

BUSINESS RESPONSIBILITY GUIDELINES FOR THE PHARMACEUTICAL SECTOR IN INDIA

*Report s of the Advisory Group Meeting
30th October, 2014, New Delhi*

Consumer Unity and Trust Society (CUTS), with support from the Indian Institute for Corporate Affairs (IICA) and Deutsche Gesellschaft für Internationale Zusammenarbeit (GIZ) Business Responsibility Initiative is developing sector specific guidelines based on the National Voluntary Guidelines (NVGs) on Social, Environmental & Economic Responsibilities of Business for the pharmaceutical sector of India. The overarching objective of drafting the pharmaceutical sector guidelines is to mainstream the NVGs into the pharmaceutical sector in order to help businesses understand, adopt and implement them so as to enable the pharmaceutical industry to grow more competent and resilient by maximising benefits, and minimizing risks, and contributing to the national development goals. The process will be stakeholder led and the guidelines would be developed with guidance of pharmaceutical business associations, government bodies and expert advisors.

In this context, the an Advisory Group meeting was organized with the objective of sharing the outcomes of the preliminary analysis done to identify the critical Environment, Social and Governance (ESG) aspects for the sector.

In Attendance:

- Vasanthi Srinivasan, Professor, IIM Bangalore and Research Advisor to CUTS
- DG Shah, Secretary General, Indian Pharmaceutical Alliance (IPA)
- Ranjana Smetacek, Director General, Organisation of Pharmaceutical Producers of India (OPPI)
- Jatish Sheth, President, Karnataka Drugs and Pharmaceuticals Manufacturers' Association
- BR Jagashetty, Former Drug Controller, Karnataka
- Neha Kumar, Deutsche Gesellschaft Fur Internationale Zusammenarbeit (GIZ)
- Trina Datta, Deutsche Gesellschaft Fur Internationale Zusammenarbeit (GIZ)
- Gayatri Subramaniam, Indian Institute of Corporate Affairs (IICA)
- Geetanjali Gaur, Indian Institute of Corporate Affairs (IICA)
- Shankar Venkateswaran, Tata Sustainability Group
- Rijit Sengupta, CUTS
- Vikash Batham, CUTS
- Tunisha Kapoor, CUTS

Opening Session

Vikash Batham welcomed the members to the meeting and discussed the development of NVGs and the need for sector specific guidelines. He mentioned that “the pharmaceutical sector is of significant importance, especially since the public interest element associated with various aspects of the business conduct is very high and has direct impact on consumer well-being. Good corporate conduct is all the more necessary, given the high private participation in the sectors.” The key objective of drafting the guidelines suited to the pharmaceutical sector is to ensure better adoption of the guidelines, consequently ensuring better quality of disclosure.

Gayatri Subramainam welcomed the members and talked about how the then president Pratibha Patil said that the NVGs would “create a revolution” while releasing the National Voluntary Guidelines in 2011. The process of developing the guidelines included stakeholder consultations pan India. These were also recognized and acknowledged by SEBI when they mandated the “Business Responsibility Reports” to be released by the top 100 companies. Thus, developing the sector specific guidelines for the pharmaceutical sector was a good initiative.

Rijit Sengupta mentioned that based on our experience in the sector and interactions with key players; there was a certain level of readiness in the pharmaceutical sector for the adoption of a BR framework, which should be adapted for the sector.

Neha Kumar mentioned that the regulatory push of SEBI for the NVGs was a positive move and that there was a need to understand the issues significant to the sectors. Issues such as sustainability and non-financial risk are important and she hoped that the industry, civil society, government etc. would take this initiative forward in terms of adoption.

Vasanthi Srinivasan, while setting the context of the meeting mentioned about the way the NVGs were designed to link business responsibility and business growth. The process adopted for developing NVGs was through inclusive stakeholder consultation to get wider participation. Some of the challenges in the implementation of the NVG guidelines are the sector specific characteristics pertaining to ESG. In the case of the pharmaceutical sector, the fact that healthcare is a public good and also there is a need for accessible and affordable healthcare makes it a challenge. The three key issues therefore were –

- * Dealing with the NVGs and achieving public good. The paradox between demographic dividend and demographic disaster in terms of public health and how stakeholders need to be critical actors in the process. The key issue was providing health for all and the main players in this regard were the pharmaceutical and the healthcare sectors. The pharmaceutical sector already has a high level of compliance embedded within itself and the cost of compliance was seen as a business responsibility (as was observed in the CUTS Project on “Business Regulation and Corporate Conduct”).The sector has a range of players – large pharma companies, a large number of mid-sized manufacturers and finally the SME’s.
- * There are inter-state variations in terms of compliance which results in a complex system.
- * The enforcement of the regulations is not uniform and though the companies are doing some outstanding work, this is not highlighted as best practices. The “Business Responsibility Report” released by companies does not present many insights in terms of practices adopted which serve the public good.

Thus, there is space for co-regulation and need to explore how the industry associations can take it forward. They have a major role to play which can also play a part in shaping the guidelines.

D G Shah mentioned that pharmaceutical industry is highly regulated and listed five critical aspects specific to the sector.

- * The responsibility of providing products (i.e. drugs) that are needed and are relevant to the country lies with the pharmaceutical industry.
- * It is also their responsibility to maintain a consistent quality which meets the standards. The issue however, is that there are multiple sets of standards and there is a need to define specific standards relevant to the country.
- * The products need to be accessible to all, in every part of the country.
- * The marketing practices adopted by the companies should not encourage over-prescription and irrational use of medicines.
- * The medicines need to be affordable to all. However, affordability is a relative term and the level may vary according to economic status.

In welfare states, the government takes up the responsibility of ensuring free medicines to the population through various schemes where the person does not have to pay at all or has to pay a minimum cost. Thus, like in any relationship, both sides have a certain responsibility. During the process of evaluation or setting up of the guidelines, the regulator is a major stakeholder and if he is irresponsible then it creates aberrations in the five areas specified above.

The industry continues to strive towards being more responsible but is governed by various regulations and regulators such as CDSCO, NPPA, DoP, SEBI and IPR related institutions among others. They are also involved in various litigations; some where the industry has also taken the government to court. The government, being a major stakeholder is responsible for creating a conducive environment for the industry.

Ranjana Smetacek agreed with the points made by D G Shah and talked about the marketing practices of the firms that are a challenge area viz-a-viz responsible conduct of the pharma industry. She informed that OPPI has a “Code of Pharmaceutical Practices” which its members are bound by and which is based on the 'International Federation of Pharmaceutical Manufacturers and Associations' Code. She said that the marketing activities taken up by firms largely depend on actions of other firms while most other aspects of the company are governed by international codes, thus, the OPPI “Code of Pharmaceutical Practices” is important for its members.

She emphasized that the patient is at the centre of this system and the companies want them to benefit and believe that he can trust the company to keep his interests at the core, however, the unfavorable media coverages and things such as sting operations create an unfavorable impression.

OPPI is also trying to promote the mandatory adoption of “Uniform Code of Pharmaceutical Marketing Practices (UCPMP)” developed by Department of Pharmaceuticals which is so far voluntary in nature. Thus, this signifies that the intent is there but it is upto the people to adopt it. It would be positive to see the government taking action and collaborations between them and industry. According to her ‘Sustainability’ is a broad term meaning different things to different people, but it is important to understand that “responsible business is good business”. Actions are being taken up by individual companies and they are even doing it at a global level but there is scope of bringing out the best practices which are tried and tested in other countries.

Neha Kumar spoke about why the sector level business responsibility lens was important and the public good aspect. “Consumer perspective was at the heart of pharma sector and the question is, could business enhance quality of life of people?”. The environmental, social and governance

aspects needed to be integrated in the business decisions and “these should not be something additional but within the processes”. Co-regulation is also an important aspect as these guidelines are voluntary, the policy makers should only nudge and it is upto the businesses to figure where they are on this journey. There are some companies doing better than the others and they include some of these practices which make them go beyond the minimum compliance level.

Shankar Venkateswaran, said that the government has two roles in this process. One is that of a regulator and the other is of upholding the social contract between businesses and the society. The role of the Ministry of Corporate Affairs is to provide a framework through NVGs. The NVGs provide a broad framework and should not be seen as another thing to comply with, but everyone should think of responsibility the same way. There is a sense of relief among various stakeholders as everyone is on the same page and talking the same language. This could have only been done by the government” he said. The stakeholders then need to figure how these universal elements apply to their industry, thus arises the need for sector specific guidelines. This is a conversation that the industry needs to have, while the role of the government is to provoke thought and then step back.

Jatish Sheth, Karnataka Drugs and Pharmaceuticals Manufacturers’ Association highlighted that there is a stringent “Standard Operating Procedure” which encompasses the work of the sector and suggested that these guidelines could be made a part of that.

National Voluntary Guidelines and its importance

Neha Kumar made a presentation in which she highlighted the fact that the NVGs were an all-encompassing framework which dealt with everything that was a part of the core business. There was a need for a “holistic Indian concept of business responsibility” dealing with the environmental, societal and economic responsibilities of businesses and also to understand how business growth and responsibility go together. These needed to touch upon the issues of materiality which was most important for businesses and focus on integration and stakeholder engagement. Value creation was an important aspect to understand how businesses can go beyond creating profits as well as reporting, to effectively communicate to relevant stakeholders. This would also help in identifying gaps as the businesses would then look at the processes as well. The process of developing the NVGs was an extensive one spread over a couple of years and the stakeholder consultations were a part of the process. They synced international and Indian practices.

She also described the structure of the document which firstly showcased the 9 principles. Each principle had a brief description which amplified the principle and was followed by the core elements which defined how the principle would manifest itself. The next section dealt with the Implementation framework with indicators for the way these could be integrated into the business. This is followed by a chapter on specific inputs for MSMEs, case-lets to aid comprehension of good practices and business case matrix which dealt with the value propositions for businesses for each principle. The next section mapped the principles with the prevailing laws and acts in the country.

The implementation guidance lists out the steps the companies can take for adoption of the NVG principles. The companies are already reporting on the various regulatory requirements specific to the businesses and industry, thus the reporting on the NVGs cannot be burdensome and should deal with the most critical aspects that should be in the public domain. SEBI has made it mandatory to top 100 listed companies to report on NVG principles through “Business Responsibility Report” as part of their annual reports. The objective of the BRR deals more with the process and meaningful disclosure.

Vasanthi Srinivasan talked about the consumer centric approach and the need to gather the information available globally in terms of patient protection and actions being taken by different segments such as public health agencies, NGOs among others. The key drivers are increased reporting to declare and sharing the information with all stakeholders. This can create a value proposition for the firms as the quality and responsibility would be guaranteed at their end.

Shankar Venkateswaran talked about how the industry was so highly regulated and “being able to demonstrate responsibility beyond the norms would create value” and gave the example of the Chemical Industry in Europe.

Presentation and Discussion on ESG issues in Pharmaceutical sector

Vasanthi Srinivasan presented on the key ESG issues in the pharmaceutical sector which would then be used for framing the guidelines. She gave a brief overview of the sector highlighting the rapid growth, not just locally but also globally and the heterogeneity of the players in the sector. A key challenge was “access of good quality affordable healthcare”. The sector is highly regulated and there exists “an opportunity for the pharmaceutical companies because they are highly regulated” to demonstrate their actions which are beyond compliance practices.

Some of the issues which emerged include whether the sector can play a role in the distribution challenge through trade channels. This was followed by a discussion on the key stakeholders of this sector which included the Government, pharmaceutical firms, pharmaceutical associations, healthcare providers, pharmacists and patients. Philosophically all stakeholders are considered equally important but in terms of delivering public good some could be more important than others. Patient would be the key stakeholder when it comes to delivering public good.

DG Shah mentioned that trade as a stakeholder had been missed and the access to medicines is related to trade. Rijit Sengupta suggested that the relevant stakeholders should be listed out and revisited at the end to figure out the most relevant stakeholders to reach out to them. BR Jagashetty indicated that most manufacturers were not bothered to go upto the retail part of the value chain or to the consumers. Regulators found that the manufacturers were usually concerned up to the stockists but things such as spurious drugs entered the systems at a later stage of the supply chain; thus, the manufacturers should be obligated to check where his stock is moving. Vasanthi Srinivasan indicated that thus, in this sector the distribution is as critical as the back end supply chain.

This was followed by a discussion on each of the principles and core elements identified by the team in order to understand the most critical ones for the sector.

Principle 1: Ethics, Transparency and Accountability

Post the discussion it was decided to retain the following core elements –

- * Refrain from unethical promotion and marketing of drugs
- * Disseminating knowledge and sharing ‘good practices’ by the pharma industry
- * Dealings between Pharma companies and doctors

Principle 2: Providing goods and services that are sustainable over entire life cycle

- * Promote NVGs principles throughout the inward supply chain
- * Unused/date expired medicines disposal
- * Drug recalls
- * Inclusion of GMP - as a box story

Principle 3: Employees' well-being

- * Training and enforcement of occupational safety standards
- * Safe handling of chemicals and equipment (GLP)
- * Presence of employee's grievance redressal mechanism at firm level
- * Overall work place safety
- * Gender sensitivity and zero-tolerance for harassment

Principle 4: Being responsive towards stakeholders, especially the disadvantaged

- * Adequate attention to mapping of 'relevant stakeholders'
- * Development of a strategy for stakeholder engagement with special attention to: communities at risk, patients, PAP, etc.
- * A box on stakeholders identification

Principle 5: Respecting and promoting human rights

- * Well-laid out and communicated policy on 'Clinical Trials' by the firm
- * Policy for proper care and compensation in-case of mishaps
- * Engagement with human rights experts and practitioners for advocacy of best practices

The research has included clinical trial aspects of the firm predominantly in principle 5. However, there seems to be some conflicts as this could further hurt the already stuck clinical trials of new drugs in India. D G Shah highlighted how access to modern medicines is also a human right and that the medicines sold in Europe, USA and Japan among others, and which our neighbouring countries may approve, will be deprived to Indians. He also mentioned that perceptions are hampered due to anecdotal evidence in the media. Vasanthi Srinivasan indicated that though this is a crucial issue in India, given the sensitivity of the issue, the research team would need to rethink on get back to the advisory group

Principle 6: Protecting and restoring the environment

- * Achieving Energy Efficiency
- * Keeping emissions (air) and discharges (water) within the prescribed standards
- * Management of hazardous wastes
- * Moving towards better water efficient production

Principle 7: Responsible policy advocacy that enhances public good

- * Productive and continuous engagement on relevant policy matters impacting both the industry and the consumers

- * Support initiatives on key issues such as Prescription Audit, Rational Use of Drugs, etc.

Two issues emerged as critical which required further brainstorming. These are related to a) Pricing and b) Whistle blower policy

Principle 8: Supporting inclusive growth and development

D G Shah enquired the definition of “generics” in the 2nd core element which states “Continue to give adequate attention to production of good quality generic medicines”. He indicated that as per NPPA all medicines are of the same quality and hence there is no point of differentiation, however this was not true. He then discussed that bioequivalence can be established within 4 years and then he questioned how it can be established whether these are of the same quality or not. He discussed the different terminologies used in some places such as Latin America which uses the term “generic” for drugs which are bioequivalent and “similar”. Rijit Sengupta talked about how the large numbers of mergers and acquisitions which have happened in India, have implications on product lines of the Indian companies producing generic medicines.

D G Shah recommended the use of “medicines” and dropping the term “generics” from the statement. Shankar Venkateswaran spoke about affordable, good quality, low cost medicines. D G Shah questioned whether industry alone was responsible for providing these and Dr. B R Jagashetty talked about procurement.

- * Investing and developing (through R&D) innovative yet affordable medicines
- * Continue to give adequate attention to production of good quality medicines
- * Work towards improving access to essential drugs, especially in remote locations

Principle 9: Providing value to customers responsibly

- * Proper labelling and disposal of medicines
- * Promotion of ‘rational use of drugs’
- * Redressal mechanism for customers

Closing Discussions

Vasanthi Srinivasan questioned if the NVGs Guidelines needed to be different based on company size but the group agreed that such a distinction should not be made. Jatish Sheth suggested that elements which can be addressed by all (lowest common denominator) should be included. D G Shah suggested creating a matrix listing the 9 principles along with the respective core elements which would help identify any overlaps.