

## Proceedings of Interface Meeting

**“Evolving Responsible Pharmaceutical Sector through Multi-stakeholder Engagement”**

**(BRCC Project)**

**Venue: Hotel Courtyard Marriott, Ahmedabad    Date: 1<sup>st</sup> June, 2013    Time: 9:30 am to 1:30 pm**

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The programme began at 9:30 am with the registration of the members. **Ms. Shephali Raskapurwala**, Team Member, Ramana Group, welcomed all the invitees expressing that the BRCC project has brought together pharmaceutical firms, academicians and government together on one platform. She invited **Mr. Ajay Kanani**, Team Member of Ramana Group, to give the welcome address. Mr. Ajay Kanani welcomed all the invitees and dignitaries. He stated that the meeting involved discussing the issues pertaining to challenges faced by the stakeholders in the pharmaceutical sector and bringing out solution too. He mentioned that it need not result into a big change but every beginning is like a change. He again welcomed all the dignitaries on the dais and said that their presence showed their interest in bringing out any possible solution to the challenges and at the end of the session all might know their responsibility and business needs. Mr Ajay Kanani invited **Mr. Rudra Shankar**, Research Associate at CUTS International to share the opening address. Mr. Rudra Shakar gave brief introduction of CUTS as a policy making organization. He said that the purpose of the meeting was to develop blueprint of pharmaceutical sector at state level with the inputs from all to help know the solutions. He welcomed all the invitees and requested Ms. Shephali Raskapurwala to continue the proceedings. She gave brief introduction of all the dignitaries on the dais and requested all the esteemed invitees to give their brief introduction. After the introductory round, the anchor of the event, Ms. Shephali Raskapurwala invited **Shri Rajendra Jani**, MD, Ramana Group.

Shri Rajendra Jani mentioned that the genesis of any project is every Five Year Plan. The country's GDP is the prime concern and linked to that is corporate business ethics and relatedness. Globalization has had export oriented companies booming up. It will be creating an impact which can be known after 7-8 years. In such situations, how to ensure growing economy in view of more stringent ethics is coming forward. Further he mentioned that, Planning Commission is prime institution which advises the BRCC

project. Ramana Development Corporation and CUTS International are the implementers. The study was conducted in four states of Gujarat, Andhra Pradesh, Himachal Pradesh and West Bengal. In explanatory way, he stated that this study presented a view like the one gets from climbing the mountain. After we reach onto a certain level, we look forward and we look backward and then we know where we stand, how much we have covered and how much is yet to be covered. The essence of the study is a win situation for everybody. Study of all stake holders reveals that everyone knows what is good for them. The focus point is how to go further from that point. Thus, all the stakeholders are invited to know their view point in order to find ways to overcome difficulties and do better than minimal. The expectation was that the regulators, associations, industries should discuss the key challenges, issues, concerns and what should be done in short and long term. He added that a deadline needs to be delivered and contribute for blueprint to know what needs to be done. This is expected by Government of India as they don't know what happens in reality when any strategy is framed. The lower level knows it all. So, it is an opportunity for the stakeholders to present their views and suggestion to the Planning Commission. He concludes his presentation and wishes for a qualitative discussion on a later stage.

**Mr. Rudra Shankar** continues the meeting as per the agenda set and begins with his presentation. He presented a blueprint of a responsible pharmaceutical sector. The main purpose was to get inputs from key stakeholders. Workshops had been organized with the purpose of providing platform to discuss issues related to marketing and distribution. It was also called the Writeshop where the pharmaceutical sectors were invited to know their ideas regarding challenges faced by them. The way forward was to present challenges faced by state government, state regulators etc. that were discussed during the workshop. Mr. Rudra Shankar concluded his presentation and requested **Dr. K.U.Mistry**, Chairman, GPCB, to deliver the keynote address.

**Dr. K.U.Mistry** began with the importance of considering health and safety of workers working in the drug factories. He said that necessary precautions should be taken such that there shall be no hazard to the workers or environment. The gas discharge and the water discharge should be within prescribed limits. Next, he discussed issues related to pharmaceutical industry where there was huge discharge of ammonical nitrate whose treatment was difficult. Thus, there was a necessity of a route where a safe alternative was brought in to avoid the discharge of ammonical nitrate. Also, a solvent recovery plant

shall have to be established in factory premises, which could benefit all through the reuse and recycle of the solvents for its distillation. Thus, an incinerator shall be required by all industries else they have to be sent to a common incinerator. He also stated another problem of high and refract ratio. The stream is not segregated. All the discharge is mixed and thus it is difficult to find solution for their cleaning process. So, these discharges should be separated and then treated differently.

Dr. Mistry again focussed upon the necessity of health and safety of workers and stating it as a part of environment along with land, water and air. He mentioned that they were interrelated with each other and their effect is on all. Thus, there should be medical exam, toxicology, ventilation, safe handling measures to ensure safety of workers. He further talked about challenges for responsible business faced by state government which includes lack of common and operational framework to analyse CSR. He agreed that strong political will was required to provide legislation for pharmaceuticals. Global summits are organized in order to invite industries. The industrial growth rate has been going down, but Gujarat industries were not affected at greater extent. Also, there exists difficulty in coordination due to large number of departments. So there used to be delay in performance of various functions. He also mentioned that social responsibilities and business responsibilities have statutory provisions respectively. He explained that Business responsibilities were carried out by legislative requirements whereas the Corporate Social Responsibility comes for permission to carry out its desired tasks.

Talking about role of regulators, he mentioned that GPCB was making many of its procedures online and thus saving time of the concerned people. He gave example that from 5<sup>th</sup> June, 2013, there is going to be an auto- renewal of CCA and hence no need of going to office for the tasksthat can be done online. In his concluding remark, he pointed out the fact that government officials were not alone responsible for corruption. He explained that the industries who do not obey the laws, influence the government officials. Thus, it is a co-joined responsibility of both the stakeholders to reduce corrupt practices done. He stated that shortage of staff and static laws were two major challenges faced by the company. However, soon, recruitment shall be carried out. The attitude of the government officials was discussed where a participant replied that he had a good experience with the GPCB official who explained him every thing in detail with refrence to his problem. Also it was suggested that there should be a special help desk in all the offices. Dr. Mistry ended his speech by stating that sometimes it would be complex handling an industry and have a good attitude.

Mr. Rudra Shankar then invited **Shri H.G.Koshiya**, Commissioner of Food and Drug Control Administration (FDCA). Mr. Koshiya presented the FDCA perspective as a health department whose main aim is to provide quality food to its citizens. He mentioned the fact that 'Health' is a concurrent subject and hence there exists a centralized act as well as the State government has responsibilities in various judicial ways. The FDCA consists of 1300 people who draw samples from food and pharmaceutical industry. In global market, India ranks 3<sup>rd</sup> in pharmaceutical industry which provides medicines at an appropriate rate. India has an export perspective in medicine industry and hence it ranks in top 5 global nation.

Further in his speech, he stated that Gujarat was the pharmaceutical hub of the country with one-third of its share in pharmaceutical industry. He mentioned that the prime aim of FDCA was common man's interest, quality of pharmaceuticals and interest of manufacturers. He mentioned that Gujarat based pharmaceutical industry interact with their counterparts in other states and they often look upto the Gujarat model because of dedicated people, productive government policies, low budget industry food and very few cases of industry indulged in bad activities. He also mentioned that most of the cases of spurious drugs come from the Northern India with 22% failure of goods who don't meet the pharmaceutical standards as compared to 7-8% in Gujarat. Most of the companies in Gujarat do comply with regulation. In short he stated that, they had a job to remove black sheep from the manufacturing and trade department. He proudly said that the Gujarat Pharmaceutical industry in 15 years of time was enjoying global presence exploring around 200+ countries. He informed that the WTO had announced new guidelines for the pharmaceutical industry exports. Initially there used to be hue and cry from the industry to comply with revised schedule of WTO but it turned out to be blessing in disguise. Before WTO guidelines, there were 7000 units and now there are 22000 units which contribute 28% to the pharmaceutical exports of the country. He stated that Gujarat is now global pharmacy due to affordable prices and quality equivalent to international standard.

He also mentioned that they soon would be going to resort to online licensing which shall reduce the traditional route of visiting the office for collection of forms, submission of forms, query for the application, etc. He stated that Gujarat had entered the global pharmacy club and had high competency but there still existed a challenge of cost of medicines. The people living below poverty line have been

still not able to get any major access to the required medicines and thus suggesting that they need to be made more affordable.

In his concluding part, he cited that health care system increased life span. And thus appealed to the pharmaceutical companies to increase their research for a healthy life by developing new vaccines. The R&D department will have to be more dynamic and need to find new inventions which shall help in eradicating diseases like diarrhoea, malaria, malnutrition and tuberculosis. He complemented Ramana Group and CUTS International for their effort to bring out such issues.

At this point, Dr. Mistry left the meeting after inviting all to GPCB office to interact with the government officials to find out possible solutions for the problems faced by all the stakeholders.

Mr. Rudra Shankar next invited **Mr. Viranchi Shah**, Secretary, Indian Drugs Manufacturers Association (IDMA). He introduced by mentioning that Indian industries are responsible for bringing down the prices of therapeutic segments of malaria and HIV expenses in Africa. He gave example of CIPLA which provides low cost medicine in Africa and the South Africa is going to give it license to bypass production of India. He also mentioned the fact that during calamities, free medication was given to maximum number of affected. They used to import medicine from India and thus industry was giving very much. However, he also accepted the fact that there are lacunas and preventive action needs to be taken with the help of legal framework. In his opinion, it was necessary to sit with association and industries to create a positive environment. He stated that the industries have had to come forward and give them motivation to do something beyond law but never breaking the law. There can be seminars on GNP, on new requirements etc. He mentioned that when such meetings are organized, forums take initiatives, all stakeholders come together and share experiences, it shall take health scenario at greater level. But, there are gaps in existing laws. So, it requires a platform where industry and regulators come together for discussion. He stated a very good point that capital requirement is not everything. Requirements need will not capital. Initially, resistance is there. But there should be a will.

One more grave issue Mr. Shah mentioned was that of frequent changes in regulations. Whenever the government changes its law provisions, there arises a storm like situation where who shall survive and

not, has been not known. With changes in law, certain people migrate to other locations and drain money elsewhere and in some more time, the policies change again which creates favourable situation for those who have migrated. Those who migrate would like to come back and thus, there occur resources as well as time loss due to continuous changes. Hence, some policies were required to be stable. On a parting note, Mr. Shah said that incentives in CSR is good motivation. Interaction with industries and firms can help.

Mr. Rudra Shankar invited **Shri Jagdish Patel**, President, Peoples Training Research Center (PRTC). Mr. Patel began his address by saying the words “all is well” and asked if all was actually well. He stated that SC has passed order for clinical trials. There has been a suo moto PIL where it had been found that the workers are exposed to chemicals in pharmaceutical factories. He cited example of Ranbaxy’s employee who had resorted to other company’s medicine to cure his son’s illness. Hence, he expressed that he was not happy with the current health position in the country. However, he had faith that the current central government which has been working upon a Universal Health Policy. The Planning commission has appointed a High Committee for the same reason. If the civil society submits any report which can create a pressure on the government, it shall be helpful for those who don't have access to medicines and thus more states can give free medicines to government hospitals. On this point, Shri Koshiya placed his view point stating the fact that Gujarat has incorporated Tamil Nadu model and Gujarat government has been for past 30 years provided medicines to government hospitals and wherever the medicines were not available. Shri Patel replied that people come to seek help from the civil societies because the government does not help them. The common man prefers private clinics over government hospitals due to their belief of getting good treatment and medication. He added that there needs to be democratization of institutions including politics. The RTI should be also expanded to the private sector as there was nothing private in it. It shall induce more transparency. He also mentioned that the Whistle blower’s act is going to be very crucial in coming times. He said it very simply that people would be with you and motivate you but would never help when required. He brought the focus on the point that the review of laws was needed now. Citing example of Denmark, he stated that the government recognized 100 workers who had brain damage due to solvents where is in Ankleshwar, there are no such cases!. This shows that in India, health of workers is least priority. The worker goes to work as long his health permits and then he shall stop going. Later on he shall realise the loss he had on his health and life. Thus

he believed that civil society had bigger responsibility to help overcome challenges. These challenges include lack or absence of technical expertise, little influence over government, no funds for long term and CSR does not give funds genuinely to the NGOs. He concluded by saying that he still had hope that laws shall be reviewed and soon there shall be Universal Health Policy framed and implemented.

Mr. Rudra Shankar thanked all the dignitaries for their informative address and announced the open floor for discussion in order to complete the blueprint of the actions to be taken against the challenges in front of the State government, State regulators, associations, firms and civil society.

**Mr. Sanjay Jha**, MD, *Amideep Pharmaceuticals*, thanked for the invitation here again after the previous workshop. It had helped the stakeholders to know the value of various exercises done during the workshop. He asked Mr. Koshiya to give his views on the companies who have created bad image of Indian Pharmaceutical industry by providing spurious documents and bad products. Mr. Koshiya replied that, as their main aim is to protect public health, they make their best efforts to find the bad products and their dealers in the market. To put a curb on sale of bad medicines, an SMS alert has been introduced which informs all the registered wholesalers and retailers to not sell particular drug or medicine. Initially it took 60-70 days in checking, verifying and banning the spurious drugs. In the mean time, the drug used to be already consumed and thus, there would be waste of time and energy and risk of health problems. Thus, SMS alert had proved to be very useful. Regarding the bad products he stated that all is not in hands of manufacturers. Sometimes the medicines would expire before date due to poor storage conditions. Thus, supply chain management is equally important. He also added that health being a concurrent subject, its export and imports are also regulated by central government. Hence, it has been creating difficulty sometimes to stop the companies creating bad names abroad as it takes lot of time in processing.

The next participant, **Mr. Rajneesh Mitra**, VP, *Troicaa Pharmaceuticals Ltd.*, expressed that he was happy about things being performed and acted upon. He requested Mr. Rajendra Jani that along with the problems of pharmaceutical, an area of review of laws should also be added on the discussion platform. Bombay Dangerous Drugs Act 1930, Narcotic acts etc are irrelevant and non-practicable in today's time. So, if such laws are getting reviewed and non-relevant acts are being removed, it shall increase the life of the pharmaceutical industry. To this, Mr. Koshiya replied affirmatively that there are

certain pre- independent acts which Government of Gujarat is reviewing. The Government of Gujarat aims to abolish around 200 old acts and rules not practicable in today's time.

Next participant **Dr. Jagdish Parikh**, wanted information about the presence of workplace monitoring or not. If it had been there, yet the presence of pharmaceutical agents was very high. The workers have been still getting exposed to hazardous substances which might be bad. Mr. Koshiya replied that good manufacturing practices have been getting revised. Issues like requirement of place, personnel handling, male worker room for changing, sensitive product manufacturing is being taken care of. The workers are being changed every week so that they are not exposed to harsh chemicals for long period. Also, the air is changed constantly so as to filter and clean it for reuse.

**Mr. Rajiv Dhru**, CEO, *Essence Pharmaceuticals*, contributed that the effect of drugs on intermediate stage should be examined. If the drug is affected or not, analysis can be done. So, risk assessment is very good method of workplace monitoring. Dr. Jagish added further that in foreign countries air monitoring is also done. So, we need to know about this area and carry out according to the law of the land which has class 1 and class 2 area. Mr. Rudra Shankar asked Mr. Viranchi Shah to comment upon the challenges faced by the association. Mr. Shah replied that there is limited financial capacity but trade fairs, commercial activities like exhibitions, etc. are organized to get funds. The associations are developing financial capacity but financial help shall will be always welcomed. The government and the industry have dedicated people which shall be helpful in longer run. He added by commenting that it is not necessary that large firms influence the decision making. All have equal opportunity for stating their requirements and then only necessary decisions are taken. Infact, the large companies would avoid any malpractices in order to keep their reputation intact and in good name. However, this has been a misconception of big firms' influence on government.

The next participant, **Dr. Anita Mehta**, I/C Principal, *L.M. Pharmacy College* thanked for inviting. She put forward that good industries require students of pharmacy who have been the main raw material. They are the ones who are going to be a part of pharmaceutical industry and thus the industry should provide the colleges with revised syllabus, have interaction with students on changing guidelines, guide and train the students to make them industry competent. They shall be also guided about all the channels through which the product passes. Thus, students shall be well informed about all the new

rule, laws, practices to be performed in the industry. Stating further she expressed her concern that the problem lies in the fact that non- pharmacy background chemists and drugists have lack of knowledge about storage facilities and thus, resulting into sale of expired or bad medicine. She concluded by saying that the problem has not always been in manufacturing but also in retailing, there has been a need of pharmacists at all level from manufacturing to retailing and also that licence to sell drugs should be given to only pharmacists and not anyone who applies for licence to have chemist shop.

**Mr. J. D. Kalyani**, Regional Officer, GPCB shed light on the fact that bulk drugs manufacturing had hazards of pollution and negative effect on health of workers. Thus, treatment should be done through cleaner technology. This involves usage of solvents which includes chemicals which might again harm the workers. Huge amount of concentrated streams of effluents are generated which are non biodegradable. Hence they go for thermal destructors. However, it is a very expensive process and thus, due to unavailability of less revenue, they resort to unauthorized practices. He gave example that developed countries have replaced these solvents with lighter solvents or sometimes no solvents. The important cost factor of the drug manufacturing has been the cost of treatment of the disposal. And thus, it should be necessary for industries to have good relationship with the association so that the required manufacturing or treatment processes can be done in harmony with the available funds. He also mentioned the need of stricter norms, handing over small processes to Small Scale Industries so that they can become proprietors and try to remove the loopholes in the job working process through review mechanism.

Mr.Rudra Shankar asked that what should small firms do who do not have availability of newer technology like Air Handling Units. Mr. Kalyani replied that it was now necessary to develop cleaner technology so that it doesnot generate much waste and following which, cheap treatment is possible. Thus a mindset has to be developed to focus more on Research and Development. He mentioned that GPCB is the regulator and thus it should encourage to develop technologies where less waste is generated and small firms can also adopt it.

The next participant **Dr. Hardik Solanki**, Public Health Foundation, said that along with regulation there should be education and awareness. The pharmaceutical industry is over- regulated but education has

been lacking. Education should be provided by the associations to the students and all the stakeholders so that awareness can be generated. He also mentioned that pharmaceutical sector is in Small Scale Industries (SSI) and Large Scale Industries (LSI) . Thus, there issues are different. The SSI have environment issue whereas LSI have marketing issue. So there should be demarcration in rules between SSI and LSI. Mr. Koshiya replied that whether it was a big industry or small, same rules to all.

Mr. Sanjay suggested that in politians should be called in such meetings so that they can inform us about boundaries and limitations of government job. So, an overall view can be obtained.

Mr. Shelat appreciated the meeting as a good step to bring all the stakeholders together. He mentioned that instead of asking for problems faced by the industry, problems faced by regulators and policy implementors and see that the government works properly. Such effort shall give good result to industries.

Mr. Koshiya replied to all the queries together beginning from Dr. Anita and thanking L.M.Pharmacy college which has been providing students to pharmaceutical sector since 1947. The concern now was that AIOC has requested the Government of India that they don't require pharmacists as there are sufficient pharmacists. There exists a scenario where wholesalers supply products to 3-4 retailers, where as in North India, there are 80% wholesalers. Thus, illegally they sell the medicines to the patients in retail. There are 45000 registered online pharmacists. Thus, it is right of the citizen to get medicine by the registered pharmacists. He cited an example of a chemist shop in Gujarat near Rajasthan border, who was a general practitioner. The pharmacist was not present. There was huge stock of medicines brought under certain scheme. However, these medicines were not stored in required refrigerator and instead in the regular refrigerator. So, the pharmacists have to be trained at different level as their importance is needed.

He answered Mr. Mitra's query stating that they shall come out with alternative methods to solve the solvent problem and have an alternative route to have less risk of pollution.

In summarization, Mr. Rudra said that the session was enriching in terms of preparing the blueprint of the responsible pharmaceutical sector and have multi-stakeholder dialogue. The blueprint was shared with all and hence the approach shall be much stronger. He also expected that next time everyone shall be having something more in mind and make things better and forward the suggestion to all.

Mr. Rajendra Jani gave the vote stating that it was difficult to comment upon corruption. The effort was made to identify the association, regulators, firms to solve the problem. Being indian citizens, it is important that we walk together and not without anyone.

He thanked Mr. Koshiya for his immense help and shall look forward to his presence in upcoming meetings also. He thanked Mr. Jagdish Patel for his gracious presence. He also thanked Mr. Viranchi Shah who represented both firm and association, for his support.

He positively stated that now he had more strength to organize such meetings and ask for more time from all the invitees to attend the next meeting which shall be a follow up of a good report. Finally, he invited all for a group photograph which was followed by lunch.