BUSINESS RESPONSIBILITY GUIDELINES FOR THE PHARMACEUTICAL SECTOR IN INDIA

Minutes of the Stakeholder Consultation
12th December, 2014, Bangalore

Consumer Unity and Trust Society (CUTS), with support from the Indian Institute for Corporate Affairs (IICA) and DeutscheGesellschaftfürInternationaleZusammenarbeit (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. 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. The process will be stakeholder led and the guidelines would be developed with guidance of pharmaceutical business associations, government bodies and expert advisors.

The Research team at CUTS had undertaken desk research (literature review) on various facets of pharmaceutical sector for developing the outline for NVGs. On the basis of the deliberations with the experts and finalisation of the key areas during the Advisory Group meeting, the research team has developed the zero draft of the guidelines focussed on critical areas in the pharmaceutical sector.

In this context, a state level consultation meeting was organized in Bangalore with members of the **Karnataka Drugs and Pharmaceuticals Manufacturers' Association (KDPMA)**. The objective of the meeting was to share the zero draft and take inputs of the state-level actors to further refine and include any other critical aspects of the sector.

In Attendance:

- Jatish Sheth. President, Karnataka Drugs and Pharmaceuticals Manufacturers' Association (KDPMA)
- Sunil Attavar, Secretary, KDPMA
- Senior Members of KDPMA
- Vasanthi Srinivasan, Project Advisor, CUTS and Professor, IIM Bangalore
- Vikash Batham, CUTS
- Tunisha Kapoor, CUTS

Introduction:

The group mentioned that one of the major contribution and successes of the Indian Pharmaceutical Industry is the reach of the medicines as they are available in every part of the country at the same price and with the same efficacy. They suggested that each of the principles should have specific actionable suggestions and guidance on implementation for each of the core elements. Atleast for the Micro, Small and Medium Enterprises (MSME) each of the elements need to be interpreted in an actionable manner.

The broad discussions for each of the principles are mentioned in the sections below:

Principle 1: Under the issue of unethical promotions, the group suggested that specific issues of what is and is not permitted should be mentioned. The subject of free samples in terms of quantity and drugs for which this should be permitted was discussed and the group felt that products under Schedule H should not be given as free samples. The issue of bonus offers should also be addressed in terms of implementation. Good practices and samples of good governance structures should be included. In terms of the public disclosure, expenses linked with physicians should be included for better implementation. The MSME sector would also need guidance on development of an Annual Report in terms of issues to be reported.

Principle 2: The aspects of Good Distribution Practices should be brought out under this principle as it is one of the major concerns regarding the expired drugs. The pharmaceutical companies have complete control till the C & F Agents/ Super Stockists, reasonable control after drugs are passed on to the Stockists but no control after it is sent to the retailers.

Principle 3: The group believed that training on material handling and pre-employment training should also be included. Internal mechanisms for grievance redressal should be encouraged in firms.

Principle 4: The group believed that price control was not the solution and current schemes need to be made more effective to ensure availability of affordable/ free medicines to the marginalized section of society.

Principle 5: The issue of data integrity should be addressed under clinical trials. Video trials could be a possible solution to ensure compliance.

Principle 6: The core elements should also include aspects of waste management, energy reduction, renewable energy substitution and water.

Principle 7: Core Element 4 should be revised to "responsible Whistle Blower Policy".

Principle 8: A possible mechanism discussed was Pharma companies working with educational institutions to engage them in innovation

Principle 9: The box story needs to be revised as *"Pharma industry's main objective is to develop quality medicines which are affordable to all and are easily accessible"*. Another possible aspect that can be included is the pharma co-vigilance programme. A proper framework and process should be in place to address grievances of all stakeholders such as patient, doctor among others.

Some of the suggestions made by the group included:

* A simple reporting framework of 2-3 pages should be designed
* Clear guidelines on what constitutes a bribe and practices to be avoided during marketing and promotions should be listed
* Actionable implementation guidelines should be given for all elements, atleast for the MSME enterprises
* All communication should be designed in a way so that even a layman can comprehend it
* The company should have a Standard Operating Procedure for aspects covered under each of the principles to ensure adherence and implementation
* Industry Associations can develop self-certification systems to avoid multiple audits. This would signify compliance with the laws and regulations of the country

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