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CHAPTER 1: INTRODUCTION TO THE GUIDELINES

PREAMBLE

Businesses are increasingly beginning to realize that their actions impact society and the environment. They have to focus their attention on achieving the 'triple bottom line'- people, planet and profit. The National Voluntary Guidelines were designed for use by businesses across sectors and touch on the fundamental aspects – the 'spirit'– of an enterprise. However, owing to the varied nature, size, stakeholder groups and multiplicity of players involved, there was a need for developing sector specific guidelines to address the critical issues of the particular sector.

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 this sector has direct impact on consumer well-being. The overarching objective of drafting the sector guidelines is to mainstream the NVGs into the pharmaceutical sector in order to help businesses understand adopt and implement them. This would enable the pharma industry to become competitive and resilient by maximising benefits, minimizing risks, and contributing to the national development goals.

The patient is at the heart of the system and one of the unique characteristics of the industry is their role in enhancing the quality of life of the people. Access to healthcare is the right of every citizen and pharmaceutical firms are one of the main stakeholders. They have a critical role to play in the access to affordable and quality medicines across the country. The environmental, social and governance aspects are integrated within the business decisions to enable the sector to achieve both objectives; profits as well as sustainability. The pharmaceutical industry has three key consumers --- the doctors who prescribe the drug, the pharmacists who distribute the drug and the patient who consumes the drug. The final customer in this case is often an ignorant individual who depends on the expertise of the doctor for advice.

CHAPTER 2: PRINCIPLES AND CORE ELEMENTS

Principle 1: Businesses should conduct and govern themselves with Ethics, Transparency and Accountability

Brief Description

The principle recognizes that ethical conduct in all its functions and processes is the cornerstone of responsible business. The principle acknowledges that business decisions and actions, including those required to operationalize the principles in these Guidelines should be amenable to disclosure and be visible to relevant stakeholders.

The principle emphasizes that businesses should inform all relevant stakeholders of the operating risks and address and redress the issues raised.

The principle recognizes that the behaviour, decision making styles and actions of the leadership of the business establishes a culture of integrity and ethics throughout the enterprise.

Core elements

1. Businesses should develop good governance structures, Standard Operating Procedures (SOPs) and practices that ensure ethical conduct at all levels; and promote the adoption of this principle across its value chain. The board has direct accountability in this regard.
2. Businesses should not engage in unethical promotion and marketing of drugs including no/ minimum free samples to physicians. It should adhere to relevant national and or international guidelines on ethical marketing practices.
3. The businesses should publish a comprehensive annual report, including qualitative and quantitative information, enabling an assessment of the business' policies, programmes, projects and other activities.
4. Businesses should report on the status of their adoption of all principles in these Guidelines to demonstrate their commitment to responsible business practices.
5. The businesses should publicly disclose its details for important matters related to clinical trials, promotional and marketing expenses (linked with physicians) in their reporting.
6. Businesses should encourage and incorporate a responsible whistle blower policy.

Pharmaceutical Association has been long calling for mandatory status of ethical marketing guidelines and its effective operationalisation

Principle 2: Businesses should provide goods and services that are safe and contribute to sustainability throughout their life cycle

Brief Description

Good manufacturing practices (GMP) is a system for ensuring that products are consistently produced and controlled according to quality standards. The requirements specified under Schedule M, which is part of Drug and Cosmetic Act 1940, have become mandatory for pharmaceutical manufacturing units in India w.e.f July, 2005

The principle emphasizes that in order to function effectively and profitably, businesses should work to improve the quality of life of people.

The principle recognizes that all stages of the product life cycle, right from design to final disposal of the goods and services after use, have an impact on society and the environment. Responsible businesses, therefore, should engineer value in their goods and services by keeping in mind these impacts.

The principle, while appreciating that businesses are increasingly aware of the need to be internally efficient and responsible, exhorts them to extend their processes to cover the entire value chain – from sourcing of raw materials or process inputs to

distribution and disposal.

Core Elements

1. One of the key aspects of responsible business behaviour in the pharma industry is the Good Manufacturing Practices which ensures that the quality and safety of the drugs manufactured conform to the required standards. The businesses should manufacture medicines that comply with required manufacturing standards as well as other appropriate international regulatory requirements for quality, safety and efficacy.
2. Businesses should ensure that the manufacturing processes and technologies required to produce medicines are resource efficient and sustainable.
3. Proper and scientific disposal of unused/date expired medicines should be ensured.
4. Businesses should inform the prescriber (Doctors), relevant information about drugs including their safety, efficacy, content, composition and side effects etc during the launch of drugs.
5. Businesses should ensure that the trade channels, through which medicines are distributed, adhere to responsible distribution of products (Good Distribution Practices).

Principle 3: Businesses should promote the well-being of all employees

Brief Description

The principle encompasses all policies and practices relating to the dignity and wellbeing of employees engaged within a business or in its value chain.

The principle extends to all categories of employees engaged in activities contributing to the business, within or outside of its boundaries and covers work performed by individuals, including sub-contracted and home based work.

Core Elements

1. Businesses should respect the right to freedom of association, participation, collective bargaining, and provide access to appropriate grievance redressal mechanisms.
2. Businesses should provide and maintain equal opportunities at the time of recruitment as well as during the course of employment irrespective of caste, creed, gender, race, religion, disability or sexual orientation.
3. Businesses should not use child labour, forced labour or any form of involuntary labour, paid or unpaid.
4. Businesses should provide a workplace environment that is safe, hygienic humane, and which upholds the dignity of the employees. Business should communicate this provision to their employees and train them on a regular basis.
5. Management should ensure training of employees on material handling (chemicals and equipment's) and occupational hazards.
6. Businesses should create systems and practices to ensure a harassment free workplace where women and other excluded groups feel safe and secure in discharging their responsibilities.
7. Businesses should proactively persuade and support its value chain (including contract manufacturers, SMEs) to adopt this principle.

A stakeholder may be defined as any group or individual who can affect or is affected by the achievement of the organization's objectives. The need for stakeholder identification arises due to the interconnected nature of society today and no stakeholder can be looked at in isolation

8. In the context of supply chain, the businesses should ensure that the suppliers of raw materials and products adhere to the above aspects. In the context of trade and distribution, businesses should ensure that fair labour practices are followed especially with reference to the sales representatives.

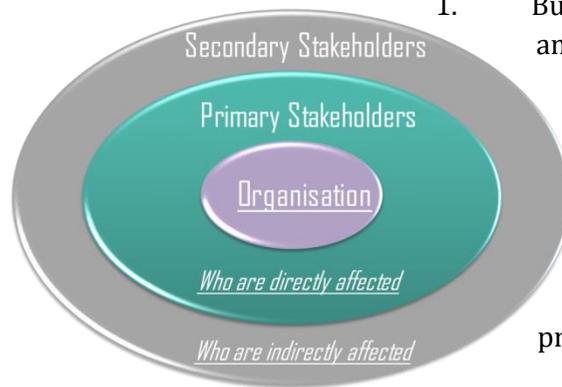
Principle 4: Businesses should respect the interests of, and be responsive towards all stakeholders, especially those who are disadvantaged, vulnerable and marginalised

Brief Description

The principle recognizes that businesses have a responsibility to think and act beyond the interests of its shareholders to include all their stakeholders.

The Principle, while appreciating that all stakeholders are not equally influential or aware, encourages businesses to proactively engage with and respond to those that are disadvantaged, vulnerable and marginalized.

Core Elements



1. Businesses should systematically identify their stakeholders, understand their concerns, define purpose and scope of engagement, and commit to engaging with them.
2. The businesses should encourage and facilitate multi-stakeholder engagement in the formulation of its policies, programmes, projects and other activities that bear upon access to medicines. This engagement should include the active and informed participation of disadvantaged individuals, communities and populations.
3. Businesses should promote adoption of good ESG (Environment, Social and Governance) practices both at the firm level and the supply chain level (including contract manufacturers).

Principle 5: Businesses should respect and promote human rights

Brief Description

The principle recognizes that human rights are the codification and agreement of what it means to treat others with dignity and respect. Over the decades, these have evolved under the headings of civil, political, economic, cultural and social rights. This holistic and widely agreed nature of human rights offers a practical and legitimate framework for business leaders seeking to manage risks, seize business opportunities and compete in a responsible fashion.

The principle imbibes its spirit from the Constitution of India, which through its provisions of Fundamental Rights and Directive Principles of State Policy, enshrines the achievement of human rights for all its citizens. In addition, the principle is in consonance with the Universal Declaration of Human Rights, in the formation of which, India played an active role.

The principle takes into account the “Corporate Responsibility to Respect Human Rights”, as referred in the United Nations “Protect, Respect, Remedy” Framework.

Core elements

1. The businesses should integrate human rights into the strategies, policies, programmes, projects and activities of the business.
2. The businesses’ clinical trials should observe the highest ethical and human rights standards, including non-discrimination, equality and the requirements of informed consent.
3. Firms undertaking clinical trials must obtain voluntary, informed consent of the prospective subject undergoing trials and follow the required protocol. The business should clearly define the compensation policy for the trial participants.
4. Businesses should, within their sphere of influence, promote the awareness and realization of human rights across their value chain.
5. Businesses should not be complicit with human rights abuses by a third party.

Principle 6: Business should respect, protect, and make efforts to restore the environment

Brief Description

The principle recognizes that environmental responsibility is a prerequisite for sustainable economic growth and for the well being of society.

The principle emphasizes that environmental issues are interconnected at the local, regional and global levels which makes it imperative for businesses to address issues such as global warming, biodiversity conservation and climate change in a comprehensive and systematic manner.

The principle encourages businesses to understand and be accountable for direct and indirect environmental impacts of their operations, products and services and to strive to make them more environment friendly.

The Principle urges businesses to follow the precautionary principle and not go ahead with a particular action if it is unsure of its adverse impacts.

Core Elements

1. Businesses should utilize natural and manmade resources in an optimal and responsible manner and ensure the sustainability of resources by reducing, reusing, recycling and managing waste.
2. Businesses should take measures to check and prevent pollution. They should assess the environmental damage and bear the cost of pollution abatement with due regard to public interest.
3. Businesses should continuously seek to improve their environmental performance by adopting cleaner production methods, promoting use of energy efficient and environment friendly technologies and use of renewable energy.
4. Businesses should develop Environment Management Systems (EMS) and contingency plans and processes that help them in preventing, mitigating and controlling environmental damages and disasters, which may be caused due to their operations or that of a member of its value chain.
5. Businesses should report their environmental performance, including the assessment of potential environmental risks associated with their operations, to the stakeholders in a fair and transparent manner.
6. Businesses should proactively persuade and support its value chain (including contract manufacturers and SMEs) to adopt this principle.
7. Businesses should ensure that drinking water and air for the members of the community remains clean and without contamination.

Principle 7: Businesses, when engaged in influencing public and regulatory policy, should do so in a responsible manner

Brief Description

The principle recognizes that businesses operate within the specified legislative and policy frameworks prescribed by the Government, which guide their growth and also provide for certain desirable restrictions and boundaries.

The principle acknowledges that in a democratic set-up, such legal frameworks are developed in a collaborative manner with participation of all the stakeholders, including businesses.

The principle, in that context, recognizes the right of businesses to engage with the Government for redressal of a grievance or for influencing public policy and public opinion.

The principle emphasizes that policy advocacy must expand public good rather than diminish it or make it available to a select few.

Core Elements

1. The pharmaceutical industry has a role to play in ensuring that its policies and practices support the fight for health in the developing world, particularly in those countries with acute shortages of resources and poor infrastructure.
2. To the extent possible, businesses should consult relevant stakeholders before policy advocacy. They should utilize the trade, industry chambers and associations and other such collective platforms to undertake policy advocacy on relevant issues.
3. Business should support initiatives on key issues that can help improve the overall healthcare status including Rational Use of Drugs, government Schemes and such like.
4. Businesses should encourage and incorporate a responsible whistle blower policy.
5. In collaboration with government and regulators, the businesses should take all reasonable measures to advocate and implement measures to address counterfeiting.

Principle 8: Businesses should support inclusive growth and equitable development

Brief Description

The principle recognizes the challenges of social and economic development faced by India and builds upon the development agenda that has been articulated in the government policies and priorities.

The principle recognizes the value of the energy and enterprise of businesses and encourages them to innovate and contribute to the overall development of the country, especially to that of the disadvantaged, vulnerable and marginalised sections of society.

The principle also emphasizes the need for collaboration amongst businesses, government agencies and civil society in furthering this development agenda.

The principle reiterates that business prosperity and inclusive growth and equitable development are interdependent.

Core Elements

1. Businesses should understand their impact on social and economic development, and respond through appropriate action to minimise the negative impacts.
 2. Business should innovate, collaborate and invest in those products, technologies and processes that promote the well-being of society.
 3. Businesses operating in regions that are underdeveloped should be especially sensitive to local concerns.
 4. The business should, within its sphere of influence, aim to address the issue of access to medicines and support the fight for health.
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Principle 9: Businesses should engage with and provide value to their customers and consumers in a responsible manner

Brief Description

This principle is based on the fact that the basic aim of a business entity is to provide goods and services to its customers in a manner that creates value for both.

The principle acknowledges that no business entity can exist or survive in the absence of its customers.

The principle recognizes that customers have the freedom of choice in the selection and usage of goods and services, and that the enterprises will strive to make available goods that are safe, competitively priced, easy to use and safe to dispose off, for the benefit of their customers.

The principle also recognizes that businesses have an obligation to mitigating the long term adverse impacts that excessive consumption may have on the overall well-being of individuals, society and our planet.

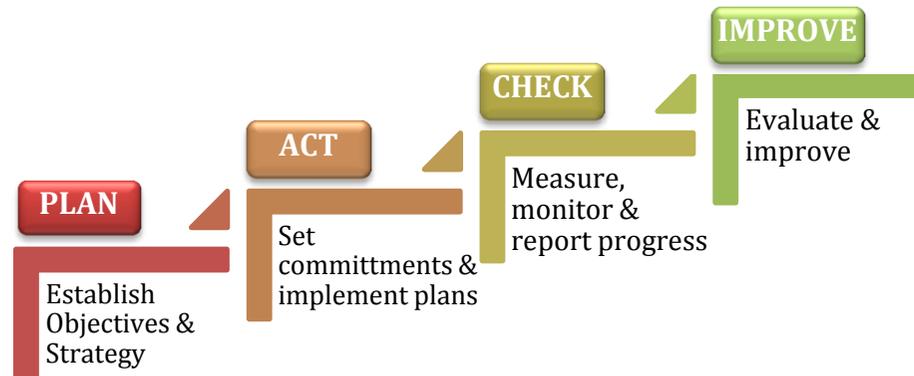
Core Elements

1. Businesses should promote their brands in a way that do not mislead or confuse the stakeholders (doctors, pharmacists and patients) or violate relevant regulation.
2. Businesses should promote innovations to reduce the cost of new drug development and its production to help make the final product affordable for the consumers and society at large.
3. Businesses should ensure that they do not restrict the freedom of choice and free competition in any manner while designing, promoting and selling their products.
4. The businesses should take effective measures to ensure that all information bearing upon the safety, efficacy, and possible side effects of a medicine are easily accessible to individuals so they can take informed decisions about its possible use. Wherever required, pharma industry should educate their consumers on safe and responsible usage of their products and appropriate disposal of unused medicines.
5. Businesses should not offer gifts in cash or in kind to persons qualified to prescribe or supply drugs including doctors, pharmacists, distributors.
6. Businesses should provide adequate grievance handling mechanisms to address customer concerns and feedback.

Pharma industry's main objective is to develop quality medicines which are affordable to all and are easily accessible

CHAPTER 3: GUIDANCE ON IMPLEMENTATION OF PRINCIPLES AND CORE ELEMENTS

Successful implementation of the Principles and Core elements that this Guideline provides require that all of them need to be integrated and embedded in the core business processes of an enterprise.



Source: ISO-9001 Implementation Guide

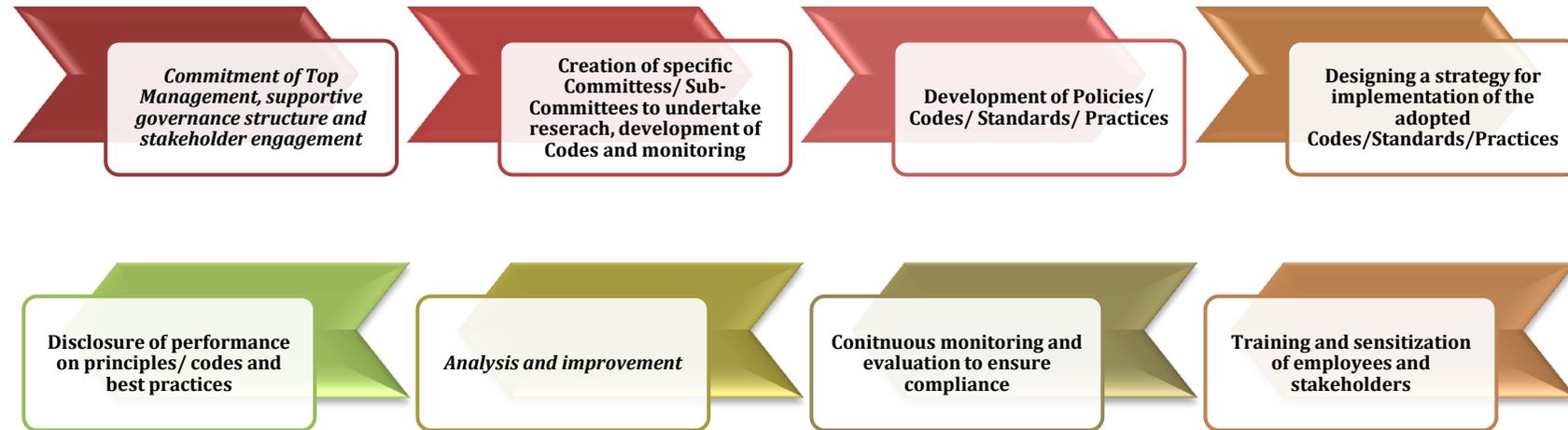
This requires, specifically that the following actions are taken:

Leadership – The Chairman/CEO/Owner-Manager should play a proactive role in convincing the board/Top Management and staff within the business that adopting these principles is crucial for success. The board and senior management need to ensure that the principles are fully understood across the organization and comprehensively executed.

Integration – These principles and core elements must be embedded in the Business policies and strategies emanating from the core business purpose of the organization. For this to happen, these must align with each business's internal values and/or must provide clear business benefits.

Engagement – Building strong relationships and engaging with stakeholders on a consistent, continuous basis is crucial.

Reporting - Implementation process includes disclosure by companies of their impact on society an environment to their stakeholders.



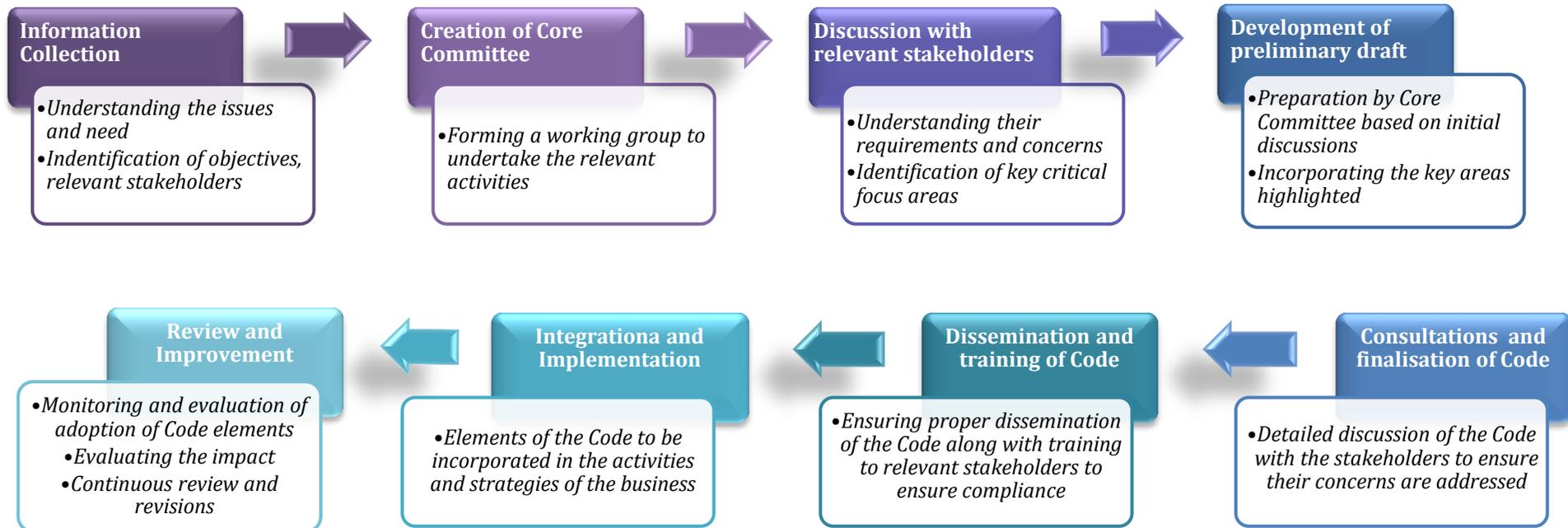
Implementation Process

- * The business should develop a Code of Conduct and also design a strategy for implementation of the adopted Codes/Standards/Practices.
- * Business should place an institutional mechanism for operationalizing of guidelines
- * Identification of activities to be carried out
- * Setting measurable physical targets with timeframe as per particular core elements
- * Time schedules and monitoring of measures
- * Allocation of budget for specific activities
- * The business should ensure monitoring and evaluation of the Standards/ Guidelines/ Codes.
- * The business should disclose its good practices and performance periodically through its communication channels such as Annual Reports, website etc.
- * The business should periodically undertake the exercise of identifying stakeholders, their concerns and impact. The business should define a strategy to engage with the stakeholders and communicate with them.

- * The business should include stakeholder engagement as a part of the process while designing programmes, policies etc. in relation to access to medicines.
- * The business should create a team to periodically engage with their value chain to educate and guide them on these principles and encourage adoption.

Development of Codes

The process listed below is one of the possible ways to design a code of conduct for any specific aspect of a business.



Source: Voluntary Codes Guide: Process for Developing Effective Codes, Government of Canada

S. No	Principle	Core Elements	Implementation Process
1)	Businesses should conduct and govern themselves with Ethics , Transparency and Accountability	<p>Businesses should develop good governance structures, Standard Operating Procedures (SOPs) and practices that ensure ethical conduct at all levels; and promote the adoption of this principle across its value chain. The board has direct accountability in this regard.</p> <p>Businesses should not engage in unethical promotion and marketing of drugs including no/ minimum free samples to physicians. It should adhere to relevant national and or international guidelines on ethical marketing practices.</p> <p>The businesses should publish a comprehensive annual report, including qualitative and quantitative information, enabling an assessment of the business’ policies, programmes, projects and other activities.</p> <p>Businesses should report on the status of their adoption of all principles in these Guidelines to demonstrate their commitment to responsible business practices.</p> <p>The businesses should publicly disclose its details for important matters related to clinical trials, promotional and marketing expenses (linked with physicians) in their reporting.</p> <p>Businesses should encourage and incorporate a responsible whistle blower policy.</p>	<ul style="list-style-type: none"> * The Board should develop a framework for monitoring implementation and accessing impact of the governance structures adopted. * The employees including those employed on contractual basis must be given adequate and regular training on the Code/ Standard adopted for ethical marketing and promotion. * The annual report should be easy to read and comprehend and must be disseminated through all communication channels. The reporting should be more granular, incorporating softer aspects apart from data. * The business should disclose its good practices and performance periodically through its communication channels such as Annual Reports, website etc. * The businesses should provide assistance, training and audit its supply chain for greater adoption of sustainable practices and adherence to the business’ codes. * The internal whistle blower policy should aim to confirm and address any deviations stated in a just and transparent manner.
2)	Businesses should provide goods and services that are safe and contribute to sustainability throughout their life cycle	<p>One of the key aspects of responsible business behaviour in the pharma industry is the Good Manufacturing Practices which ensures that the quality and safety of the drugs manufactured conform to the required standards. The businesses should manufacture medicines that comply with required manufacturing standards as well as other appropriate international regulatory requirements for quality, safety and efficacy.</p> <p>Businesses should ensure that the manufacturing processes and technologies required to produce medicines are</p>	<ul style="list-style-type: none"> * The business should design an implementation process to comply with the Good Manufacturing Practices and continuous monitoring and impact evaluation should be conducted. * The businesses should innovate, adopt industry best practices, and develop technologies for sustainable production. * The businesses should attempt to reduce the quantity of drugs returned post expiry by engaging with the distribution channels. They should encourage proactive actions in terms of regular return of soon-to-expire drugs.

S. No	Principle	Core Elements	Implementation Process
		<p>resource efficient and sustainable.</p> <p>Proper and scientific disposal of unused/date expired medicines should be ensured.</p> <p>Businesses should inform the prescriber (Doctors), relevant information about drugs including their safety, efficacy, content, composition and side effects etc during the launch of drugs.</p> <p>Businesses should ensure that the trade channels through which medicines are distributed, adhere to responsible distribution of products (Good Distribution Practices).</p>	<ul style="list-style-type: none"> * The businesses should provide assistance, training etc. to its trade channels on adoption of responsible distribution practices
3)	<p>Businesses should promote the wellbeing of all employees</p>	<p>Businesses should respect the right to freedom of association, participation, collective bargaining, and provide access to appropriate grievance redressal mechanisms.</p> <p>Businesses should provide and maintain equal opportunities at the time of recruitment as well as during the course of employment irrespective of caste, creed, gender, race, religion, disability or sexual orientation.</p> <p>Businesses should not use child labour, forced labour or any form of involuntary labour, paid or unpaid.</p> <p>Businesses should provide a workplace environment that is safe, hygienic humane, and which upholds the dignity of the employees. Business should communicate this provision to their employees and train them on a regular basis.</p> <p>Management should ensure training of employees on material handling (chemicals and equipment's) and occupational hazards.</p> <p>Businesses should create systems and practices to ensure a harassment free workplace where women and other excluded groups feel safe and secure in discharging their responsibilities.</p> <p>Businesses should proactively persuade and support its value chain (including contract manufacturers, SMEs) to adopt this principle.</p>	<ul style="list-style-type: none"> * The business should create an impartial and independent grievance redressal mechanism to handle employee concerns. Such a mechanism should allow for anonymous feedback and complaint. * Periodic feedback sessions to understand employee concerns and needs should be conducted. * The business should ensure periodic training is undertaken for the employees to train them on occupational hazards and safe handling issues. * The business should have a mechanism in place to effectively handle any cases of mishaps due to occupational hazards and the same should be communicated to all employees. * Continuous identification of risks/ threats to different employee groups to design measure to address their concerns. * Businesses should communicate these policies to their supply chain for their adoption and attempt to source materials from suppliers complying with their standards.

S. No	Principle	Core Elements	Implementation Process
		<p>In the context of supply chain, the businesses should ensure that the suppliers of raw materials and products adhere to the above aspects. In the context of trade and distribution, businesses should ensure that fair labour practices are followed especially with reference to the sales representatives.</p>	
4)	<p>Businesses should respect the interests of, and be responsive towards all stakeholders, especially those who are disadvantaged, vulnerable and marginalized</p>	<p>Businesses should systematically identify their stakeholders, understand their concerns, define purpose and scope of engagement, and commit to engaging with them.</p> <p>The businesses should encourage and facilitate multi-stakeholder engagement in the formulation of its policies, programmes, projects and other activities that bear upon access to medicines. This engagement should include the active and informed participation of disadvantaged individuals, communities and populations.</p> <p>Businesses should promote adoption of good ESG (Environment, Social and Governance) practices both at the firm level and the supply chain level (including contract manufacturers).</p>	<ul style="list-style-type: none"> * The business should define a strategy to regularly engage with the stakeholders and communicate with them. * The business should develop effective communication channels to communicate their practices/ policies/ activities with stakeholders and also receive feedback from them. * The business should ensure proper attention and deliberation is provided to all feedback received and if considered significant, should be incorporated into the strategy/ policy. This should also be communicated to stakeholders. * The business should include stakeholder engagement as a part of the process while designing programmes, policies etc. in relation to access to medicines. * The business should undertake programmes, activities, projects to sensitize and provide training to all relevant stakeholders including the supply chain level on various aspects of these Guidelines and adoption of the same. The businesses should, in time, source from suppliers compliant with these practices.
5)	<p>Businesses should respect and promote human rights</p>	<p>The businesses should integrate human rights into the strategies, policies, programmes, projects and activities of the businesses.</p> <p>The businesses' clinical trials should observe the highest ethical and human rights standards, including non-discrimination, equality and the requirements of informed consent.</p>	<ul style="list-style-type: none"> * The business should source their materials from suppliers who follow the guidelines relating to human rights and also conduct audits to access their compliance. * The business should sensitize and provide training to relevant stakeholders including supply chain level on human rights concerns and guidance in terms of incorporating these in

S. No	Principle	Core Elements	Implementation Process
		<p>Firms undertaking clinical trials must obtain voluntary, informed consent of the prospective subject undergoing trials and follow the required protocol. The business should clearly define the compensation policy for the trial participants.</p> <p>Businesses should, within their sphere of influence, promote the awareness and realization of human rights across their value chain.</p> <p>Businesses should not be complicit with human rights abuses by a third party.</p>	<p>strategies, policies, programmes etc.</p> <ul style="list-style-type: none"> * The business should create a Committee/ Sub Committee to engage with human rights experts and work with them to integrate the essence of the issues into policies and further communicate the best practices. * The businesses should have a well-defined transparent mechanism for clinical trials such as consent on video to ensure compliance.
6)	Business should respect, protect, and make efforts to restore the environment	<p>Businesses should utilize natural and manmade resources in an optimal and responsible manner and ensure the sustainability of resources by reducing, reusing, recycling and managing waste.</p> <p>Businesses should take measures to check and prevent pollution. They should assess the environmental damage and bear the cost of pollution abatement with due regard to public interest.</p> <p>Businesses should continuously seek to improve their environmental performance by adopting cleaner production methods, promoting use of energy efficient and environment friendly technologies and use of renewable energy.</p> <p>Businesses should develop Environment Management Systems (EMS) and contingency plans and processes that help them in preventing, mitigating and controlling environmental damages and disasters, which may be caused due to their operations or that of a member of its value chain.</p> <p>Businesses should report their environmental performance, including the assessment of potential environmental risks associated with their operations, to the stakeholders in a fair and transparent manner.</p> <p>Businesses should proactively persuade and support its</p>	<ul style="list-style-type: none"> * The businesses should set periodic targets for lowering their carbon footprint. These should be set for individual activities such as increasing use of renewable energy, reducing water consumptions etc. * The businesses should access its performance on environment management and analyse the impact of their activities. * The business should sensitize and provide training to relevant stakeholders for optimum use of resources and ensure wastage is in check. Businesses should source from suppliers who follow guidelines in this regard. * The business should study the national and international best practices, engage with experts and suggest methods of improving energy sustainability. * The business should disclose its performance, risks, innovations and best practices on environmental aspects to all stakeholders through their communication channels.

S. No	Principle	Core Elements	Implementation Process
		<p>value chain (including contract manufacturers and SMEs) to adopt this principle.</p> <p>Businesses should ensure that drinking water and air for the members of the community remains clean and without contamination.</p>	
7)	<p>Businesses, when engaged in influencing public and regulatory policy, should do so in a responsible manner</p>	<p>The pharmaceutical industry has a role to play in ensuring that its policies and practices support the fight for health in the developing world, particularly in those countries with acute shortages of resources and poor infrastructure.</p> <p>To the extent possible, businesses should consult relevant stakeholders before policy advocacy. They should utilize the trade, industry chambers and associations and other such collective platforms to undertake policy advocacy on relevant issues.</p> <p>Business should support initiatives on key issues that can help improve the overall healthcare status including Rational Use of Drugs, government Schemes and such like.</p> <p>In collaboration with government and regulators, the businesses should take all reasonable measures to advocate and implement measures to address counterfeiting.</p>	<ul style="list-style-type: none"> * The business should cooperate with agencies undertaking initiatives to improve healthcare and make efforts to adopt the recommendations of such studies. * Stakeholder consultations should be a part of any policy/ activity designing to ensure their needs and concerns are addressed through these measures. * The businesses should have measures in place such as random checks etc. to intercept any counterfeit drugs. The businesses should engage and work together with the supply chain and trade to check the presence of counterfeit drugs.
8)	<p>Businesses should support inclusive growth and equitable development</p>	<p>Businesses should understand their impact on social and economic development, and respond through appropriate action to minimise the negative impacts.</p> <p>Business should innovate, collaborate and invest in those products, technologies and processes that promote the wellbeing of society</p> <p>Businesses operating in regions that are underdeveloped should be especially sensitive to local concerns.</p> <p>The business should, within its sphere of influence, aim to address the issue of access to medicines and support the fight for health.</p>	<ul style="list-style-type: none"> * The businesses regularly assess the impact of their actions on society, environment and the businesses and take proactive measures to reduce any negative impacts. * The business should design programmes, activities to address the issue of access to essential drugs. * The businesses should undertake activities to understand and map the issues of the underdeveloped regions and marginalized communities. The businesses should formulate activities/ policies to address the same.
9)	<p>Businesses should engage with and</p>	<p>Businesses should promote their brands in a way that do not mislead or confuse the stakeholders (doctors, pharmacists</p>	<ul style="list-style-type: none"> * The business should also ensure monitoring of their promotion

S. No	Principle	Core Elements	Implementation Process
	<p>provide value to their customers and consumers in a responsible manner</p>	<p>and patients) or violate relevant regulation.</p> <p>Businesses should promote innovations to reduce the cost of new drug development and its production to help make the final product affordable for the consumers and society at large</p> <p>Businesses should ensure that they do not restrict the freedom of choice and free competition in any manner while designing, promoting and selling their products.</p> <p>The businesses should take effective measures to ensure that all information bearing upon the safety, efficacy, and possible side effects of a medicine are easily accessible to individuals so they can take informed decisions about its possible use. Wherever required, pharma industry should educate their consumers on safe and responsible usage of their products and appropriate disposal of unused medicines.</p> <p>Businesses should not offer gifts in cash or in kind to persons qualified to prescribe or supply drugs including doctors, pharmacists, distributors.</p> <p>Businesses should provide adequate grievance handling mechanisms to address customer concerns and feedback</p>	<p>activities to ensure these are compliant with the applicable laws and regulations.</p> <ul style="list-style-type: none"> * The business should undertake systematic programmes/ activities to educate consumers on medicine usage and disposal. * The business should disclose its performance, including deviations and corrective actions, to all stakeholders and wider public using their communication channels. * The grievances registered should be addressed in a time-bound manner. There should be a mechanism to register direct consumer complaints which should be communicated to them. * The businesses should set targets for marketing activities such as free samples, bonus offers, gifts etc. to subsequently reduce or remove wherever not necessary. * The businesses should develop clear guidelines for its employees on the do's and don't's of marketing which clearly defines what constitutes a bribe.

CHAPTER 4: BUSINESS RESPONSIBILITY REPORTING FRAMEWORK

Business Responsibility Report - Suggested Framework

Part –A: General Information about the company

Part A of the report includes basic information and data about the operations of the business entity so that the reading of the report becomes more contextual and comparable with other similarly placed businesses. It may be written in a free format incorporating at least the following:

A-1: Basic Details of the Business

- Basic details of the business – Name; nature of ownership; details of the people in top management; location of its operations - national and international; products and services offered; markets served;
- Economic and Financial Data – Sales; Net Profit; Tax Paid; Total Assets; Market Capitalization(for listed companies); number of employees
- Corporate Identity Number (CIN) of the Company
- Name of the Company
- Registered address
- Website
- E-mail id
- Financial Year reported
- Sector(s) that the Company is engaged in (industrial activity code-wise)
- List three key products/services that the Company manufactures/provides (as in balance sheet)
- Total number of locations where business activity is undertaken by the Company
 - Number of International Locations (Provide details of major 5)
 - Number of National Locations
- Markets served by the Company – Local/State/National/International

A-2: Financial Details of the Business

- Paid up Capital (INR)
- Total Turnover (INR)
- Total Taxes Paid (INR)
- Total profit after taxes (INR)
- Total Spending on Corporate Social Responsibility (CSR) as percentage of profit after tax (%)
- List of activities in which expenditure on CSR has been incurred

A-3: Other Details of the Business

- Does the Company have any Subsidiary Company/ Companies?
- Do the Subsidiary Company/Companies participate in the BR Initiatives of the parent company? If yes, then indicate the number of such subsidiary company(s)
- Do any other entity/entities (e.g. suppliers, distributors etc.) that the Company does business with; participate in the BR initiatives of the Company? If yes, then indicate the percentage of such entity/entities? [Less than 30%, 30-60%, More than 60%]
- Company's priorities in terms of Principle and Core Elements
- Reporting Period/Cycle
- Any Significant Risk that the business would like its stakeholders to know
- Any Goals and Targets that were set by the top management for improving their performance during the Reporting Period

A-4: BR Information

1) Details of Director/Directors responsible for BR

- Details of the Director/Director responsible for implementation of the BR policy/policies
 - DIN Number
 - Name
 - Designation
 - Contact Number
 - E-mail id

2) Principle-wise (as per NVGs) BR Policy/policies (Reply in Y/N)

S. No	Questions	Good Governance & Ethical Marketing & Promotion	Safety & Sustainability	Employee's well being	Stakeholders Engagement	Human rights	Environment Protection	Socio Economic development, innovations for BoP and CSR	Customer Satisfaction and Stakeholder Whistleblower Policy
1.	Do you have a policy/policies for....								
2.	Has the policy being formulated in consultation with the relevant stakeholders?								
3.	Does the policy conform to any national /international standards? If yes, specify? (50 words)								
4.	Has the policy been approved by the Board? Is yes, has it been signed by MD/owner/CEO/appropriate Board Director?								
5.	Does the company have a specified committee of the Board/Director/Official to oversee the implementation of the policy?								
6.	Indicate the link for the policy to be viewed online?								
7.	Has the policy been formally communicated to all relevant internal and external stakeholders?								
8.	Does the company have in-house structure to implement the policy/policies.								
9.	Does the Company have a grievance redressal mechanism related to the policy/policies to address stakeholders' grievances related to the policy/policies?								
10.	Has the company undertaken training programmes for employees and other								

	stakeholders?								
11.	Has the company carried out independent audit/evaluation of the working of this policy by an internal or external agency?								
12.	Has the company formally communicated the performance on the policy to the relevant stakeholders?								

3) If answer to S.No. 1 against any principle, is 'No', please explain why:

S. No	Questions	Good Governance & Ethical Marketing & Promotion	Safety & Sustainability	Employee's well being	Stakeholders Engagement	Human rights	Environment Protection	Socio Economic development, innovations for BoP and CSR	Customer Satisfaction and Stakeholder Whistleblower Policy
1.	The company has not understood the Principles								
2.	The company is not at a stage where it finds itself in a position to formulate and implement the policies on specified principles								
3.	The company does not have financial or manpower resources available for the task								
4.	It is planned to be done within next 6 months								
5.	It is planned to be done within the next 1 year								
6.	Any other reason (please specify)								

4) Governance related to BR

- a. Indicate the frequency with which the Board of Directors, Committee of the Board meet to assess the BR performance of the Company. Within 3 months, 3-6 months, Annually, More than 1 year
- b. Does the Company publish a BR or a Sustainability Report? What is the hyperlink for viewing this report? How frequently it is published

Part -B: Principle wise performance

Part-B of the report incorporates the basic parameters on which the business may report their performance.

Principle 1 – Ethics, Transparency and Accountability

- Does the company have a statement on ethical codes of conduct? Provide details of the process followed to ensure that the same are communicated to stakeholders and followed. How are deviations, if any, addressed?
- Have the employees (permanent and contract) in-charge of marketing and promotion activities been trained on the policy of ethical marketing and promotion? Yes/ No
- Is there a procedure in place for undertaking monitoring and evaluation of the marketing & promotion activities? What is this procedure? Describe briefly.
- Does the company conduct regular monitoring and evaluation of its marketing and promotions activities under this policy? Yes/ No. How many checks were undertaken in the past financial year? How many deviations were observed, what was the nature of these what actions were taken to correct these deviations?
- How much did the company spend (INR) on marketing and promotions in the past financial year? What was the percentage change in the amounts spent compared to the previous year.
- Does the company publish an annual report, including qualitative and quantitative information? If yes, please provide the link of the same.
- Does the company promote sustainable consumption of resources including recycling? Does this extend to the other stakeholders including supply chain and distribution? List upto 3 instances which highlight such practices adopted by the company.
 - i)
 - ii)
 - iii)
- How many stakeholder complaints have been received in the past financial year and what percentage was satisfactorily resolved by the management? If so, provide details thereof, in about 50 words or so.
- Does the company have a whistleblower policy? If Yes, does the whistleblower policy covers only the company or extends to the Group/Joint Ventures/Suppliers/Contractors/Other Stakeholders.

Principle 2 – Products Life Cycle Sustainability

- Does the company manufacture medicines in compliance with schedule M (GMP) and or current World Health Organisation Good Manufacturing Practice Guidelines, as well as any other appropriate international regulatory requirements? Yes/ No. If No, provide reasons why and by when the company plans to have a policy in place?
- Does this policy cover only the company? Yes/ No. Does it extend to the Group/Joint Ventures/ Suppliers/Contractors/Other stakeholders?
- Provide details of the process followed to ensure that the same are communicated to stakeholders and followed. How are deviations, if any, addressed?
- What are the procedures/ practices followed to address the issue of counterfeiting? Does this extend to its distributors/ suppliers etc.
- Did the company find/ receive complaints regarding counterfeit drugs in the past year? If Yes, how many such complaints were received in the past financial year? Please provide details of the medicines and actions taken to address the issue. List upto 3 such cases :
 - i)
 - ii)
 - iii)
- What are the process/ procedures/ actions taken by the company to undertake proper disposal of unused/ date expired medicines? Does the company communicate this to its stakeholders including consumers?
- Does the company interact with the prescribers regularly to educate them on relevant information about the drug? Briefly describe the various types of such interactions undertaken by the company.
- Does the company engage with distributors/ suppliers/ wholesalers to promote the adoption of good distribution practices? Yes/ No. If Yes, what is the frequency of such engagements. Is there a procedure in place to ascertain compliance?

Principle 3 – Employees' well-being

- Please indicate the Total number of employees.
- Please indicate the Total number of employees hired on temporary/contractual/casual basis.
- Please indicate the Number of permanent women employees.
- Please indicate the Number of permanent employees with disabilities
- Do you have an employee association that is recognized by management? What percentage of your permanent employees is members of this recognized employee association?
- Please indicate the Number of complaints relating to child labour, forced labour, involuntary labour, sexual harassment in the last financial year and pending, as on the end of the financial year.

S.No.	Category	No of complaints filed during the financial year	No of complaints pending as on end of the financial year
1.	Child labour/forced labour/involuntary labour		
2.	Sexual harassment		
3.	Discriminatory employment		

- What percentage of your under mentioned employees were given safety & skill up-gradation training in the last year?
 - Permanent Employees
 - Permanent Women Employees
 - Casual/Temporary/Contractual Employees
 - Employees with Disabilities
- Number of training and skill up-gradation programmes organized during the reporting period for employees
- Does the company have a grievance redressal mechanism for employees? Indicate the number of grievances submitted by the employees and how many were successfully resolved in the reporting period.
- Number of incidents of delay in payment of wages during the reporting period
- What are the processes in place to ensure workplace safety and hygiene? How many deviations were observed during the reporting period? How were these concerns addressed?
- Do the policies relating to employee well-being and safety extend to other relevant stakeholders Group/Joint Ventures/ Suppliers/Contractors/Others? How does the company educate these stakeholders on these policies? Is there a procedure to ensure compliance? Briefly describe the same.

Principle 4 – Stakeholder Engagement

- How does the company engage with each group of stakeholders? Also, list the number of meetings conducted with each group of stakeholders-
 - i)
 - ii)

- iii)
- iv)
- v)
- Does the company undertake multi-stakeholder engagement for formulation of policies, projects etc.? Yes/ No. If No, what are the possible reasons and how does the company plan to address it? If Yes, indicate how this was done for policies/ projects in the reporting period. List upto 3 instances –
 - i)
 - ii)
 - iii)
- Are there any special initiatives taken by the company to engage with the disadvantaged, vulnerable and marginalized stakeholders. If so, provide details thereof, in about 50 words or so.
- Does the company have a person/ committee in-charge of stakeholder grievances? If No, what are the reasons and future plan of the company in this regard? If Yes, how many cases of grievances were recorded in the reporting cycle and how many of these were successfully addressed?
- How does the company incorporate good Environmental, Social and Governance practices in their processes? List upto three instances highlighting these.
 - i)
 - ii)
 - iii)
- Does the company promote the adoption of good Environmental, Social and Governance practices at supply chain level?
- Does the company have processes in place to ensure their activities do not result in contamination of air and water for the community? Briefly describe these processes.

Principle 5 – Human Rights

- Does the policy of the company on human rights cover only the company or extend to the Group/Joint Ventures/Suppliers/Contractors/Other Stakeholders?
- Does the company promote/ spread awareness of the human rights policy to its stakeholders?
- How many stakeholder complaints have been received in the past financial year regarding human rights violations and what percent was satisfactorily resolved by the management?
- If the company runs clinical trials on human beings, does the company ensure that voluntary and informed consent is obtained for trial

participants? Briefly describe how this is ensured.

- Does the company have a compensation policy for trial participants? Is this communicated to them? How many cases of compensation occurred in the past year? How many of these were resolved and compensation awarded to the participant? What is the average time taken to provide the compensation?

Principle 6 – Environment

- Does the policy related to Principle 6 cover only the company or extends to the Group/Joint Ventures/Suppliers/Contractors/Other Stakeholders.
- Has the company adopted sustainable practices for production? List 3 instances where the company has managed to integrate sustainability into its manufacturing and production.
 - i)
 - ii)
 - iii)
- What was the energy consumption of the company during the reporting period? List 3 activities undertaken by the company which have helped reduce the energy consumption. How much energy was saved using these processes?
 - i)
 - ii)
 - iii)
- What was the total amount of water consumed
- Does the company have procedures in place for sustainable sourcing (including transportation)?
- Does the company have a mechanism to recycle products and waste? If yes what is the percentage of recycling of products and waste (separately as <5%, 5-10%, >10%). Also, provide details thereof, in about 50 words or so.
- What is amount of water consumed at the company including any subsidiaries/ joint venture? Does the company have a mechanism to recycle water? If yes what is the percentage of recycling of water (separately as <5%, 5-10%, >10%). Also, provide details thereof, in about 50 words or so.
- Does the company have a policy/ process for discharge of water and effluents? Briefly describe the treatment done before discharge and the destination of disposal.
- What was the quantum of greenhouse gas emissions by the company (including any subsidiaries and joint ventures)? Has this reduced as compared to the previous period? Is yes, by how much? What are the steps being taken to reduce emissions? List upto 3 instances.
 - i)
 - ii)
 - iii)
- Does the company identify and assess potential environmental risks?

- Has the company undertaken any other initiatives on – clean technology, energy efficiency, renewable energy, etc. Y/N. If yes, briefly describe these initiatives and provide hyperlink for web page etc.
- Are the Emissions/Waste generated by the company within the permissible limits given by CPCB/SPCB for the financial year being reported?
- Number of show cause/ legal notices received from CPCB/SPCB and the number which are pending (i.e. not resolved to satisfaction) as on end of Financial Year.
- Does the company report its environmental performance including the assessment of potential environmental risks associated with their operations, to the stakeholders? Is yes, please provide the link to access the same.

Principle 7 – Policy Advocacy

- Is your company a member of any trade and chamber or association? If Yes, Name only those major ones that your business deals with:
 - i)
 - ii)
 - iii)
 - iv)
- Have you advocated/lobbied through above associations for the advancement or improvement of public good? Yes/No; if yes specify the broad areas and briefly describe the stand of the company on each of these areas. List upto 3 cases.
 - i)
 - ii)
 - iii)
- .
- How does the company address the issue of access to medicines and support the fight for health? List upto 3 instances describing the actions taken by the company in this regard.
 - i)
 - ii)
 - iii)

Principle 8 – Inclusive Growth

- Does the company have specified programmes/initiatives/projects in pursuit improving access to medicines, particularly in underdeveloped areas and marginalized groups? If yes details thereof.

- What is your company's direct contribution to community development projects- Amount in INR and the details of the projects undertaken (apart from the ones mentioned in Pt. 1).
- Have you taken steps to ensure that this community development initiative is successfully adopted by the community? Please explain in 50 words, or so.
- Has the company invested in any new/ innovative technologies? Yes/ No. If yes, please provide details thereof.

Principle 9 - Value to Consumers

- Has the company taken any initiatives to enhance consumer's knowledge on safety, labeling and safe disposal of medicines? Yes/ No. If yes, please provide details in brief.
- How many consumer complaints did the company receive in the financial year? What percentage of these were successfully resolved.
- Is there any case filed by any stakeholder against the company regarding unfair trade practices, irresponsible advertising and/or anti-competitive behaviour during the last five years and pending as on end of financial year. If so, provide details thereof, in about 50 words or so
- Did the company carry out any consumer survey regarding concerns/ side effects of their medicines? Yes/ No. If yes, please provide details and any concerns expressed in brief.
- Does the company have a grievance redressal mechanism in place for consumers? If yes, how many complaints were received in the past year and what percentage of these was resolved successfully? If no, by when does the company plan to have such a mechanism in place?

Part -C

Part C of the report incorporates two important aspects on BR reporting. Part C-1 is a disclosure on by the business entity on any negative consequences of its operations on the social, environmental and economic fronts.

C-1

- Brief Report on any material/significant negative consequences of the operations of the business entity

C-2

- Brief on Goals and Targets in the area of social, environmental and economic responsibilities that the business entity has set for itself for the next Reporting Period

ANNEXURES

Annexure A: The Business Case for following the Guidelines for the Social Environmental and Economic Responsibilities for Business

The pharmaceutical sector, owing to its significant impact on human life, is governed by multiple regulations and laws. Adopting these guidelines will help the firms streamline their processes and also help minimise negative social, environmental and economic impacts. This also has a positive impact on the brand image and can help a brand's public image. Since the sector has a strong link with public welfare any undesirable information about a company's actions can have a severe negative impact on the brand as well as the sector. Thus, adoption of these guidelines has the potential to positively impact not only the business but also the society and environment.

One of the objectives which all pharmaceutical firms work to achieve is to ensure access to medicines for all in even the remotest part of the country. The principles emphasize that businesses should keep in mind the well-being of society while taking any decisions. Thus, if businesses have adopted these guidelines, it will ensure that their policies/ activities, while primarily prioritising the business impact will also work towards the betterment of society. Hence, the goals of ensuring access to medicines for all will be realised.

Another critical aspect of many pharmaceutical firms is advocating rational use of drugs. Though the final decision of recommending medicines lies with the prescriber, the pharmaceutical firms can ensure they undertake activities to educate prescribers, pharmacist and if possible even end consumers on this aspect.

Promoting Rational Use of Drugs: A suggested Approach



Adopting all principles under these voluntary guidelines will lead to overall benefits for the business, some of which are illustrated in the table below:

Principle	Revenue growth and market access	Cost savings and productivity	Access to capital	Risk management/ license to operate	Human capital	Brand value/ reputation
Ethics, Transparency & Accountability	New customers, Loyal customers, Expanding to new markets	Cost reduction due to removal of ambiguities, Reduced litigations, Better utilization of resources	Increased attractiveness to investors, banks, financial markets	Positive image creation, improving goodwill towards the company, better relations with value chain	Employee satisfaction and loyalty, Increased attractiveness for potential employees	Enhanced brand image, Potential differentiating factor, Better acceptability by foreign regulators
Safe and Sustainable goods & services	New customers, Loyal customers, New markets	Increased efficiency across activities, reduced cost due to greater streamlining of operations	Seen as a secure investment opportunity, lower liability issues	Reduced cases of inferior product quality, Reduced risk of action from regulators and NGOs	High employee morale, productivity, satisfaction	Better brand image, seen as a dependable brand, Potential differentiating factor
Well - being of Employees	Higher productivity	Higher productivity due to greater satisfaction and morale, minimized litigations		Improved relations leading to lesser disruptions, improving goodwill towards the company	Increased Loyalty, Attract and retain Employees, Better performance	Employer of choice, Enhanced brand image
Responsiveness to all Stakeholders	Greater understanding of stakeholder concerns will lead to better product development, Increased market share, Loyal customer-base	Increased efficiency across activities and value chain	Increased attractiveness to investors, banks, financial markets	Positive image creation, better relations with value chain	Employee satisfaction and loyalty, Increased attractiveness for potential employees	Enhanced brand image, Potential differentiating factor
Promoting Human Rights	New customers, Loyal customers	Minimized litigations	Increased attractiveness to investors, banks, financial markets	Positive image creation; for consumers, communities, NGOs, regulators, Government etc., improving goodwill towards the company	Employee satisfaction and loyalty, Increased attractiveness for potential employees	Enhanced brand image
Protecting the	Environmentally	Lower cost due to greater		Positive image creation;	Increased	Enhanced brand

Principle	Revenue growth and market access	Cost savings and productivity	Access to capital	Risk management/ license to operate	Human capital	Brand value/ reputation
Environment	conscious buyers will shift to the brand, acceptance in new markets	energy efficiency, Less danger Of externalities emerging as liabilities.		for consumers, communities, NGOs, regulators, Government etc.	attractiveness for potential employees	image
Responsible Policy Advocacy	Stimulates growth, access to new markets	Likelihood of policy/ regulatory advocacy leading to new models resulting in lower costs	Attractive to investors, banks, financial markets	Positive image creation	Increased attractiveness for potential employees	Enhanced brand image, Seen as a responsible and dependable brand
Supporting Inclusive Development	New customers, access to new markets	Innovation leading to new models and reduced cost	Newer sources of funding such as social venture funds	Enhanced image and greater support from governments, regulators etc., improving goodwill towards the company	New sources of trained employees, Employee loyalty	Enhanced brand image, seen as a responsible brand, Potential differentiating factor
Providing Value to Customer	New customers, Increased customer loyalty, access to new markets	New markets, Innovations leading to reduced costs, Increased efficiency across activities and value chain	Attractive to investors, banks, financial markets	Reduced cases of customer complaints, enhanced brand image	Increased attractiveness for potential employees towards growing firm	Enhanced brand image, Potential differentiating factor

Annexure B: Indicative List of Relevant Laws & Acts Mapped Against Principles

List of Laws (Indicative)	<u>Principle 1</u> Ethics, Transparency & Accountability	<u>Principle 2</u> Safe and Sustainable goods & services	<u>Principle 3</u> Well – being of Employees	<u>Principle 4</u> Responsiveness to all Stakeholders	<u>Principle 5</u> Promoting Human Rights	<u>Principle 6</u> Protecting the Environment	<u>Principle 7</u> Responsible Policy Advocacy	<u>Principle 8</u> Supporting Inclusive Development	<u>Principle 9</u> Providing Value to Customer
Pharmaceutical Policy, 2002	<i>Overarching policy</i>								
The Drugs & Cosmetics (Amendment) Act, 2008		✓	✓						
Schedule M (Good Manufacturing Practices)		✓	✓	✓					
Schedule Y (Clinical Trials)		✓			✓				
The Sales Promotion Employees (Conditions of Service) Act, 1976	✓		✓						
The Drugs Price Control Order (DPCO), 2013	✓						✓		
The Drugs & Cosmetics Act, 1940-Section 17-B							✓		
The Drugs and Magic Remedies (Objectionable Advertisement) Act, 1954	✓								✓
The Pharmacy Act, 1948		✓							✓
Narcotic Drugs and Psychotropic Substances (Amendment) Act, 2001	✓	✓							✓
Trade Marks Act, 1999	✓	✓					✓		
The Patents (Amendment) Act 2005	✓	✓							✓
Biodiversity Act, 2002		✓				✓			✓
Industrial Disputes Act, 1947	✓		✓		✓		✓		
Factories Act, 1948	✓		✓		✓		✓		
Companies Act, 2013	✓			✓			✓		
Trade Union' Act, 1956			✓		✓		✓		
Equal Remuneration Act, 1976	✓		✓		✓				
Bureau of Indian Standards Act, 1986		✓					✓		✓

List of Laws (Indicative)	<u>Principle 1</u> Ethics, Transparency & Accountability	<u>Principle 2</u> Safe and Sustainable goods & services	<u>Principle 3</u> Well – being of Employees	<u>Principle 4</u> Responsivene ss to all Stakeholders	<u>Principle 5</u> Promoting Human Rights	<u>Principle 6</u> Protecting the Environment	<u>Principle 7</u> Responsible Policy Advocacy	<u>Principle 8</u> Supporting Inclusive Development	<u>Principle 9</u> Providing Value to Customer
Consumer Protection Act, 1986		✓		✓					✓
Environment (Protection) Act, 1986	✓	✓		✓		✓	✓		
Prevention of Corruption Act, 1988	✓			✓			✓		✓
Public Liability Insurance Act, 1991	✓		✓		✓	✓		✓	✓
Persons with Disabilities (Equal Opportunities, Protection of Rights and Full Participation) Act, 1995	✓		✓		✓		✓	✓	
Trade Marks Act, 1999		✓					✓		✓
Designs Act, 2000		✓							✓
New Competition Act, 2002	✓						✓		✓
Commissions for Protection of Child Rights Act, 2005			✓		✓		✓		
Right to Information Act, 2005	✓		✓	✓			✓		
Micro, Small and Medium Enterprises Development Act, 2006								✓	
Protection of Human Rights (Amendment) Act, 2006			✓		✓		✓		
Land Acquisition (Amendment) Bill, 2007	✓			✓	✓	✓	✓	✓	
Hazardous Waste (Management, Handling and Transboundary Movement) Rules, 2008	✓	✓	✓			✓			✓
Laws in 'Section A' * (Labour Laws)	✓		✓		✓		✓		
Laws in 'Section B' ** (Environmental Laws)	✓	✓		✓		✓	✓		
Laws in 'Section C' *** (Economic/Finance Laws)							✓	✓	
Uniform Code of Pharmaceutical	✓								✓

List of Laws (Indicative)	<u>Principle 1</u> Ethics, Transparency & Accountability	<u>Principle 2</u> Safe and Sustainable goods & services	<u>Principle 3</u> Well – being of Employees	<u>Principle 4</u> Responsivene ss to all Stakeholders	<u>Principle 5</u> Promoting Human Rights	<u>Principle 6</u> Protecting the Environment	<u>Principle 7</u> Responsible Policy Advocacy	<u>Principle 8</u> Supporting Inclusive Development	<u>Principle 9</u> Providing Value to Customer
Marketing Practices									

*Section A (Labour Laws)	** Section B (Environmental Laws)	*** Section C (Economic/Finance Laws)
Workmen's Compensation Act, 1923	Wildlife Protection Act, 1972	Essential Commodities (Amendment) Act, 2006
Children (Pledging of Labour) Act, 1933	Water (Prevention and Control of Pollution) Act, 1974	Union Duties of Excise (Distribution) Act, 1979
Payment of Wages Act, 1936	Water (Prevention and Control of Pollution) Cess (Amendment) Act, 2003	Central Excise Tariff Act, 1985
Industrial Employment (Standing Orders) Act, 1946	Air (Prevention and Control of Pollution) Act, 1981	Customs (Amendment) Act, 1985
Employees State Insurance Act, 1948	Forest (Conservation) Act, 1980 – Amendments in 1988	Taxation Laws (Amendment and Miscellaneous Provisions) Act. 1986
Minimum Wages Act, 1948	National Environment Tribunal Act, 1995	Direct Tax Laws (Amendment) Act, 1989
Employees Provident Fund and Miscellaneous Provisions Act, 1952	National Environmental Appellate Authority Act, 1997	Foreign Trade (Development and Regulation) Act, 1992
Maternity Benefits Act, 1961	Energy Conservation (Amendment) Act, 2010	Securities and Exchange Board of India Act, 1992
Payment of Bonus Act, 1965	Coastal Aquaculture Authority Act, 2005	Customs and Central Excise Laws (Repeal) Act, 2004
Contract Labour (Regulation & Abolition) Act, 1970	Special Economic Zones Act, 2005	National Tax Tribunal Act, 2005
Payment of Gratuity Act, 1972		Medicinal and Toilet Preparations Act 1955
Bonded Labour System (Abolition) Act, 1976		
Inter- State Migrant Workmen (Regulation of Employment and Conditions of Service) Act, 1979		
Child Labour (Prohibition & Regulation) Act, 1986		
Vishaka v. State of Rajasthan, (1997) 6 SCC 241		

Annexure C: Resources

- ❖ Good Manufacturing Practices
- ❖ Minimum National Standards for Pharmaceutical manufacturing and Formulation Industry by CPCB
- ❖ ISO 14000: Environmental management
- ❖ UN Human Rights Guidelines for Pharmaceutical Companies in relation to Access to Medicines
- ❖ The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)
- ❖ National Pharmaceutical Pricing Authority
- ❖ WHO-Counterfeit Drugs
- ❖ Uniform Code for Pharmaceutical Marketing Practices
- ❖ International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) Guiding Principles on Ethical Conduct and Promotion
- ❖ WHO Ethical Criteria for medicinal drug Promotion
- ❖ WHO- Guidelines for good clinical practice (GCP) for trials on pharmaceutical products
- ❖ WMA Declaration of Helsinki - Ethical Principles for Medical Research Involving Human Subjects
- ❖ The Global Reporting Initiative (GRI) Guidelines
- ❖ Business and the Millennium Development Goals: A Framework of Action by IBLF
- ❖ Constitution of India
- ❖ Corporate Action Plan on Climate Change by TERI BCSD India
- ❖ Corporate Responsibility: Private Initiatives and Public Goals by OECD
- ❖ Draft Indian Standard on Guidance on Good Governance by Bureau of Indian Standards
- ❖ Final Draft ISO 26000: International Standard
- ❖ Guidelines on CSR for Public Sector Undertakings: March 2010
- ❖ Meeting Changing Expectations: Corporate Social Responsibility by WBCSD
- ❖ Prime Minister's 10 Point Charter
- ❖ Corporate Social Responsibility Policy, Rules 2014

Annexure D: The Methodology adopted for formulating the guidelines

The process of development of sector specific guidelines was stakeholder led and these were developed with guidance of pharmaceutical business associations, government bodies and expert advisors. The methodology adopted has been detailed below:

PREPARATORY WORK AND FORMATION OF THE ADVISORY GROUP

In order to achieve the objective of the project CUTS partnered with the relevant stakeholders to create a small group that would provide advice and guidance during this process. An Advisory Group was formed and they were an integral part of the process of formation of the guidelines for the pharmaceutical sector.

The Advisory Group had members from some of the major Associations such as Organisation of Pharmaceutical Producers of India, Indian



RESEARCH ON CORE ESG ISSUES OF THE PHARMA SECTOR

The research team focussed on *desk research (literature review)* on the various facets of pharmaceutical sector for developing the outline for NVGs. Further, the literature review also included a brief review of international practices to identify similar guidelines for the sector, which would be useful while designing the guidelines for the sector in India.



ADVISORY GROUP MEETING

The first contact meeting of the group was organised in Delhi on 30th October, 2014 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.

The Advisory Group guided the identification and helped prioritise the critical areas in the pharmaceutical sector from the perspective of responsible business practices.



ZERO DRAFT OF THE GUIDELINES

On the basis of the deliberations and finalisation of the key areas, the research team prepared the draft National Voluntary Guidelines for the pharmaceutical sector in India

The guidelines 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 were shared with the Advisory Group representatives for their comments/inputs.



STAKEHOLDER CONSULTATION (STATE LEVEL)

A State level consultation meeting was organised in Bangalore on 12th December, 2014 with members from the Karnataka Drugs and Pharmaceuticals Manufacturing Association (KDPMA). The main objective of the meeting was to take inputs of the state-level actors on the draft guidelines. Their active participation in the preparation of the voluntary guidelines was essential in order for those guidelines to be capable of being implemented and widely supported.



CONSOLIDATION AND FINALISATION OF GUIDELINES

On the basis of the deliberations and feedback from the stakeholders and Advisory Group, the research team refined and finalised the zero draft of the guidelines for the pharmaceutical sector