Mapping of Key Environmental, Social and Governance (ESG) Issues in Indian Pharmaceutical Sector

ESG Aspect	Explanation	Applicable Regulations	General Standards	Key Concerns*
ENVIRONMENTAL				
Manufacturing and Quality Standards	- Problems relating to drug safety and side effects[45] - Quality assurance ensured by end-product testing[45] - Manufacturing equipment checks, manufacturing defects, manufacturing processes[45] - Quality of raw materials	- The Drugs & Cosmetics Act, 1940 - Good Manufacturing Practices – Schedule M		- A PIL was filed against Ranbaxy for allegedly manufacturing and selling of the adulterated drug. The petitioner cited the pharma giant's case in the US where Ranbaxy USA admitted to selling substandard and adulterated drugs. The pharma giant was asked to pay a fine of 500 million dollars[1] - A Parliamentary committee has uncovered a nexus between doctors, government bodies and pharmacy companies to approve new drugs without the mandatory clinical trials. The report has scrutinised more than 40 drugs. No data was available for three of the drugs. But of the other 39, 28 per cent did not undergo Phase III clinical trials in India. 10 per cent got approval on the basis of inadequate clinical trials and 33 per cent of these are not permitted for sale in the US, Canada, UK and Australia.[2] - The US Food and Drug Administration (FDA) has expressed concerns over the manufacturing process of at least one product at drugmaker Cadila Healthcare's Moraiya facility[3] - Ranbaxy pleaded guilty to 'felony charges' related to the manufacture and distribution of certain 'adulterated' drugs made at the Dewas and Paonta Sahib units and agreed to pay $500 million to US authorities as penalty. This followed a series of actions by the USFDA, which in 2008 banned the import of 30 generic drugs produced by Ranbaxy at the two plants for violation of manufacturing norms.[4] - Ranbaxy USA acknowledged that FDA's inspection of the

[1] http://ibnlive.in.com/news/evidence-against-ranbaxy-likely-to-be-furnished-in-sc/413544-7.html
[2] http://ibnlive.in.com/news/drug-safety-norms-being-severely-compromised/257556-3.html
[3] http://businesstoday.intoday.in/story/usfda-flags-production-at-cadila-healthcare-moraiya-unit/1/208723.html
[4] http://businesstoday.intoday.in/story/ranbaxy-recalls-29790-packs-of-anti-allergy-drug-in-us/1/205790.html

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				Paonta Sahib facility in 2006 found incomplete testing records and an inadequate program to assess the stability characteristics of drugs.[5] - Ranbaxy USA also admitted to making false, fictitious, and fraudulent statements to the FDA in Annual Reports filed in 2006 and 2007 regarding the dates of stability tests conducted on certain batches of medicines.[23] - Drug major Ranbaxy recalled its generic version of cholesterol-lowering drug Lipitor from the US market leading to temporary disruption in the supply. The generic version of Lipitor is supplied to the US market from its two facilities - New Brunswick-based Ohm Laboratories and Mohali plant in India.[6] - Dr. Reddy's initiated a major recall, withdrawing over 13,500 bottles of a blood pressure medicine because the pills weren't properly dissolving. Wockhardt Ltd., another Indian generic maker, also recalled nearly 110,000 bottles of the exact same drug for the exact same reason. - The Union health ministry has banned the use of polyethylene terephthalate (PET) or plastic containers in liquid oral formulations for primary packaging of drug formulations for paediatric use, geriatric use and for use in case of pregnant women and women of reproductive age group. Reports of environmental/health hazards because of increasing exposure to endocrine disrupter chemicals known as phthalates etc. were on the rise. Hence the move to phase out PET was taken in the public interest.[7] - FDA issued a warning letter to Sun Pharma on issues of

[5] http://www.justice.gov/opa/pr/generic-drug-manufacturer-ranbaxy-pleads-guilty-and-agrees-pay-500-million-resolve-false
[6] http://businesstoday.intoday.in/story/ranbaxy-generic-lipitor-recall-us/1/190094.html
[7] http://www.pharmabiz.com/NewsDetails.aspx?aid=84455&sid=1

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				missing fundamental raw data and information necessary to document its analysis. The company has taken on a practice of unofficially testing samples and then discarding the results while reporting results from others tests.[8]
Energy Efficiency	- Pharma manufacturing is a chemical process involving energy-intensive factory processes[42] - There is a lot of refrigeration, air-conditioning, steam generation and distribution, power transmission, pump systems, lighting, compressed air and fans and blower systems[42]	- Factory Act 1948 - Environment Protection Act 1986 - Environment Protection Act 1986 - Hazardous Wastes (Management and Handling) Rules, 1989 - Environment Protection Act 1986 - The Water (Prevention and Control of Pollution) Act - **The Central Pollution Control Board (CPCB)**: statutory organisation under the Water (Prevention and Control of Pollution) Act, 1974. CPCB was entrusted with the	**Minimum National Standards for Pharmaceutical manufacturing and Formulation Industry by CPCB** **Responsible Care Guiding Principle** Responsible Care is the global chemical industry's environmental, health and safety (EHS) initiative to drive continuous improvement in performance. Responsible Care is an ethic and a commitment that seeks to build confidence and trust in an industry that is essential to improving living standards and the quality of life	
Air Emissions	- Pharmaceuticals industry is identified as one of the 17 categories of grossly polluting industries in India - Particulates consisting of manufactured or in-process product can be emitted from bulk (e.g. fermentation) and secondary manufacturing.[43]			- The Maharashtra Pollution Control Board (MPCB) had issued notices to as many as three companies in the city and ordered a major pharmaceutical company to shut down for flouting pollution control norms. The Aurangabad unit of a pharmaceutical company was asked to shut down after it was found that it was flouting norms resulting in non-achievement of the desired results on pollution control front. the company was not connected to the common effluent treatment plant. Moreover, they purchased a plot adjacent to their plant and started dumping treated effluent there without prior permission from the MPCB.[9] - A thick pall of smoke enveloped Kudikadu village near Cuddalore. It made people ill; over 120 persons had to be hospitalised after they complained of nausea, giddiness and

[8] http://www.in-pharmatechnologist.com/Regulatory-Safety/Sun-Pharma-hit-with-warning-letter-over-data-issues
[9] http://timesofindia.indiatimes.com/city/aurangabad/Maharashtra-Pollution-Control-Board-orders-pharma-firm-to-shut-down/articleshow/23430848.cms

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		powers and functions under the Air (Prevention and Control of Pollution) Act, 1981. The standard focuses on Effluent/ emission in the pharmaceutical industry -	**ISO 14000: Environmental management-** provides practical tools for companies and organizations looking to identify and control their environmental impact and constantly improve their environmental performance -	eye irritation. The white smoke was bromine gas and its source: pharma company Shasun Pharmaceuticals, which abuts the village.[10]
Toxicity and Waste	- A significant proportion of pharma waste is classified as hazardous because it contains solvents and chemicals used to manufacture active pharmaceutical ingredients[42] - Other hazardous wastes include lubricants, fluorescent lights and even the carcasses of animals used in research[42] - Industry / chemical waste disposal, Organic waste contamination			- Around 90 companies around the town of Patancheru manufacture active pharmaceutical ingredients, or assemble final drug products, send their waste to Patancheru Enviro Tech Ltd. Waste flowing out this treatment plant India pollutes the region's waters with some of the highest levels of pharmaceuticals ever detected in the environment. They raise concerns for the health of wildlife and ecosystems in the region, as well as underscoring little-studied potential effects on human health.[11] - The AP Pollution Control Board (PCB) cracked down on six pharmaceutical companies in and around Hyderabad for not complying with environmental norms, especially in the treatment of spent solvents (the impure residue left behind after distillation of solvents). These units were Lakshmi Saraswathi Chemicals & Organics Pvt Ltd, Sri Harsha Organic, Apex Drugs & Intermediates Ltd, Shruti Laboratories, SKR Chemicals and Sujith Chemicals. The findings suggested that these industries, instead of disposing the spent solvents - they should ideally be incinerated in cement plants - are selling these to construction companies who in turn use it to produce bitumen (material used in the laying of roads). The burning of bitumen with these impure solvents releases many toxic elements into air creating a foul smell and leading to serious health issues.[12] - Industrial pollutants have made the water unfit for

[10] http://www.indiawaterportal.org/news/gentle-critical-pollution-centre-science-and-environments-evaluation-pollution-status-vapi
[11] http://www.nature.com/news/2009/090204/full/457640a.html
[12] http://timesofindia.indiatimes.com/city/hyderabad/6-pharma-cos-face-PCB-axe/articleshow/11346329.cms

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				consumption over the past 20 years in Toansa village. The primary suspects are three drug units owned by Ranbaxy Laboratories Ltd, DSM Anti-Infective India Pvt Ltd (based in the Netherlands) and Montari Industries (which packed up in 2001). In November 2005, residents of 11 villages of Balachaur tehsil in Nawashahr district got a shock -- the Nawashahr Water Supply and Sanitation Department (WSSD) served a notice asking them not to draw water from any of the 200 hand pumps supplying drinking water and proceeded to mark them with red crosses. The department asked the villagers to use the piped water supplied to them.[13] - The Maharashtra Pollution Control Board (MPCB) issued notices to 84 companies asking them to upgrade their technology so that pollution caused due to emission of effluent and sewage remains within permissible limits.[27] - Bulk drug maker Orchid Chemicals & Pharmaceuticals Ltd closed a factory in Chennai after an order of Tamil Nadu's pollution control agency on disposal of solid waste.[14] - In January 2008, the Gujarat Pollution Control Board, GPCB, asked 15 polluting industrial units in Ankleshwar to close down. The regulatory body said the units violated environmental and pollution control guidelines. There are some major companies in the list including United Phosphorous, Cadila Pharmaceuticals, Lupin and Wockhardt. The units did not treat effluents under norms and did not operate their treatment plants efficiently.[15] - A Glenmark company plant established in Samlik-Marchak

[13] http://www.downtoearth.org.in/node/%207202
[14] https://in.news.yahoo.com/orchid-chemicals-plant-shut-pollution-concerns-120620065.html
[15] http://www.downtoearth.org.in/node/4237

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				in East Sikkim has been polluting the surrounding area by discharging chemical waste. The pollutant emerging from the outlets of the plant is making the ground water of the place toxic and pungent smelling. Residents, villagers relying on ground water in the score of this area in Samlik-Marchak are unable to consume water or cook food properly due to unbearable smell that comes from the water. Even the health of children and adults have deteriorated in several occasion after consuming the chemically contaminated water.[16]
Water Usage and pollution	- Water is used for processing, cooling, cleaning, general site uses, drinking, food services and sanitation. Sites that manufacture active pharmaceutical ingredients use large amounts of water, while R&D sites and offices use less[42] - Contamination of waste water			- A village in Jinnaram mandal of Medak district, Domadugu was identified as a critically polluted area by the Central Pollution Control Board (CPCB). Its ground water and pond water were found to be highly contaminated with hazardous chemical elements from the effluents released by the bulk drug manufacturing industries in the locality. Unaware of the toxicity levels of the ground water, people from the poorer sections were using it for drinking till a few months back. Stomach cancer, death of foetus, repeated bouts of vomiting and early deaths due to various health ailments caused by the consumption of polluted ground water.[17] - Goa State Pollution Control Board (GSPCB) had issued a showcause notice to Sandu pharmaceuticals limited. The inspection report analysis indicated that the effluent treatment plant (ETP) installed at the unit was not being satisfactorily operated and operation of the unit was causing water pollution in the surrounding vicinity.[18]
Product Life Cycle	- Begins with process design and continues through	- Environment Protection Act 1986		- The Andhra Pradesh Pollution Control Board (APPCB) ordered closure of 12 manufacturing units of various

[16] http://voiceofsikkim.com/glenmark-tosses-lives-of-people-by-polluting/
[17] http://www.deccanchronicle.com/140120/news-current-affairs/article/bitter-medicine-village
[18] http://timesofindia.indiatimes.com/city/goa/GSPCBs-showcause-notice-to-Sandu-pharmaceuticals-over-water-pollution/articleshow/25253026.cms

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	manufacturing to patient use and eventual disposal[42] - Unused medicines disposal: discourage disposal to the drain or directly to sewage systems[42] - Environmental impact of packaging for the products due to manufacturing, material, PVC content[42]	- **ISO 15378:2006**: Primary packaging materials for medicinal products - Drug & Cosmetic Act, 1940 and Drug & Cosmetic Rules, 1945		pharma companies, including Aurobindo Pharma and Hetero Drugs, in and around Hyderabad for allegedly violating pollution norms. These units were found using un-consented products and changing the product mix. This only further increased the pollution load.[19] - Luna village and surrounding areas in Padra taluka of Gujarat's Vadodara district now have borewells that spew reddish brown water. Laboratory tests by the Gujarat Pollution Control Board (GPCB) showed that nearly half the borewells in the region are contaminanted by effluents produced by the neighbouring pharmaceutical and industrial dyes, which give the water the reddish brown hue. To keep the villagers from protesting loud, the polluting industries are giving out cash and cheques as ad hoc payments for the damage they are causing.[20]
Procurement, and Supply Chain Quality Management	- Product specifications in tenders favor certain supplier(s)[48] - Awarding contracts to suppliers that do not meet criteria[48] - Lack of consequences for poor supplier performance[48]	- The Drugs & Cosmetics Act, 1940		- Drugmaker Ranbaxy Laboratories Ltd suspended all shipments of pharmaceutical ingredients produced at two local factories to review processes and controls. The Toansa and Dewas plants were banned from shipping products to the United States following quality concerns.[21]
SOCIAL				
Occupational/ Employment Health and Safety	Standards should be in place for: - Chemical safety, hazardous materials, viruses etc. - Safe handling of equipment's	- Factory Act 1948		- Pharmaceutical factory manufacturing polyacrylate, several workers exposed to the dust of this substance were found to be suffering from irreversible lung diseases. Two female workers and one male worker died of the disease and several others are suffering. When the Gujarat High Court instructed National

[19] http://archive.indianexpress.com/news/ap-pollution-board-orders-aurobindo-pharma-other-companies-to-shut-units/974085/
[20] http://www.downtoearth.org.in/content/polluters-get-away-making-ad-hoc-payment-farmers
[21] http://ibnlive.in.com/news/ranbaxy-suspends-drug-ingredients-shipment-from-2-plants/454166-7.html

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	- Personal health safety - Measures for ensuring safety trainings			Institute of Occupational Health to examine the existing workers, it found 12 workers to be suffering from lung disease and 17 from liver disease. This disease is still not listed in the list of diseases for which compensation may be claimed, and also not listed in list of notifiable diseases.[22] - Ranbaxy: A machine explosion at the Toansa facility left worker Rajan Sikka with shattered bones in his face, memory loss and partial paralysis. In early October, a contract worker there died from inhaling poisonous gas, according to a police account cited in his postmortem report. The worker had been handling chemicals after being asked to fill in for a technician who went on a break, according to a coworker and family members citing accounts from the worker's colleagues. Laborers who handle chemicals at the Ranbaxy factory are required to train for a month and a half, however two former contract workers said they received three to four days of training before starting work. Ranbaxy requires workers to wear safety gear, said three current and former contract workers citing company rules. Those requirements are haphazardly enforced or ignored.[23]
Labour laws	There are four key objectives of the ILO in regards to 'decent work':[42] - fundamental principles and rights and international labour standards - employment and income opportunities - social protection and social security	- The Sales Promotion Employees (Conditions of Service) Act, 1976 - The Contract Labour (Regulation & Abolition) Act, 1970		- Maharashtra General Kamgar Union vs Cipla Limited And Ors.: under Item 1(a) by way of victimisation; (b) not in good faith, but in the colourable exercise of the employers right; (d) for patently false reasons; and (f) in utter disregard of the principles of natural justice in the conduct of domestic enquiry orwith undue haste of Scheduled IV of the MRTU and PULP Act[24] - **Hindustan Antibiotics Ltd . vs . The Workmen and Ors**.: The case debated on an appeal filed against the fixation of wage scales by the industrial tribunal under Section 10 of the Industrial Disputes Act (14 of 1947) and whether the public

[22] http://www.amrc.org.hk/system/files/India_0.pdf
[23] http://www.bloomberg.com/news/2014-03-06/flies-found-by-fda-threaten-indian-town-built-on-generics.html
[24] http://indiankanoon.org/doc/1979210/

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	- social dialogue and tri-partism Principles are generally breached in relation to[42] - Employees' freedom of association - Complaints and grievance redressal - Wage policies - The right to negotiate collectively - The eradication of forced and child labour - The ban on discrimination in respect of employment and occupation - Discrimination in the workplace - Use of child or forced labour			sector under takings could claim special treatment for fixation of wages. Further, the object of the law was to provide equality to all the industrial workers and there could be no discrimination between the public sector undertakings and the private sector[25]
Access to Affordable Medicines	- Pharmaceutical products play an important role in healthcare. Along with well-trained and motivated health professionals, medicines are among the most effective ways to prevent, alleviate and cure disease	- IP laws - (TRIPS) - The Drugs Price Control Order (DPCO), 1995 - National Pharmaceutical Pricing Authority	UN Human Rights Guidelines for Pharmaceutical Companies in relation to Access to Medicines*	- **Novartis AG v. Union of India and Others**: Novartis AG (Novartis) challenges the order of the Intellectual Property Appellate Board (IPAB) rejecting its patent application for Gleevec, an anti-cancer drug used to treat chronic myeloid leukemia.[26] - **Bayer vs Natco compulsory licensing (CL)**: in relation to Bayer's patented anti cancer drug (Nexavar), Natco is now free to manufacture and sell a generic version of Nexavar, but will

[25] http://indiankanoon.in/docfragment/576659/?formInput=increase%20authorized%20share%20capital

* Published in the report to the General Assembly of the UN Special Rapporteur on the right to the highest attainable standard of health (UN document: A/63/263, dated 11 August 2008).

[26] http://www.lawyerscollective.org/access-to-medicine/atm-current-cases.html

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	- The role of the pharmaceutical industry is to provide medicines at an affordable price and ensuring patients access to innovative and life saving medicines - **R&D:** Lack of R&D to address the dearth of dedicated products for diseases that predominantly affect poor people in developing countries[42] - The primary function of the research-based pharmaceutical corporations is to create value by discovering and producing effective medicines, vaccines and services that improve patients' well-being, and can be sold in markets at a profit. As well as increasing shareholder value, this contributes significantly to the quality and protection of life and helps make the world a better place.	(NPPA)		have to pay a 6% royalty on the net sales (every quarter) to Bayer. Further, it can only charge Rs 8800 for a monthly dose (120 tablets) of the drug. Natco also committed to donating free supplies of the medicines to 600 needy patients each year.[27] - Nine pharmaceutical companies have been fined Rs 2500 crore by the National Pharmaceutical Pricing Authority (NPPA) for overcharging customers. The NPPA imposed penalty after the drug makers, which also include Ranbaxy, Dr. Reddy's Lab, Glenmark, Cipla and Cadilla, were overcharging patients on Doxofylline.[28] - US pharmaceutical major Merck Sharp and Dohme (MSD) has filed a petition which had alleged that the Indian pharma company has violated its intellectual property right (IPR) over its anti-diabetes medicines, Januvia and Janumet, by coming in the market with their own drugs containing the same salts.[29] - A study on drug pricing by the Ministry of Corporate Affairs revealed exorbitant profit margins on 21 common drugs manufactured by Indian companies. Though pricing regulations of the National Pharmaceutical Pricing Authority (NPPA) say that companies can keep a profit margin of maximum 100 per cent over the cost of production of a drug, mark-ups of 200 to 500 per cent were found to be very common, with the highest profit margin being 1122 per cent for a drug manufactured by Glaxo Smithkline. Even price controlled drugs are sold at such exorbitant profit margins.[30]

[27] http://spicyip.com/2012/03/breaking-news-indias-first-compulsory.html
[28] http://ibnlive.in.com/news/9-pharmaceutical-companies-fined-with-rs-2500-for-overcharging/407906-7.html
[29] http://zeenews.india.com/business/news/companies/drug-patent-row-us-firm-files-appeal-against-interim-order_73877.html
[30] http://www.financialexpress.com/news/500-profit-margins-on-drugs-study/978062/0

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	- **IP:** Intellectual Property Rights played a huge role in getting easy access to affordable medicines[42] - Industry has a vital contribution to make through the responsible use of patents to ensure broad access to existing life-saving medicines. This can include applying differential pricing strategies and market segmentation to make medicines more affordable for those with low purchasing power – provided there is political safeguarding to prevent diversion of medicines to mature markets. - Drug pricing have a key role in ensuring access			
Counterfeit Drugs	- They could have the right active ingredient but at the wrong dose.[56] - Counterfeit drugs are illegal and may be harmful to health.[56] - Recycling using used vials with intact labels, refilling and	- The Drugs & Cosmetics Act, 1940- Section 17-B	**WHO-Counterfeit Drugs**: Guidelines for the development of measures to combat counterfeit drugs	- The charges against Glaxo include rejected or expired drugs leaving factory premises, which are then recycled and sold in places as far away as Agra. The Glaxo factory was even shut down and its licence was suspended.[31,14] - Vardhaman Pharmaceuticals, a private company in Himachal Pradesh, is under scanner for producing spurious drugs. The licence of Vardhaman Pharmaceuticals lapsed in 2009. The company manufactured fake drugs and labelled them with

[31] http://indiatoday.intoday.in/story/maharashtra-food-and-drugs-administration-seizes-spurious-drugs-purchased-by-bmc/1/303190.html

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	re-labelling with packaging similar to branded drugs, imitation, manufacturing without knowledge, reuse beyond expiry date[53] - Timely communication of counterfeit drugs to relevant authorities and consumers - Quality control checks by companies; o Purchasing samples from their own stock from chemists etc. o Use of holograms, barcodes etc to determine authenticity			the government supply stickers. These fake medicines were supplied to Central government, Tripura, Chhattisgarh and Uttar Pradesh.[32] - Expired drugs belonging to a leading Bangalore-based drug company were found in a Chennai dumpyard by ragpickers. These "expired drugs" – that is, drugs past their expiry date expired drugs belonging to a leading Bangalore-based drug company were found in a Chennai dumpyard by ragpickers. These "expired drugs" – that is, drugs past their expiry date[14]
GOVERNANCE				
Ethical Marketing& Distribution	- One of the most controversial as well as sensitive relation the pharma industry share with is the healthcare professional (doctors) - Doctors are offered incentives in cash or in kind to prescribe and promote drugs including kickbacks, gifts, free samples and consulting agreements[42]	- **The Drugs and Magic Remedies (Objectionable Advertisement) Act, 1954**: provides to control the advertisements regarding drugs; it prohibits the advertising of remedies alleged to possess magic	- India specific guidelines (Uniform Code for Pharmaceutical Marketing Practices) should be followed in this regard - International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) Guiding Principles on	- **Cadila Pharmaceuticals Ltd. vs. State of Kerala**: dealt with the definition of the term drug. Many ingestible are given fancy names in order to claim that they are not 'drugs'. The EC 350 (Vitamin E and C) capsules and Cecure (multi-vitamin capsules) that were sold in medical shops as 'dietary supplements'. The issue before the Court was whether vitamin capsules fall under the definition of 'drugs' under the Drugs and Cosmetics Act and therefore, required license.[33][34] - Pharmaceutical companies fund foreign trips for doctors and their families in return for pushing their products. The documents also show that the doctors prescribe drugs

[32] http://ibnlive.in.com/news/vardhman-pharmaceuticals-under-scanner-for-producing-spurious-drugs/428776-3-254.html
[33] http://www.cehat.org/humanrights/caselaws.pdf
[34] The "spurious drugs" gene and its pervasiveness, Srinivasan, Indian Journal of Medical Ethics Vol VII No 3 July - September 2010

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	- Drug promotion has an important bearing on the RUD; drug prices and availability and use of essential drugs all making in central public health issue	qualities in India - The Indian Prevention of Corruption Act of 1988 -	Ethical Conduct and Promotion - WHO Ethical Criteria for medicinal drug Promotion: Elaborates ethical criteria for the promotion of medicinal drugs	without proper clinical trials. The documents consisting travel details of a group of 11 doctors and their families from Madhya Pradesh, who went on a seven-day long trip to London and Scotland between May 24 and May 31 , apart from the travel agency Zenith Hospitality, mentions INTAS - a pharmaceutical company based in Ahmedabad which manufactures psychiatric drugs. [35] - Many gifts for doctors are listed in an Abbott sales-strategy guide for the second quarter of 2011, such as a coffee maker, some cookware, a vacuum cleaner etc. As laid out explicitly in the guide, doctors who pledge to prescribe Abbott's branded drugs, or who've already prescribed certain amounts, can expect some of these items in return. Biocon routinely gives doctors iPads, iPods, mobile phones. [36]
Safety of Clinical Trial Participants	- Failure to acquire free, prior and informed consent from patients, or failing to pay adequate compensation - People who undergo clinical trials are exploited and are not well informed about risk [44] - Some CROs (Contract Research Organizations) that carry out trials on behalf of the sponsors: lack adequate infrastructure and knowledge[49] - Pharma companies pressurize or lure underprivileged people to undergo clinical trials	- The Drugs & Cosmetics Act, 1940- Schedule Y - The Clinical Trials Registry - India (CTRI) has been made mandatory by the DCGI.	- WHO- Guidelines for good clinical practice (GCP) for trials on pharmaceutical products: set globally applicable standards for the conduct of such biomedical research on human subjects. - **International Conference on Harmonization of Technical**	- In 2009, the States of Andhra Pradesh and Gujarat launched a research project for the vaccination against the human papilloma virus (HPV) which can cause cervical cancer. Adolescent girls between the ages of 10 – 14 in the States of Andhra Pradesh and Gujarat were to be vaccinated. The vaccines were provided by GlaxoSmithKline and Merck. In April 2010, however, the Government of India suspended the program as several violations of ethical standards by PATH were widely reported by human rights organizations. In 2011, a parliamentary enquiry committee found that the process of informed consent was inadequate (especially questioning the fact that school head masters signed consent forms on behalf of the children, calling it "wrongful authorization")[37]

[35] http://ibnlive.in.com/news/pharma-firms-funding-foreign-trips-for-doctors/271997-3-236.html
[36] http://ibnlive.in.com/news/in-india-giftgiving-drives-drug-makers-marketing/295471-17.html
[37] file:///C:/Users/TUK/Downloads/Case%20Summary,%20Clinical%20Trials,%202014-02-11.pdf

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	- Lack of medical care or compensation given in case of adverse effects, injury or death		**Requirements for the Registration of Pharmaceuticals for Human Use (ICH)**: guidelines defining quality, safety, efficacy & related aspects for developing and registering new medicinal products in Europe, Japan and the United States - WMA Declaration of Helsinki - Ethical Principles for Medical Research Involving Human Subjects: set of ethical principles regarding human experimentation developed for the medical community by the World Medical Association (WMA)	- In 2004, doctors at the Bhopal Memorial Hospital and Research Centre (BMHRC), established exclusively for treating the victims of the 1984 gas leak, recruited unsuspecting survivors for clinical trials without their knowledge or consent; 14 participants died during the course of the trials. This information came out when an RTI was filed regarding information as to the details of the protocol of the research.[38] - In 2011, CDSCO suspended the licence of Hyderabad-based CRO Axis Clinicals Ltd for recruiting illiterate women for a trial without obtaining proper consent. Following the incident, DCGI ordered an investigation into the operation of all 10 CROs in Andhra Pradesh.[7] - The death of 254 Indian women from modest backgrounds in the course of a 15-year US-funded clinical trial for a cervical cancer screening method and the women who died were part of a control group kept without screening to study death rates in unscreened populations. It is a well-established fact that any kind of cervical screening reduces the incidence of the cancer. Yet, almost 140,000 women in the control arm of the trial were not screened. After a complaint made to it, the United States Office for Human Research Protections (OHRP) determined that the women were not given adequate information to give informed consent.[39] - On 22 October 2013, the Supreme Court had stopped 157 clinical trials over serious problems in adherence to both the Helsinki guidelines on medical research, which state that "the benefits, risks, burdens and effectiveness of a new intervention must be tested against those of the best current

[38] http://blog.medicallaw.in/clinical-trials-in-india/
[39] http://timesofindia.indiatimes.com/india/Row-over-clinical-trial-as-254-Indian-women-die/articleshow/34016785.cms

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				proven intervention" and the guidelines of the Indian Council of Medical Research, which specify that a placebo can be used only if the disease is self-limiting or when no proven preventive, diagnostic, or therapeutic method exists.[40] - Pharmaceutical companies Quintiles and Sanofi did not follow norms while conducting clinical trials of their new drugs on Bhopal gas leak survivors, as per the health ministry. During hearings the court had ordered the health ministry not to proceed with the clinical trials of 157 new drugs/formulations till a stricter regime was put in place. The pharmaceutical firms were not paying the mandatory compensation due to Bhopal gas disaster survivors, who had volunteered to be subjects in the clinical trial of new drugs and formulations.[41]
Firm level Policies and Procedures	- Companies should establish and maintain appropriate procedures to ensure compliance with relevant codes and applicable laws and to review and monitor all of their activities and materials in that regard. - Lack of proper compliance with internal code of conduct - Training of employees on relevant practices, codes and guidelines[55]	Self-regulation aspects of the firm		

[40] http://www.humanrights.asia/news/ahrc-news/AHRC-STM-070-2014
[41] http://timesofindia.indiatimes.com/india/Bhopal-gas-victims-used-as-guinea-pigs-for-drug-trials/articleshow/27495772.cms

ESG Aspect	Explanation	Applicable Regulations	General Standards	Key Concerns*
	- Grievance redressal mechanisms			
Information Management	- Information not available, not trusted, or not used for decision making due to lack of reliability or timeliness[48] - Information not publicly available, resulting in lack of transparency and accountability[48]	Self-regulation aspects of the firm	Business Responsibility Reports as per SEBI guidelines under NVG for top 100 listed companies	
Dialogues with stakeholders	- Interactions with patients/community organisation	Self-regulation aspects of the firm		
Disseminating knowledge and sharing best practices	- In all cases, all relevant laws and regulations must be observed and companies have a responsibility to check requirements, in advance of preparing promotional material or events.	Self-regulation aspects of the firm		
Meaningful contribution in policy dialogues	- Such dialogues should give priorities to patient and social wellbeing rather than personal benefits	Self-regulation aspects of the firm		

**Some key exposures have been reported here*

References

- [42]Issues for Responsible Investors-Pharma and Healthcare Sector, RepRisk, May, 2010
- [43]Environmental, Health, and Safety Guidelines- Pharmaceuticals and Biotechnology Manufacturing, International Financial Corporation & World Bank Group, April, 2007

- [44]http://www.sustainalytics.com/sites/default/files/pharma_asiainsight_july2013_0.pdf?utm_medium=email&utm_source=ActOn+Software&utm_content=email&utm_campaign=TEST-Reminder%20-%20Pharma%20in%20China%20and%20India%20Webinar%20on%20Thursday&utm_term=DOWNLOAD%20NOW
- [45]Sustainability Accounting Standards: Health care sector-medical equipment and supplies, EY
- [46]Environmental, Health, and Safety Guidelines- Pharmaceuticals and Biotechnology Manufacturing, International Financial Corporation & World Bank Group, April, 2007
- [47]http://www.sustainalytics.com/sites/default/files/pharma_asiainsight_july2013_0.pdf?utm_medium=email&utm_source=ActOn+Software&utm_content=email&utm_campaign=TEST-Reminder%20-%20Pharma%20in%20China%20and%20India%20Webinar%20on%20Thursday&utm_term=DOWNLOAD%20NOW
- [48]Pharmaceuticals and the Public Interest – The Importance of Good Governance, USAID & SPS, April, 2011
- [49]http://www.pharmafocusasia.com/clinical_trials/issues-concerns-conducting-clinical-trials-india.html
- [50]http://www.theguardian.com/guardianweekly/story/0,,1807960,00.html
- [51]http://a-capp.msu.edu/sites/default/files/files/AFRICABACKGROUNDERfinal.pdf
- [52]http://www.cdcgroup.com/Documents/ESG%20Publications/esgtoolkitappendices.pdf
- [53]http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2755136/
- [54]http://www.thealternative.in/business/pharma-secure-fighting-fake-drugs-in-india/
- [55]OPPI Code of Pharmaceutical Practices, 2012
- [56]http://www.fda.gov/drugs/resourcesforyou/consumers/buyingusingmedicinesafely/counterfeitmedicine/default.htm