper disposal)	- Waste management system - Physical verification - Awareness level of staff about laboratory waste management

B. Marketing

Key Question(s)	***Input Data***	***Data Source***
How transparent are labs in providing information to consumers?	- Information about rates/charges - Interaction of staff with consumers	- Laboratory websites, brochures and other information materials - Consumer feedback
How effective have labs been in handling consumer grievances?	- Information about consumer grievances, and the promptness with which they are handled	- Information available with State/District Consumer Forum - Consumer feedback - Newspaper reports - Report from other independent sources
Have labs been engaged in anti-competitive practices and deceptive practices (UTPs)?	- Evidence of UTPs	- Information available with State/District Consumer Forum - Consumer feedback - Newspaper reports - Report from other independent sources

C. Distribution

Key Question(s)	*Input Data*	*Data Source*
Have laboratories indulged in unfair means to influence doctors for referring patients to them?	- Cuts/ commissions provided to Doctors for referring patients	- Discussions with doctors associations - Discussions with diagnostic laboratory associations - Complaints, allegations received on this issue from various sources – newspaper, reports, etc.

III. MEDICAL DEVICE MANUFACTURERS

A. Distribution

Key Question(s)	*Input Data*	*Data Source*
Have the manufacturers indulged in unfair means to (push) sell its products	- Evidence of such practices by these companies	- Discussions with doctors, experts working in the hospital sector

IV. HEALTH INSURANCE PROVIDERS

A. Marketing

Key Question(s)	*Input Data*	*Data Source*
How transparent are the firms in providing information to consumers? How prompt have these firms been in reimbursements to clients (consumers)?	- Information about policies - Interaction of staff with consumers	- Websites, brochures and other information materials - Information about reimbursements by firms to consumers - Consumer feedback
How effective have these firms been in handling consumer grievances?	- Information about consumer grievances, and the promptness with which they are handled	- Information available with State/District Consumer Forum - Consumer feedback - Newspaper reports - Report from other independent sources
Have these firms been engaged in deceptive practices (UTPs)?	- Evidence of UTPs	- Information available with State/District Consumer Forum - Consumer feedback - Newspaper reports - Report from other independent sources

B. Distribution

Key Question(s)	***Input Data***	***Data Source***
Have these firms indulged in anti-competitive practices?	- Evidence of such practices	- Discussions with senior staff in these firms - Complaints, allegations received on this issue from various sources – newspaper, reports, etc.

Annexure 2

Guidance Note for Field-work in States

This note presents a scheme for undertaking the field-work in the four states[9] under the BRCC project. It would be used as the basis for finalising the sampling frame and survey tools to be used for undertaking the field-work.

Research Problem 1: What is the level of adverse environmental impact (especially in terms of pollution) from pharmaceutical companies in the state? Why have the available regulatory safeguards[10] not worked in places where impacts were found to be significant? What should be done to make these regulations work, so that such adverse environmental impacts may be minimised?

A. Sampling Site: Districts with high concentration of pharmaceutical manufacturing units (especially Bulk Drug manufacturing units)

B. Overview of the Sampling Methodology

SN	Research Output	Inputs	Method & Tools
1	Situation Analysis (status of the problem)	i. Stakeholder inputs/ feedback (Respondents=N; classification/spread of N)	Perceptions and feedback from relevant stakeholders, including communities, NGOs, district administration, State Pollution Control Boards, experts, industry associations, etc. *(Collectives as well as individual organisations from among different (problem specific) stakeholder/respondent groups to be covered)*
		ii. Analysis of ground realities	i. Site visit ii. Discussion with communities and other key stakeholders iii. Available reports (State, Central Government independent agencies, NGOs) iv. Media review
		iii. History of evolution of relevant regulations	i. Review of recent administrative reforms introduced in the state ii. Relations between Legislative – Judiciary – Executive
2	Drivers/Causal Factors	i. Process of development of law/regulations/rules, and its enforcement mechanisms	Assessment of the process, especially of state-level regulations, rules, ordinances, etc. (that specify measures to be taken by firms to ensure that environmental impacts of their activities are within the standards/threshold levels), and understanding among relevant stakeholders of its implementation mechanism
		ii. Agency (and/or department) effectiveness	Analysis of various critical factors of the responsible department/agency – (i) staff number, (ii) allocated budget, (iii) staff capacity, (iv) infrastructure, (v) reporting/communication, (vi) powers to impose

SN	Research Output	Inputs	Method & Tools
			penalties, (vii) coordination with other agencies, departments, (viii) review of actions taken and impacts, etc. [*Regulatory Capacity and Competence*]
		iii. Political economy issues	*State – Business Relations:* Interviews with business leaders/associations and Government representatives to ascertain the nature and degree of engagement
			Centre – State Relations: Interviews with key Government representatives and opinion leaders in order to ascertain the nature and degree of such relations, especially from the perspective of responsible business conduct
		iv. Industry's efforts	Collection of information about efforts made by industries (individual and associations) to mitigate negative impacts (and the triggers thereof), peer pressure/response, including amount invested in such mitigation, 'good practices', etc.
		v. Role played by Government	i. Political leadership ii. Facilitating role played by the state/district/local government in promoting good corporate conduct
		vi. Role of technology and access to the same	i. Involvement of technology (ICT) in governance ii. Availability of support for such technology in the state/ national level
3	Way Forward (BRCC implications)	i. Stakeholder inputs/ feedback	i. Inputs gathered from relevant stakeholders including: NGOs, district administration, state government departments, experts, industry associations, etc. *(collectives as well as individual organisations from among different (problem specific) stakeholder/ respondent groups)* ii. Discussions at State Focus Group Dialogues
		ii. Emerging recommendations	Recommendations for policy and practice changes

Research Problem 2: What is the current status of incentives (cuts/ commissions) provided by pharmaceutical companies to doctors and chemists in the state? What impact does it have on 'Rational Use of Drugs'? Why have these incentives continued to be provided by the companies, in spite of regulatory safeguards[11] being in place? What can be done to ensure that companies undertake their marketing activities keeping in view the principle of 'Rational Use of Drugs'?

Research Problem 5: How prevalent is the act of 'cuts/commissions to doctors (individuals/in hospitals)' among diagnostic service providers in the state? Why have these cuts/commissions to doctors existed in spite of regulatory safeguards[12] in place? How to combat the situation? What have been the efforts of hospital associations and other such collectives to deal with the problem? What are the regulatory barriers, if any?

A. Sampling Site: Selected cities/towns in each state

B. Overview of the Sampling Methodology

SN	Research Output	Inputs	Method & Tools
1	Situation Analysis (status of the problem)	i. Insider information	Interview with a group of MRs from 3 cities in each state (Respondents=N=? à classification/spread of N?)
		ii. Key stakeholder inputs	Perceptions and feedback from relevant stakeholders including: pharmaceutical associations, hospital associations, chemist associations, medical associations, NGOs, Government department, experts, doctors, etc.
		iii. Analysis of ground realities	i. Review of reports by State, Central Government, independent agencies, NGOs, etc. to assess the nature and degree of the problem (prevalence of cuts/ commissions in state and their implication on 'rational use of drugs') ii. Media review iii. Consumer feedback (while gathering prescriptions from private hospitals)
		iv. History of evolution of relevant regulations	i. Review of recent administrative reforms introduced in the state ii. Relations between Legislative – Judiciary – Executive
		v. Prescription analysis[13] (Implications for Rational Usage of Drugs, rational diagnosis & treatment)	Analysis of 250 prescriptions from each state. Such prescriptions should be made by the doctors based in private hospitals selected in the sampling frame
2	Drivers/Causal Factors	i. Law development and its enforcement mechanism	Review of state-level regulations, rules, ordinances, etc. and understanding among relevant stakeholders of its implementation mechanism
		ii. Agency (and/or department) effectiveness	Analysis of various critical factors of the responsible department/agency – (i) staff number, (ii) allocated budget, (iii) staff capacity, (iv) infrastructure, (v) reporting/communication, (vi) powers to impose

SN	Research Output	Inputs	Method & Tools
			penalties, (vii) coordination with other agencies/ departments, (viii) review of actions taken and impacts, etc. [*Regulatory Capacity and Competence*]
		iii. Political economy issues	*State – Business Relations:* Interviews with medical associations, hospital associations, chemist associations, and Government representatives to ascertain the nature and degree of engagement
			Centre – State Relations: Interviews with key Government representatives and opinion leaders in order to ascertain the nature and degree of such relations, especially from the perspective of responsible business conduct
		iv. Efforts made by industries (pharmaceutical companies, medical association, hospital associations)	Collection of information about efforts made by industries (individual and associations) to mitigate negative impacts (and the triggers thereof), peer pressure/response, including amount invested in such mitigation, 'good practices', etc.
		v. Role played by Government	Facilitating role played by the state/district/local government in promoting good corporate conduct
		vi. Role of technology and access to the same	i. Involvement of technology (ICT) in governance ii. Availability of support for such technology in the state/ national level
3	Way Forward (BRCC implications)	i. Stakeholder inputs/ feedback	i. Inputs gathered from relevant stakeholders including: NGOs, district administration, state government departments, experts, industry associations, etc. *(collectives as well as Individual organisations from among different (problem specific) stakeholder/ respondent groups)* ii. Discussions at State Focus Group Dialogues
		ii. Emerging recommendations	Recommendations for policy and practice changes

Research Problem 4: What is the current status of bio-medical waste management practices being followed by hospitals and diagnostic service providers in the state? If the situation is problematic, why is it so – in spite of regulatory safeguards?[14] How can the situation be corrected? What have been the steps taken up by the hospital associations/industry bodies to deal with the problem? What are the good practices? What are the drivers of good practices and how can these be scaled up or replicated?

A. Sampling Site: Selected cities/towns in each state

B. Overview of the Sampling Methodology

SN	Research Output	Inputs	Method & Tools
1	Situation Analysis (status of the problem)	i. Stakeholder inputs/ feedback (Respondents=N=? classification/spread of N?)	Perceptions and Feedback from relevant stakeholders including: NGOs, State Pollution Control Board, Waste management companies, hospital associations, district/ local administration, experts, etc.
		ii. Analysis of ground realities	i. Site visit ii. Discussion with communities and other key stakeholders iii. Review of available reports (State, Central Government independent agencies, NGOs) to assess the nature and degree of the problem iv. Media review
		iii. History of evolution of relevant regulations	i. Review of recent administrative reforms introduced in the state ii. Relations between Legislative – Judiciary – Executive
2	Drivers/Causal Factors	i. Existing law and its enforcement mechanism	Review of state-level regulations, rules, ordinances, etc. and understanding among relevant stakeholders of its implementation mechanism
		ii. Agency (and/or department) effectiveness	Analysis of various critical factors of the responsible department/agency – (i) staff number, (ii) allocated budget, (iii) staff capacity, (iv) infrastructure, (v) reporting/communication, (vi) powers to impose penalties, (vii) coordination with other agencies/ departments, (viii) review of actions taken and impacts, etc. [*Regulatory Capacity and Competence*]
		iii. Performance of Waste Management system/firms	Review of the system Interview with key stakeholders to gather their feedback
		iv. Political economy issues	*State – Business Relations:* Interviews with hospital associations, waste management companies and relevant Government departments to ascertain the nature and degree of engagement
			Centre – State Relations: Interviews with key Government representatives and opinion leaders in order to ascertain the nature and degree of such relations, especially from the perspective of responsible business conduct

SN	Research Output	Inputs	Method & Tools
		v. Efforts made by industries (hospital associations, medical associations, etc.)	Collection of information about efforts made by industries (individual and associations) to mitigate negative impacts (and the triggers thereof), peer pressure/response, amount invested in such mitigation, 'good practices', etc.
		vi. Role played by Government	Facilitating role played by the state/district/local government in promoting good corporate conduct
		vii. Role of technology and access to the same	i. Involvement of technology (ICT) in governance ii. Availability of support for such technology in the state/ national level
3	Way Forward (BRCC implications)	i. Stakeholder inputs/ feedback	i. Inputs gathered from NGOs, State Pollution Control Boards, Waste management companies, medical associations, hospital associations, district/local administration, experts, etc. *(collectives as well as individual organisations from among different (problem specific) stakeholder/respondent groups)* ii. Discussions at State Focus Group Dialogues
		ii. Emerging recommendations	Recommendations for policy and practice changes

Research Problem 6: What is the extent to which standard treatment protocol is being followed in the state by (private) healthcare providers? If there are deviations, what are the reasons for these and other instances of non-compliance? How can it be ensured that hospitals promote alignment with standard treatment protocol? Are there adequate measures undertaken by the healthcare providers to respect the diagnosis and treatment related queries of clients (patients and their attendants etc.)? Are there any self-regulatory mechanisms in place?

A. Sampling Site: Selected cities/towns in each state

B. Overview of the Sampling Methodology

SN	Research Output	Inputs	Method & Tools
1	Situation Analysis (status of the problem)	i. Stakeholder inputs/ feedback (Respondents=N=? classification/spread of N?)	Perceptions and Feedback from relevant stakeholders including: NGOs, government health department, hospital associations, experts, medical associations, etc. *(collectives as well as individual organisations from among different (problem specific) stakeholder/ respondent groups)*
		ii. Analysis of ground realities	i. Review of available reports (State, Central Govt. Independent agencies, NGOs) to assess the nature and degree of the problem ii. Media review iii. Consumer feedback (while gathering prescriptions from private hospitals)
		iii. History of evolution of relevant regulations	i. Review of recent administrative reforms introduced in the state ii. Relations between Legislative – Judiciary – Executive
		iv. Prescription analysis	Analysis of 250 Prescriptions from each state. Such prescriptions should be made by the doctors based in private hospitals selected in the sampling frame
2	Drivers/Causal Factors	i. Regulation development and enforcement mechanism	Review of state-level regulations, rules, ordinances, etc. and understanding among relevant stakeholders of its implementation mechanism
		ii. Agency (and/or department) effectiveness	Analysis of various critical factors of the responsible department/agency – (i) staff number, (ii) allocated budget, (iii) staff capacity, (iv) infrastructure, (v) reporting/communication, (vi) powers to impose penalties, (vii) coordination with other agencies/ departments, (viii) review of actions taken and impacts, etc. [*Regulatory Capacity and Competence*]
		iii. Political economy issues	*State – Business Relations:* Interviews with medical associations, hospital associations, chemist associations and Government representatives to ascertain the nature and degree of engagement
			Centre – State Relations: Interviews with key Government representatives and opinion leaders in order to ascertain the nature and degree of such relations, especially from the perspective of responsible business conduct

SN	Research Output	Inputs	Method & Tools
		iv. Efforts made by industries (hospital associations, medical associations, etc.)	Collection of information about efforts made by industries (individual and associations) to mitigate negative impacts (and the triggers thereof), peer pressure/response, amount invested in such mitigation, 'good practices', etc.
		v. Role played by Government	Facilitating role played by the state/district/local government in promoting good corporate conduct
		vi. Role of technology and access to the same	i. Involvement of technology (ICT) in governance ii. Availability of support for such technology in the state/ national level
3	Way Forward (BRCC implications)	i. Stakeholder inputs/ feedback (Respondents=N=? à classification/spread of N?)	i. Inputs gathered from relevant stakeholders including: NGOs, district administration, state government departments, medical associations, hospital associations, chemist associations, experts, industry associations, etc. ii. Discussions at State Focus Group Dialogues
		ii. Emerging recommendations	Recommendations for policy and practice changes

Research Problem 3: What is the current status of presence of expired drugs in the market in the state? If they are present, why have they continued to be present in the market, in spite of regulatory safeguards in place? What should be done to make betterments in the drug supply chain in the market?

It was discussed, that effort would be made to address this issue (problem), while undertaking the field-work related to the problems 2 & 5.

Annexure 3
List of Targeted Stakeholders for Administering the Questionnaire Survey

The following table provides an idea of the specific respondents who need to be targeted for the questionnaire survey and interviews to be conducted for gathering information to address specific research problems. This list would help in the process of framing specific questionnaires (list of questions0 to be developed for each of the respondents to be approached during the field-work.

Research Problems	**Targeted Respondents**			
	Government/Regulation	**Business**		**Stakeholders**
		Individual Firm	**Association**	
Environmental impacts of pharma manufacturing	• CPCB (Ministry of Environment and Forest) • DGCI (Ministry of Health and Family Welfare) • SPCB (Department of Environment) • DC (DHFW) • Department of Industries (State) • DCGI (National + State) • Ministry of Chemical and Fertilizer (Dept. of Pharma) • MoCI • DIPP • Planning Commission • MCA (National Voluntary Guidelines, Companies Act) • Department of Environment • SPCB • Department of Health and Family Welfare • DCA (State + Regional) • Department of Industries (State + Regional) • Local Govt. - ULBs - GPs • District Administration	• Pharmaceutical Firms - Bulk Drugs - Formulations	• CII (National + State) • IPAI (National + State) • OPPI (National + State) • IPAs (National + State) • IDMA (National + State) • BDMA (National + State) • FICCI (National + State) • ASSOCHAM (National + State) • PHDCCI (National + State) • Local Pharmaceutical Collectives • State Industries Collectives • Local Industries Collectives • State Pharmaceuticals Collectives	• Media • Academia • NGOs • CBOs • Experts • Institutions • Individuals
Management of Bio-medical Waste by Hospitals	• Ministry of Environment and Forest • CBGB (National + Regional) • Ministry of Family and Health Welfare • Planning Commission	• Hospitals • Bio-Medical Waste - Entities (Workers) • Solid Waste Management (Entities)	• IMA (National + State + Local) • Hospital Associations (National + State + Local)	• Media • Academia • NGOs • CBOs • Experts • Institutions • Individuals

Research Problems		Targeted Respondents		
	Government/Regulation	Business		Stakeholders
		Individual Firm	Association	
	• High Level Expert Group-India • MCI (National + State) • MCA (National Voluntary Group, Companies Act) • Department of Environment • SPCB (State + Regional) • Department of Environment • SPCB (State + Regional) • Department of Health and Family Welfare • Local Govt. -ULBs -GPs • District Administration		• CII (National + State) • FICCI (National + State) • ASSOCHAM (National + State) • PHDCCI (National + State) • State Hospital Association • State Bio-Medical Waste Association • State Industries Collectives • Local Health Association • Local Industries Collectives	
Incentives by pharma firms to doctors/ hospitals	• Ministry of Health and Family Welfare • Planning Commission • MCI (National + State) • MCA (National Voluntary Guidelines, Companies Act) • Department of Health and Family Welfare (State) • Local Government - ULBs - GPs • District Administration	• Pharmaceutical Firms • Hospitals	• IMA (National + State) • Hospital Associations (National + State) • CII (National + State) • FICCI (National + State) • ASSOCHAM (National + State) • PHDCCI (National + State) • State Hospital Association • State Industries Collectives • Local Hospital Association • Local Industries Collectives	• Media • Academia • NGOs • CBOs • Experts • Institutions • Individuals
Cuts/ commissions provided by Diagnostic Centres to doctors/ hospitals	• Ministry of Health and Family Welfare • Planning Commission • MCI (National + State) • MCA (National Voluntary Guidelines, Companies Act) • Department of Health and Family Welfare (State) • Local Government - ULBs - GPs	• Hospitals	• IMA (National + State) • Hospital Associations (National + State) • CII (National + State) • FICCI (National + State) • ASSOCHAM (National + State) • PHDCCI (National + State) • State Hospital Association • State Industries Collectives	• Media • Academia • NGOs • CBOs • Experts • Institutions • Individuals

Research Problems		Targeted Respondents		
	Government/Regulation	Business		Stakeholders
		Individual Firm	Association	
	• District Administration		• Local Hospital Association • Local Industries Collectives	
Adherence to Standard Treatment Protocol by doctors/ hospitals	• Ministry of Health and Family Welfare • Planning Commission • MCI (National + State) • MCA (National voluntary Guidelines, Companies Act) • Dept. of Health and Family Welfare (State) • Local Government - ULBs - GPs • District Administration	• Pharmaceutical Firms • Hospitals	• IMA (National + State) • Hospital Associations (National + State) • CII (National + State) • FICCI (National + State) • ASSOCHAM (National + State) • PHDCCI (National + State) • State Hospital Association • State Industries Collectives • Local Hospital Association • Local Industries Collectives	• Media • Academia • NGOs • CBOs • Experts • Institutions • Individuals

Endnotes

1 Private sector accounts for about 75 percent of the total healthcare expenditure in the country

2 A classic example is 'Coronary Stent', which has sometimes been prescribed even when not required

3 GMP Guidelines are provided by USFDA, MHRA (UK), TGA, WHO and EU

4 The 'Drug & Pharmaceuticals' industry is categorised as one of the 17 major polluting industries by the Central Pollution Control Board (CPCB), and is therefore required to take such clearances from the Government.

5 Using the Minimum National Standards (MINAS) of 1988-89, prescribed by the Central Pollution Control Board (CPCB), New Delhi

6 Bureau of Indian Standards (BIS) has created a portal on Occupational Health and Safety Management System (OHSMS) for obtaining IS 18001 (2000)

7 State and District Consumer Forum and also information available with Consumer Organisations in states/national level

8 These gifts can be anything from providing support for undertaking Continued Medical Education, to foreign travel, conference participation, EMIs for utilities and even cash

9 Andhra Pradesh, Gujarat, Himachal Pradesh & West Bengal

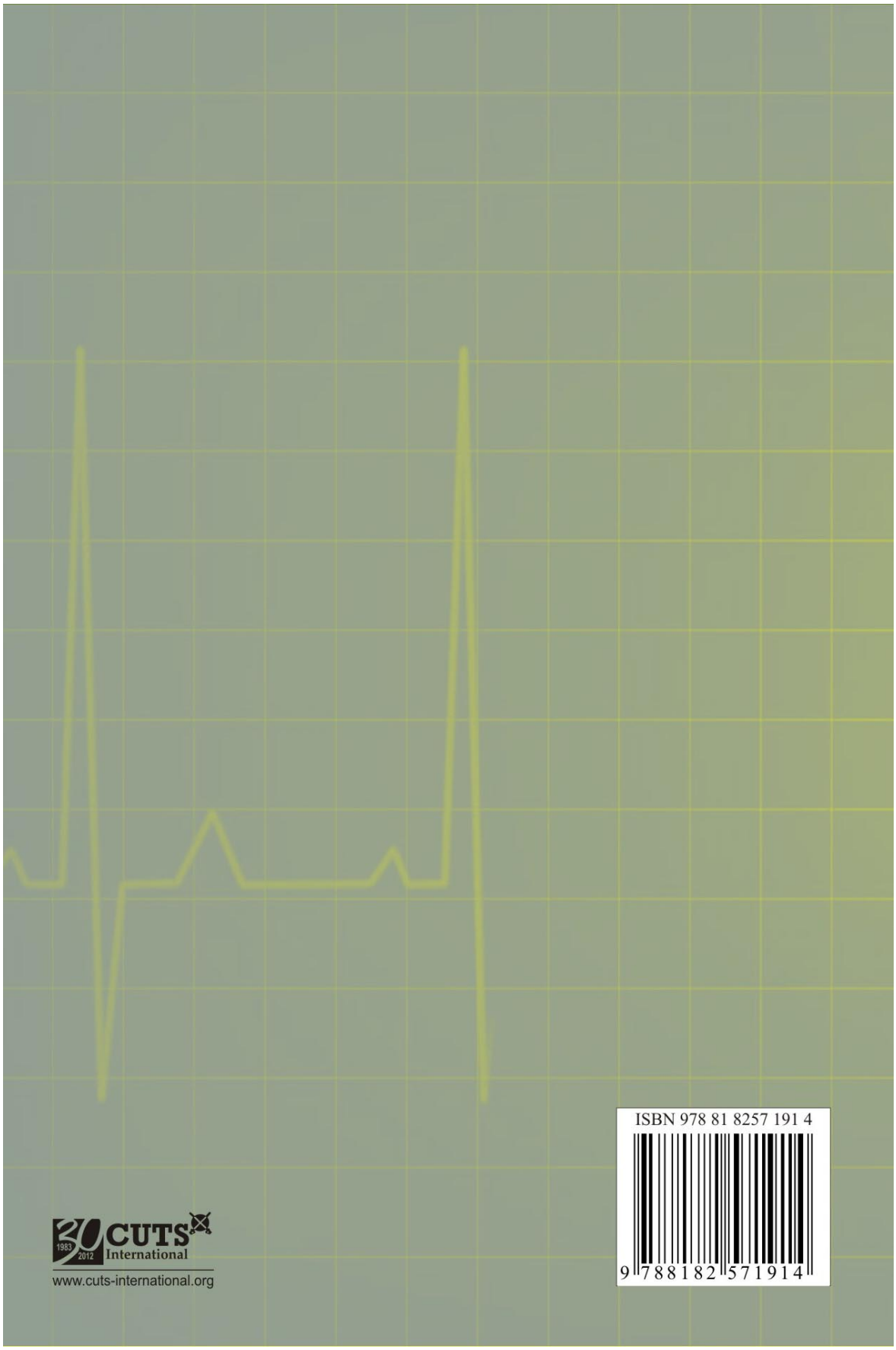
10 Environmental Regulations – e.g., Water Act, Air Act, EIA Notification, Environmental Protection Act, etc.; and Standards stipulated for compliance monitoring

11 Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulation 2002

12 *Op cit*

13 CUTS has already done this in an earlier project (COHED project, www.cuts-ccier.org/cohed) and the same technique can be used here

14 The Bio-Medical Waste (Management & Handling) Rules 1998



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