

## Exploring the Interplay Between Business Regulation and Corporate Conduct in India (BRCC Project)

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### STATE INCEPTION MEETING

**Ahmedabad, April 20, 2012**

The programme commenced with the welcome by **Ajay Kanani** from Raman Development Consultants (RDC) Pvt. Ltd. RDC is the state partner in Gujarat under the BRCC Project. RDC will carry out the research work and look after all the activities of the project across the state. This State Inception Meeting has been organised by RDC in the state of Gujarat.

Kanani then invited **Programme Officer of the BRCC Project, CUTS International, Vikas Batham** to deliver opening remarks. He provided a brief overview of CUTS and explained the importance of the project to all the invited participants

**Ketan Gandhi**, CEO of RDC made a brief presentation on the overview of BRCC project. He also explained the objective of the workshop which was to address the needs and how the situation can be corrected, how the research should be taken up, inputs from stakeholders, their needs, any correction needed in the present ways that have been selected.

After a short briefing by **Ketan Gandhi**, the session was taken up by **Jagdish Patel, Director, 'Peoples' Training and Research Centre'** at Vadodara. He cited live examples of few cases observed in the pharmaceutical factories, diseases and deaths caused by the unsafe working conditions and improper employment norms. Suggestions for issues to be looked upon are as follows:

- Since this is an era of deregulation, but the laws that exist are of regulatory nature pertaining to the earlier times; hence change in these laws is essential
- ISO standards are set by the government even then they are not followed by firms and legal provisions are not respected, hence studying these aspects is essential
- Lack of human resource department and development in various pharmaceutical companies

- Labour standards are not followed. The increase in hiring of temporary workforce rather than permanent is also an issue of concern. Therefore, examining this aspect of labour and employment should be done

There is a high level of occurrence of diseases such as dermatitis; deafness etc. among the workers in such pharmaceutical manufacturing factories, ways and means to reduce them should be looked upon. Another cause of concern is the exposure of male workers to female hormones in factories producing the same, which makes their life so difficult.

The Employees' State Insurance (ESI) Act is applicable to this industry even then it is not put on use properly. The employees are not given the benefits of this Act, even basic things such as identity cards are not issued to the workers, which causes difficulty in claiming compensation henceforth. There is no toxicity limit set for highly toxic chemicals. Another issue is that the private healthcare sector is not well monitored.

**Mahendra Patel, President of Gujarat Chamber of Commerce and Industry** was invited to share his views on the topic, as he also was a key speaker for the workshop. He talked about the existing code of conduct saying it is already present, but it is dependent on how we take an active step to support that. He opined that the flaw in the system is in the "unclean" regulations, where bodies do not know how to interpret the law. Many laws overlap each other, and their proper implementation is not understood. According to him, even government has limitations, and associations many a times do not support them in passing of various laws, and acts that stricken the control upon them leads to such problems of ineffective administration and following of laws.

There is very tough competition in the market among firms, all providing similar kind of products, some producing extremely high quality products, and some low, hence pricing is a problem, which further leads to unethical practices and firms to behave unethically to survive in the market.

**N Lalitha, Professor, Gujarat Institute of Development Research** made a presentation on 'Standards in Pharmaceuticals and Consumers Missing Links.' The presentation was very helpful as she threw light on a lot of missing links in the pharmaceutical sector. She mentioned how medicines are distributed in the country and how the distribution and marketing needs a change. She stated about:

- How the cradle-to-grave approach should be followed?
- The irrational use of drugs
- The wrong proportion of drugs being included in medicines and hence not adhering to the standard required quantities

- There is more than one ministry that regulates the pharmaceutical sector causing implementation problems in the laws
- The pharmacy curriculum needs an important curriculum revision
- There is an immense lack of trained teachers in medical colleges, at the graduation as well at the post graduation level, which needs a revision
- Teachers who have good experience research knowledge in the sector should be employed at such levels, and is not prevailing in the real scenario

**Suggestions are as follows**

- There should be some mechanism to register every patent and proprietary medicine of undisclosed formula
- Good Manufacturing Practice that is the good manufacturing practice should be followed, there is a need to change the direction of research and development in the country
- There should be adherence to the green accounting practices by companies in the country in the pharmaceutical sector, which surprisingly very less firms follow. Even the big pharmaceutical firms are not following these practices except one or two like Dr. Reddy's Laboratories
- The price differentials among similar drugs should be looked upon, standard pricing should be done, pharmaceutical-co-vigilance practices should be followed.

***K U Mistry, Chairman, Gujarat Pollution Control Board (GPCB)*** stated about the lack of staff in government departments, which leads to the difficulty in the management of problems and monitoring healthcare as well as pharmaceutical units. He said that the responsibility to look after the bio medical waste treatment and management of hospitals and healthcare units rests with the Health Department but the Pollution Control Board is looking after it with less staff and extra workload.

The workload is more and the staff is less, leading to improper management problems. Even the GPCB has regulations and limitations, due to which many areas are not in their hands to control lessening the effectiveness of such bodies.

Small factories do have effluent treatment plant. In fact, Gujarat is a state where maximum number of pollution control practices are followed, but with the increase in the capacity of plants, the capacity of the treatment plants have not been increased and upgraded. Moreover, they have a problem of capacity; many factories do not follow norms, thus leading towards various problems of waste management and pollution control. There are finance problems that lead to the employment of workers on contract in such departments; hence irregularity in the availability of staff prevails.

**Mehul Shah, President, Ahmedabad Medical Association** stated various researches that the World Health Organisation has conducted in the health sector, and how it can be utilised effectively to maintain standards in the pharmaceutical and healthcare sector. They act as guidelines to make such rules, and the importance of following them. All the bodies involved in this process should be aware of the basic rules and regulations, how changes in the basic rules are to be brought so that effective implementation can be done. Similar procedure for costing by hospitals and the healthcare units should be followed and cost cutting, wherever possible, should be implemented.

One suggestion was put forth by Mehul was that mechanisms should be developed to maintain the registry of patients/registration with specific diseases, so that a useful database can be developed. There should be neutral bodies to regulate all such things. The Media should act in a responsible manner, and publish only that news which is relevant and does not adversely impact the society.

Ketan Gandhi invited all the stakeholders of the workshop for a discussion, questions and answers, if they have any, hence the session was left open for a discussion.

#### **Some of the discussion points include**

- The increasing use of OTC drugs
- The usage of without prescription drugs and how it affects the society as a whole
- User-friendly services should be given to the consumers from both the sectors
- Affordability of consumers should always be looked upon
- Community should be actively participating in the decision making and policy forming
- Irrational practices by doctors
- Ineffective governing bodies
- Lack of uniformity
- Uninformed, ignorant and huge information asymmetry
- inefficient regulation and control
- Poor monitoring and surveillance practices
- Hazardous drugs are available
- Need of a rational drug policies
- Brand v/s generic names
- Sensitisation will make a difference
- Micro, small and medium enterprise (MSME) should be focused upon by our project as the large corporate are already in place
- Hindrances in implementation of such programmes to adhere to norms etc. by the MSMEs is the money or lack of finance

- MSMEs are not healthy in terms of money and comprise 90 percent of all pharmaceutical companies
- Drug price control is impacting badly, where the money in the companies to implement such programmes will come from.
- Compliance with the GMP standards is an area of constraint
- Issues related to unethical clinical trials and their impacts
- MR's should act in a responsible manner, the benefits as well as the side effects of the drugs should be discussed completely

Question was raised on the further usage of the project and will it actually help us, to which the CUTS team (Sameer Chaturvedi, Vikas Batham) and RDC team answered by talking about how the process will go on, and how the advocacy to change the policies and laws through this project will be done, and what will be the future course of action.

Some suggestions were put forth by participants:

- Education towards community pharmacy
- Good prescribing practices
- Conducting prescription audits
- Communities should be included for deregulation of the regulations, rules and acts

**Annexure 1**

<b>List of Participants</b>			
<b>Sr. No.</b>	<b>Name of the Dignitary</b>	<b>Designation/Name of the Organisation</b>	<b>Remarks</b>
1	K U Mistry	Chairman, Gujarat Pollution Control Board, Government of Gujarat, Gandhi Nagar	
2	Mahendra Patel	President, Gujarat Chamber of Commerce and Industry, Ahmedabad	
3	Jagdishbhai Patel	Director, Peoples Training And Research Centre, Vadodara	
4	Mehul Shah	President, Ahmedabad Medical Association, Ahmedabad	
5	N Lalitha	Professor, Gujarat Institute of Development Research, Ahmedabad	
6	Jasubhai Patel	Secretary, Gujarat Voluntary Health Organisation, Ahmedabad	
7	Malodiya	Ex. Project Director, Ahmedabad Aids Control Society, Ahmedabad	
8	Darshana Patel	Programme Officer, Centre for Environment Education, Ahmedabad	
9	Dipesh Patel	Representative of President, Common Bio-medical Waste Treatment Facility's Association of India, Rajkot	
10	Reema Parikh	Programme Officer, Centre for Environment Education, Ahmedabad	
11	R S Joshi	Executive Secretary, Indian Drug Manufacturer Association (IDMA), Ahmedabad	
12	K S Chabra	Managing Director, Hindustan Biosynth, Vadodara	
13	Vikas Batham	Programme Officer, CUTS International, Jaipur	

14	Sameer Chaturvedi	Assistant Director, CUTS International, Jaipur	
15	Ketan Gandhi	CEO, Raman Development Consultants Pvt. Ltd., Ahmedabad	
16	Ajay Kanani	Project Coordinator (BRCC), Raman Development Consultants Pvt. Ltd., Ahmedabad	
17	Nazhat Khan	BRCC Project Team, Raman Development Consultants Pvt.Ltd., Ahmedabad	
18	Kishor Shrimali	BRCC Project Team, Raman Development Consultants Pvt. Ltd., Ahmedabad	
19	Vaishali Raval	BRCC Project Team, Raman Development Consultants Pvt. Ltd., Ahmedabad	
20	Mehul Bhatia	BRCC Project Team, Raman Development Consultants Pvt. Ltd., Ahmedabad	