Summary & Way Forward

Interstate Regulators' Forum Meeting

4th & 5th October, 2013-Goa

I. Introduction

An Interstate Regulators meeting was organised by Consumer Unity & Trust Society (CUTS-International) on 4th & 5th October, 2013 in Goa. The main objective of organising this meeting was to explore the possibilities of creating a 'Forum of State-Level Regulators' to enhance regulatory effectiveness of the pharmaceutical and the private healthcare sectors in India. State level regulators play a lead role in regulating these sectors. Hence, performance of these sectors (from a societal or public interest perspective) depends on the regulatory capacity of such state-level regulators.

The idea of forming such a Forum emerged from the findings of a project entitled *"Exploring Interplay between Business Regulation & Corporate Conduct in India" (BRCC project)*. It highlighted that there exists lack of cooperation and coordination between state-level regulators of different in the above sectors across states which often impede the process of replication of good practices adopted by one state in other states. Further, there is considerable differences with regards to the capacity of state-level regulators, which could also be addressed by the help of such a forum.

Apart from this, the forum would also provide a platform to the regulators where they could exchange their ideas, knowledge and discus various issues related to pharmaceutical and private healthcare sector and devise a common solution for them.

The meeting commenced with Vikash Batham, Senior Programme Officer representing CUTS in the meeting, welcoming participants and explaining the objective and importance of the event. He provided brief of the BRCC project and shared some of the emerging conclusion and the important role played by Pollution Control Board and the State Drug Control Authority in both the sector

II. Day I Proceedings (4th October, 2013)

The discussion begin with the Chair Dr SL Rao, Board of Governor, ISEC, highlighting and stressing upon the importance of independent regulation or independence of regulation. He gave example of institutions such as Reserve Bank of India (RBI) and Telecom Regulatory Authority of India (TRAI), which have been exceptional in terms of regulating the respective industries. The ensuing discussion also highlighted how leading Indian pharmaceutical firms failed to comply with foreign regulations and have been fined by the USFDA recently, which has earned bad name for the entire industry. Other crucial issues raised by Dr Rao were about the lack of penal powers of regulators and the human resource constraints particularly among the regulators in both these sectors

Subsequently, we discussed issues pertaining to sale of fake and spurious drugs and over the counter sale of drugs. S L Rao was of the opinion that around 40 percent of the drugs available in the market are fake or spurious. However, one of the drugs controllers present during the meeting said that it is around 0.5 percent only. Problem of information asymmetry among the consumers regarding healthcare issues was next point raised during the meeting. It was accepted that awareness of consumers on such issues needs to be improved.

Importance of self-regulation and co-regulation was also discussed during the meeting as it can play a very important role in terms of ensuring responsible conduct by the pharmaceutical and private healthcare sectors in India. However, majority of participants were of the opinion that without stringent public-regulation, self-regulation will not work in a country like India.

Then aspects such as qualification of regulators, lack of independent tribunal, were highlighted. Subsequently, one of us discussed about importance of availability of information in public domain and the vital role that RTI and e-governance can play in this regard.

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Importance of transparency was next point discussed and implementation related challenges were highlighted by CUTS. It was observed by the house that strengthening of state regulators in terms of human resource, use of technology etc. is very important for proper implementation of policies. This would have a carry on effect on the ability of regulators to regulate/monitor/discipline such sectors of considerable public interest element as is the case with pharma and private healthcare. It was reiterated that capacity of different states in terms of regulatory capacity was not uniform.

The issue of 'product recall' of substandard drugs was raised. One of the state drugs controller in the meeting mentioned that lack of co-ordination and electronic connectivity amongst the state-level regulators affect the process of 'product recall'. Though companies have standard operating procedures for recall of sub-standard drugs based on its classification on severity of product failure, however authentic and full-proof product recall from all the shelves across the country is still not guaranteed. Better coordination and cooperation between the states for effective tracking of spurious drugs was stressed upon in order to improve upon this particular aspect.

Better co-ordination and electronic connectivity among state- level regulators would ensure effective process of 'product recall'.

Taking discussion forward on this issue, it was emphasized that there is urgent need for an effective system for product tracking and tracing in order to weed out spurious drugs. However, considering the large geographical cover of the country and challenges related to electronic connectivity especially in the rural pockets, poses a greater challenge in designing and ensuring effective tracking and tracing surveillance system for all products that move in the market. The system is necessary to repose ad rebuild the confidence, trust and reliability in the minds of the consumers about the product quality.

One of the important points brought to the house was about the loosely regulated Ayurvedic and cosmetic industry, where usage of heavy metals such as mercury can cause serious health hazards. Licencing need to be controlled in both the industry as there ia a very large informal sector emerging in both herbal and cosmetic products which is raising

concers of quality standards. State interference in appointment of Chairperson of State Pollution Control Boards which often turns out to be a political decision, and has implications on the effectiveness of the pollution control board[1].

Multiplicity of regulators in both pharma and healthcare sector sometimes lead to conflict of interests. For example, quality standards fall under the Ministry of Health and Family Welfare (i.e., Central Drug Standard Control Organisation), whereas pricing (National Pharmaceutical Pricing Authority) comes under Department of Pharmaceuticals, under the Ministry of Chemicals and Fertilisers.

Then there was an issue of standard operating procedure in granting of license, which differs from one state to another. The next item discussed was on 'clinical trials' which is regulated by the Central Drug Standard Control Organisation (CDSCO). However, information is often not provided promptly to state drug control authority when a clinical trial is approved by the CDSCO.

Regarding Bio-Medical Waste (BMW) management, it was observed that infrastructure, knowledge and technology were available, but compliance was weak. Even though, the BMW Rules have been in operation for nearly 15 years, yet our country's experience on bio-medical waste management has been quite modest.

It was accepted by most of the participants that bio-medical waste management should be part of accreditation process of hospitals. It would encourage hospitals to manage waste properly. Other points raised regarding BMW management were weak inspection, lack of availability of data on CPCB website, mechanism to track the waste coming out of hospitals etc. It was discussed that there should be localized solution for proper management of BMW. The proper segregation and collection of medical waste is a critical problem in rural areas

Bio-medical waste management should be made part of Hospital accreditation process

[1] The same issue had been reported in a news article (published in The Hindu, 22nd July 2013), see: http://www.thehindu.com/news/national/political-meddling-proves-toxic-for-pollution-control-boards/article4937838.ece

Satish Sinha of Toxic Links mentioned that in India at the state level, the State Pollution Control Board is the primary enforcement authority that further delegates responsibilities to the regional and sub-regional offices. The Central Pollution Control Board is the central authority that provides technical assistance and guidance to SPCBs to coordinate activities among the states. There exists several challenges with respect to the above institutional arrangements resulting in weak enforcements, such as the insufficient coordination and engagement between the two authorities coupled with lack of comprehensive standard compliance and significant human and technical capacity constraints, deter effective functioning of the system

III. Day II Proceedings (5th October, 2013)

The second day's discussion started with Mr. M. Madangopal, Principal Secretary, Health & Family Welfare, Karnataka sharing his opinion on various issues regarding healthcare sector in India. He stated that public healthcare spending in India is around 1.5 % of GDP and it ranks among lowest in the world. While the public health sector due to administrative procedures is forced to maintain at least some minimum standards and requirements and is subject to public audit, the private health sector operates without any significant controls and restrictions

Given this landscape of the health sector in India, an independent health sector regulator is required more to focus on healthcare service delivery mechanism and its related components other than licencing, certifications and accreditations to ensure the performance standards and accountability of the providers. The regulator, however, needs to be responsible not only for issues such as pricing, quality and contract adherence, but also safety, and compliance to environmental norms

He informed that the High level Expert Group report on Universal Health Coverage (UHC) recommended such provisions and the government is taking measures and intedned to provide universal coverage.

He spoke about the implementation and enforcement of Clinical Establishment Act. There has been considerable amount of resistance from various elements of the private health care sector particularly private providers to accept in principle the applicability of certain regulation to their profession, however, many states have implements the act .

He mentioned that today the health infrastructure of India is in dismal condition, it needs radical reforms to deal with new emerging challenges. On the one hand the role of private players is continuously increasing in healthcare sector, but simultaneously healthcare facilities are getting costly, and becoming non-accessible for the poor. The government hospitals are facing the problem of lack of resources and infrastructure. There are inadequate number of beds, rooms, and medicines. Further, 32 percent of the bed strength in India lies with 150 top private hospitals.

IV. Way forward

After in-depth discussions on various issues related to pharmaceutical and private healthcare sector, participants gave their suggestions on what could be possible way forward to overcome all the existing challenges which would ultimately lead to better accessibility and affordability of healthcare services for common people.

- State-level regulators need to **improve coordination and cooperation** among them in order to tackle common issues related to pharmaceutical and private healthcare sector in effective manner. This would enhance the performance and behavior of the firms in these two sectors.
- There should be provision for **training of state drug controller authorities** by Central Drug Standard Control Organisation (CDSCO) on the following: (i) issuing license to drug manufacturing and sales establishments; (ii) licensing of drug testing laboratories; (iii) approval of drug formulation for manufacture; (iv) monitoring of quality of drugs and cosmetics; (v) investigation and prosecution in case of contravention of legal provisions; (vi) pre and post licensing inspection; (vii) recall of sub-standard drugs; etc.

- **Application of e-governance** tools in day-to-day functioning of state level regulators. This would help in improving the process of communication between regulators within the state as well as regulators of different states.
- '**Prescription audit**' for ascertaining rational usage of drugs.
- Strengthening of regulatory capacity in terms of human resources and use of technology.
