

State-Business Interface Meeting (SBIM)

Effective regulation of Pharmaceutical Industry for better business

December 11, 2013

Time: 6:00 pm to 8:30 pm (followed by dinner)

Venue: India International Centre, New Delhi

I. Background

Over the period from 2011-13, CUTS implemented a project that helped identify elements of business regulation in the Pharmaceutical and Private Healthcare sectors, that had implications for responsible business in these sectors (BRCC project, www.cuts-ccier.org/brcc/). The project and the experience has helped CUTS emerge as a key resource organisation on the issue of ‘responsible business’ – engaging in the process of contributing to the evolution of the CSR regime in the country (under the new Companies Act 2012). The BRCC project has helped link business regulations with business responsibility, in the following manner:

- The *research*, helped better understand the influence of business regulation (sectoral) on performance and behaviour of firms (i.e., responsible business).
- The *outreach and advocacy* activities helped gather critical information about weaknesses in regulation and implementation processes that need to be strengthened for better business behaviour.

This project has shown that one way for pursuing ‘responsible business’ for better uptake in India comprise the following:

- Assessment of the impact of business regulation on responsible business in a sector
- Deeper sectoral examination to improve weaknesses in business regulation (having negative implications on business responsibility) and their implementation process

The methodology developed to conduct the research under the BRCC project was based on the nine Principles & Core Elements of the “National Voluntary Guidelines on Social, Environmental & Economic Responsibilities of Business” (NVGs). These guidelines present a framework that explains how business can integrate responsible behavior in their core model of doing business. Subsequently, Securities and Exchange Board of India (SEBI) in August 2012 came out with a circular (for top 100 listed companies) which mandate inclusion of Business Responsibility Reports (BR report) based on NVGs, as part of their Annual Reports.

CUTS is keen to take the discussion forward to explore how pharma firms could promote Business Responsibility (BR) and behave as better business in India given the public interest interface of the industry. CUTS also realises, especially from the BRCC project experience that

some key stakeholders need to lead this discourse. With this objective, CUTS wants to organise a State-Business Interface Meeting, which would try to facilitate a discourse among senior policy makers and industry leaders in the pharmaceutical sector, to develop a common understanding on feasibility and importance of BR in the sector. The meeting would help develop clarity on the role that central and state governments, regulatory agencies and business associations need to play in moving this agenda forward.

One of the anticipated outcomes from the event would be identification of positive changes that can be brought about in the process of implementing policies and regulations in the pharmaceutical sector to promote responsible business. It would also throw some light on the manner in which some of the key stakeholders need to improve their interactions.

II. Targeted Participants

Participants for the meeting would include leaders of pharma sector (*IPA, OPPI, IDMA, CIPI, etc.*), central level regulators (*Directorate General of Health Services, Central Drugs Standard Control Organisation, Central Pollution Control Board, etc.*), policymakers (*Ministry of Environment & Forest, Department of Pharmaceuticals, Ministry of Corporate Affairs, Planning Commission etc.*) and select civil society representatives.

III. Issues to be discussed

Some of the key issues that would be discussed during the meeting are as follow

- a. Elements of Business Responsibility (BR) in the pharmaceutical sector
- b. Opportunity in promoting BR in the pharmaceutical sector
- c. Process related reforms in implementing pharmaceutical sector policies and their impact on business behaviour
- d. Interactions between key stakeholders in the pharmaceutical sector
- e. Expected role of each stakeholder group in preparing the ground for adoption of BR

IV. Agenda

The meeting would be conducted by CUTS and moderated by Shri Arun Maira with a small group of relevant stakeholders (10-12 senior level senior government officials and business leaders) to discuss issues and chart a way forward for better business in the Pharma sector in India.