State-Business Interface Meeting (SBIM)

Effective Regulation of Pharmaceutical Industry for Better Business – Issues and Suggested Action

New Delhi, December 11, 2013

1. Introduction

1.1 One of the objectives of CUTS work in the area of business responsibility has been to understand how effective business regulation can promote better business. CUTS has undertaken a project (referred to as the BRCC project) in the Pharmaceutical and Private Healthcare sectors in India, in order to examine this issue.

1.2 In order to have clarity on how some of the identified weaknesses in the process of implementation of regulations in the Pharmaceutical sector can be rectified for promoting responsible business in India, CUTS organised a *State-Business Interface Meeting* in New Delhi, on December 11, 2013. The objective of the meeting was to facilitate a discourse among senior policymakers and industry leaders in the pharmaceutical sector, to identify some action points for improving the process of interaction between the various key stakeholder groups, which seem to hinder effective enforcement of regulations in the Pharma sector.

1.3 The meeting marked an occasion to initiate the process of identification of positive changes that can be brought about in ways in which key stakeholders interact (or they don't) in the process of implementation of certain regulations that affect performance and even public perception of the sector. The anticipated outcome was for the leaders of industry and policymakers to throw some light about ways in which some of the key stakeholders could improve their contribution to the process of pharmaceutical regulation, as a means to promote responsibility in this sector. Here is a report of the proceedings of this meeting.

2. Proceedings

2.1 The meeting commenced with Rijit Sengupta, Director, CUTS International welcoming all the participants. He provided a brief description of the background to this meeting and its overall objective.

2.2 Vasanthi Srinivasan, Chair, Centre for Corporate Governance and Citizenship, Indian Institute of Management-Bangalore (IIM-B) and Research Adviser of the BRCC project provided a detailed insight of the project and highlighted some of its key findings. She briefly took the participants through the process by which this project was implemented, including the motivation behind selecting the pharmaceutical sector, the approach to undertaking research, and the anticipated outcome from the discussions. She added that the methodology adopted for conducting the study utilised the framework of National Voluntary Guidelines on Social, Environmental and Economic Responsibilities of Business (referred to as NVGs), to identify critical elements of business responsibility in the Pharmaceutical sector. On the basis of the research and stakeholder discussions during the implementation of this project, it appeared that the Pharmaceutical sector in India was ready for some exploratory work in the area of business responsibility. It was evident that there were certain systemic issues pertaining to regulation that needed further improvement, if the discussion on business responsibility in the sector was to be translated into actions. From the perspective of this project, she explained, business regulation was segregated into three components: (i) public regulation, (ii) self-regulation and (iii) co-regulation.

2.3 Arun Maira, Member, Planning Commission, Government of India and Chair of the Project Advisory Committee of the BRCC project shared his opinion on what could be some actions for promoting better business in the pharmaceutical sector. He observed that one of the key goals of the pharmaceutical sector from a public/societal interest point of view was to provide quality medicines at affordable prices to citizens. He indicated that in this context it was critical to assess the quality of prevailing regulations in the pharmaceutical sector. He cautioned against too much emphasis on explaining the 'business case' of promoting CSR/business responsibility in the sector, given its nature. Mr. Maira indicated that a discussion was necessary to assess the current state of the quality of regulation and the overall regulatory framework, to assist

the pharmaceutical sector in achieving both its long-term growth objective and the expectation of society.

2.4 Further, he said that the process and frequency of stakeholder interactions at the central as well as the state level, had considerable implications on the quality of regulation in the pharmaceutical sector. He emphasised that the locus for improving regulatory performance in the pharmaceutical sector was at the state level; hence action to improve the quality of regulation in the pharmaceutical sector should start from the state-level.

2.5 In this context he introduced the *India Backbone Implementation Network* (IBIN) - an initiative of the Planning Commission which identifies stakeholders whose engagement is critical in improving the process of implementation of key policies – and facilitates a dialogue between them to equip them to think of solutions. Such an open and deliberative process requires a deep understanding of the situation at hand so that the right skills and techniques may be applied. The IBIN approach, he thought can be applied for improving the effectiveness of pharmaceutical regulation – thereby providing the enabling environment for pharmaceutical firms to be responsible. An IBIN project on 'medicines' has been initiated (managed by IMS & Manford Alliance), and he encouraged CUTS to explore synergies with the same. In order to take the discussions forward – he urged the participants to provide their thoughts on - 'What could be some of the salient features of a good process for regulating the pharmaceutical sector at the state level?'

2.6 D G Shah, Secretary General, Indian Pharmaceutical Alliance (IPA) highlighted the fact that interaction of pharmaceutical industry with regulators and government departments at the state level was minimal, and restricted to the state pollution control board. He informed that on many occasions industry associations have come forward and engaged with the state government on regulatory matters. To ensure such alignment with regulatory requirements, associations have often pro-actively developed rules and regulations for member. He added that state governments on such occasions have provided the necessary support also. However, he lamented that such a process has not been institutionalised, in spite of some efforts.

2.7 He also provided some idea of sectoral associations in the pharmaceutical sector. There were three main large pharmaceutical associations working at the national level, and a number of state level pharmaceutical associations. He added that the three national pharmaceutical associations (viz. Indian Pharmaceutical Alliance or IPA; Indian Drug Manufacturers' Association or IDMA; and Organisation of Pharmaceutical Producers of India or OPPI) have been working together much more now than they did earlier.

2.8 He stated that it is quite evident that pharmaceutical firms lack the spirit of self-regulation. According to him, there should be a process of dis-incentives for firms in case of non-compliance of regulation. However, he said that there are many firms which comply with regulation and have set high standards in terms of meeting social as well as environmental standards but due to some reason such good practices have remained confined to certain regions in the country, and not been replicated in other parts. He stressed upon the requirement for replication of such 'good practices' – something that pharmaceutical associations can do.

2.9 D S Dharmshaktu, Deputy Directorate General, Directorate General of Health Services (DGHC), Government of India, opined that the role of pharmaceutical associations was critical for determining the overall conduct of the pharmaceutical sector. Showing his dissatisfaction over the entire process of policymaking, he stated that there were four major weaknesses in the process – (i) little preparation, (ii) no institutional memory, (iii) very little evidence, and (iv) not much brainstorming.

2.10 He stressed upon collection of evidences from the field in order to enhance the quality of policymaking and implementation in India. He asserted that impractical rules were bound to be violated. He also thought that standards needed to be developed according to size and nature of firms, and generalisation should be avoided. Flawed representation of various stakeholders (government departments, regulators, business associations, others, etc.) in discussions for developing and implementing policies was a major weakness, he thought.

2.11 Tabrez Ahmad, Secretary General, Organisation of Pharmaceutical Producers of India (OPPI) began by lamenting the absence of real stakeholders coming forward to defend their cause in the policymaking process in the sector. In case of pharmaceutical

products, it is consumers who should be communicating directly with firms, associations, government departments to raise existing issues, however such practice seldom takes place in our system (or culture), creating a wide gap between the real problems and possible solutions. He further added that there should be transparency and adequate information about the role and functioning of sectoral associations in the public domain. He complained that we don't examine the counterfactual (i.e., the cost of not having a particular regulation), while developing regulations in a sector. He suggested identifying processes that would ensure that central and state level regulators better coordinate their actions, which was currently absent.

2.12 D G Shah agreed that there is absence of cooperation and coordination between the central and state level regulators, which leads to poor regulatory performance. It also affects proper identification of issues and preparing strategies to mitigate them.

2.13 Deducing from the earlier discussions, Arun Maira asserted that greater efforts were needed in identifying and propagating 'good practices' in the pharmaceutical sector. Such good practices should be identified at two levels:

(i) 'good practices' adopted by firms in complying to certain regulation; and
(ii) 'good practices' in evolving and implementing regulations/laws/statutory requirements in the pharmaceutical sector.

2.14 Team members of IBIN present in the meeting provided the following inputs on the discussion:

(i) Improving the role and quality of sectoral associations
(ii) Fixing the quality of regulatory institutions
(iii) Improving the process of interaction between key stakeholders.

3. Emerging Way Forward

3.1 Towards the end of the meeting few ***action points*** were discussed in order to strengthen the role and functioning of pharmaceutical association in promoting better business in the sector.

(i) Mapping of sectoral associations across states;

(ii) Documentation of 'good practices' (from the perspective of 'responsible business) of members with the support of pharmaceutical associations

(iii) Identification of 'good practices' adopted in development of policy/law/statues and their effectiveness,

(iv) Use the above evidence to initiate a process of discussion between business and the government in order to improve the level of mutual trust between them.