CUTS Project Brief

National Voluntary Guidelines for the Pharmaceutical Sector in India

Background & Context

Under the aegis of the Ministry of Corporate Affairs, the National Voluntary Guidelines on Social, Environmental and Economic Responsibilities of Business (NVGs) was developed and the process was managed by the Indian Institute for Corporate Affairs (IICA) and Deutsche Gesellschaft f r Internationale Zusammenarbeit (GIZ).The NVGs were adopted in mid-2011 presents a framework comprising 9 Principles and 48 Core Elements and is intended to provide a holistic idea of how CSR can be operationalised in sectors. It is not only applicable for companies operating in India, but also on Indian transnational corporations (TNCs) operating outside the country.

Though, the NVGs are designed for use by all businesses and sectors and therefore touch on the fundamental aspects – the 'spirit'– of an enterprise, the issues vary from sector to sector and thus, the application of NVG would also be different. The IICA-GIZ Business Responsibility Initiative has identified pharmaceutical as one of the sectors for which sectoral guidelines needs to be developed based on the NVGs.

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.

The overarching objective of drafting the pharma sector guidelines is to mainstream the NVGs into the pharma sector in order to help businesses understand, adopt and implement them so as to enable the pharma industry to grow more competent and resilient by maximising benefits, and minimizing risks, and contributing to the national development goals.

Project Activities

(i) Preparatory Work and Formation of the Sub- Group

A Sub-group comprised of 8-10 members will be formed which will play an integral role (advisory) in formation of the guidelines for the pharmaceutical sector.

The Sub-group will be chaired by the representative of one pharmaceutical association which also includes representatives from IICA, GIZ, and relevant government department, representative of small state level associations, CSO and pharmaceutical subject experts. The formation of the sub-group will be done over emails.

(ii) Research on core ESG issues of the Pharma sector

The task would involve undertaking **desk research (literature review)** on various facets of pharmaceutical sector for developing the outline for NVGs.

Supported by:

The first contact meeting of the group will be organised to discuss the following key issues:

- Brief the group details regarding the project and their role/expectations
- Sensitise the group regarding the need/importance of NVGs and sector specific guidelines
- Share the outcomes of the preliminary analysis and the critical areas that have been identified to be vetted by the core group.

On the basis of the deliberations and finalisation of the key areas, the research team will prepare an outline that will help in designing the zero draft of the guidelines focussed on critical areas in the pharmaceutical sector.

(iii) Zero draft of the Guidelines

On the basis of the outline developed, CUTS would take the lead to draft the NVGs for the pharmaceutical sector in India for the critical areas, as have been identified.

The guidelines will set out principles and internationally accepted standards for responsible practices. They would provide a framework so that governments/business would be able to use when developing their own strategies, policies, legislations, programmes and activities.

The draft guidelines will also be shared with the Sub-group representatives for their comments/inputs.

(iv) Stakeholder Workshops (State level)

Two State level workshop (Gujarat and Karnataka) will be organised for taking their inputs on the draft guidelines from state-level actors.

The consultations will include representative of pharma industry (from both large and MSME) and pharma associations and IICA GIZ, working group for sector guidelines and other subject experts.

(v) Consolidation and finalisation of Guidelines

Comments and feedback received from the state level consultations and the Sub-group would be taken into consideration to finalise the guidelines.

(vi) Dissemination of final Guidelines

Online dissemination of the final Guidelines would be organised in consultation the IICA-GIZ to release the guidelines at the national level.

Expected Outcomes

- Identification of the critical areas in the pharmaceutical sector from the perspective of responsible business practices
- Designing national voluntary guidelines suited to the issues of the pharmaceutical sector