Bitter Pill:
How Inclined Are Companies to Deliver National Health Policy Outcomes?

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A report by

PARTNERS IN CHANGE
Promoting Human Rights in Business

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Bitter Pill: How Inclined Are Companies to Deliver National Health Policy Outcomes?

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Bitter Pill: How Inclined Are Companies to Deliver National Health Policy Outcomes?
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Chapter 1: Introduction: National Health Policy 2017 and the role of the Private sector

- Pradeep Narayanan

1.1 Government’s own diagnosis of ill health of health situation

The National Health Policy, 2017\(^1\), is accompanied with a separate document called Situation Analyses: Backdrop\(^1\) to the National Health Policy-2017. An analysis of the latter suggests that the policy makers are well aware of four noteworthy Facts. Firstly, immediately after listing successes and failures of the previous policy, the report states, “We also need to keep in mind that high degree of inequity in health outcomes and access to health care services exists in India. This is evidenced by indicators disaggregated for vulnerable groups and between and within States”. The report attaches a significant importance to the need to address inequity in health access and health outcomes. Secondly, the report makes it clear that increased out of pocket expenses on health by households have impoverished a significant population. It states, “The fact however remains that inability to cover the entire spectrum of health care needs, through increased public investment has led to a rise in the out of pocket expenditure and consequent impoverishment. Over 63 million persons are pushed to poverty every year due to health care costs. In 2011-12, the share of out of pocket expenditure on health care as a proportion of total household monthly per capita expenditure was 6.9% in rural areas and 5.5% in urban areas. This led to an increasing number of households facing catastrophic expenditures due to health costs (18% of all households in 2011-12 as compared to 15% in 2004-05).” Thirdly, the report points towards unethical pricing by the private health care service providers, when it states, “It has been observed that, in 2014 the average amount spent per child birth as inpatient in private hospitals was nine times that spent in public hospitals for both rural and urban areas across all quintiles.” Further, it states, “There is evidence of supplier induced demand and lack of standard treatment practices, leading to aberrations such as unnecessary injections, irrational treatment regimens and excessive medications being provided in the private medical sector”. The report goes on to conclude, “In terms of comparative efficiency, public sector is value for money.” Fourthly, the report clearly identifies “the failure to attain threshold minimum levels of public health expenditure, as the single most important constraint” to achieve the desired health outcomes. The Government spending on healthcare in India is only 1.15% of GDP, while it states that, “Most expert groups have estimated 2.5 % as being realistic and achievable public health expenditure target”. It suggests, “At such levels of expenditure, “purchasing,” would have to be mainly from public providers for efficient use of resources with purchasing from private providers only for supplementation”.

Thus, the Government’s own analysis of facts and evidences diagnoses the reasons of poor health performance as (a) inequity in health access, (b) increased out of pocket expenses on health by households, (c) presence of unethical pricing by private health care providers and poor regulatory system; and (d) much reduced public health care expenditure compared to many other countries.

1.2 National Health Policy 2017: Critical role for Private Sector

The recently launched National Health Policy 2017\(^1\) with its focus on ‘comprehensive and universal wellness' envisions India to be on the map of ‘healthy’ countries by the year 2030. It builds on the progress of the previous policies in trying to “inform, clarify, strengthen and prioritize the role of the government in shaping health systems in all its dimensions”, in the face of changing health priorities, the emergence of a robust health care industry, the exponential increase in the health care costs expenditure and rising economic growth that facilitates enhanced fiscal capacity.

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\(^1\) Available on: http://www.mohfw.nic.in/showfile.php?lid=4275
The policy aims to achieve universal access to health care by ensuring improved access and affordability to healthcare services while emphasising the need for strategic partnerships with the non-governmental sector and the private sector. The policy aligns itself to the Sustainable Development Goals (SDGs) and aims to achieve its aims by increasing the health expenditure of the government to 2.5% by 2025 from the existing 1.15%. It also aims to ensure the availability of paramedics and volunteers as well as primary and secondary care services at the district level according to need by 2015 (improving health infrastructure and resource). There is a move to increase in the life expectancy, a decrease in the current USMR, the MMR, the IMR, stunting of under five children and in the prevalence of blindness and disease burden and ensuring that everybody has access to safe drinking water and sanitation (cross sectoral goals). It also aims to increase the utilization of public health facilities by up to 50% by 2025 while ensuring adequate antenatal care and a complete immunization of newborn children by the age of one year.

In the new policy, there is a stated shift from providing primarily public services to new, strategic partnerships with private health providers, which it is believed, will further open opportunities for the best treatments with the prospect to fill the gaps in public and private services in health care. The private sector has been roped in to fill “critical” gaps and pitted as a better vehicle to achieve the stated aims within the timeline. The justification provided for preferring private enterprises is summarised in the image alongside and section below:

i. Sourcing services: by developing strategic partnerships with private sector players, along with providing free primary care through the public sector, the policy looks for sourcing deficit through strategic purchase of/investment in secondary and tertiary care services from public sector hospitals, non-governmental organisations and the commercial private sector for the critical gap filling of services that have none or few takers such as diagnostic services, ambulance services, rehabilitative and palliative care services and the managing of rare and orphan diseases, till the public systems of resource provision are strengthened. The private sector can also be brought in for reimbursement of fees provided for health services.

ii. Ease of access to marginalised sections: The policy aims at collaborating with the non-governmental sector in providing easier access to secondary and tertiary care among the marginalised sections of the rural populations, especially in terms of geographical and infrastructural challenges. It also provides for admitting designated/subsidised beds to a few deserving patients in private hospitals and charitable organisations who get referred to from public hospitals. The gender friendly environment of the private sector is also presented as a justification for provision of better health services to women.

iii. Capacity building and resource mobilisation: the need for new medical colleges, nursing institutions, as well as strengthening and expanding the existing medical colleges is best done through the use of both public and private sector in order to increase the human resource pool of doctors and specialists while focusing on those regions that have a deficit of the same. Besides recommending the establishment of a national healthcare standards organisation and the development of a pool of disaster linked medical teams, the policy recommends the engagement...
of private sector to train and skill many small private healthcare providers and policy advocates in areas that are remote/under-serviced.

iv. Corporate Social Responsibility: The policy provides for resource mobilisation towards the health sector, through earnings of the corporate sector and medical tourism, under the banner of hospitality arrangements. It also emphasises the engagement of the private sector in organ donation awareness, occupational health as well as several other services that could be linked to their CSR engagements.

v. Regulation and drug pricing: the policy emphasises the need of regulating establishments, regulating drug trials, research on affordable drugs and the private sector as a means to enable enabling access to free drugs such that the treatment is carried out, drop outs reduced and cases of the infection contained.

vi. Creation of digital health platforms: the policy calls for the need of engagement of the private sector in creating a health information system for registering patients, documenting diseases and health events and which is easily made accessible to both public and private health care providers.

In its attempt to make progressive steps towards universal and affordable access to healthcare services and to make Indian villages “Health and Wellness Centres”, the health policy has leaned heavily on creating synergies and partnerships with non-governmental organisations and the private sector to fill critical gaps.

The National Medical Commission Bill, 2017: Some Salient Features

- The bill seeks to repeal the Indian Medical Council Act, 1956 and abolish the Medical Council of India with a new body to ensure transparency.
- Bill seeks to create a twenty member body called National Medical Commission selected by a Search Committee consisting of seven members including the Cabinet Secretary and three experts elected by the central government thus abolishing Medical Council of India which consisted of members elected by the medical practitioners only.
- Formation of Medical Advisory Council, which will be a primary platform through which the state/union territories can put forth their views and concerns before the National Medical Commission. This Advisory council will also advise the NMC on measures to enable equitable access to medical education.
- Formation of Four autonomous boards namely – 1. Under-Graduate Medical Education Board and 2. Post-graduate Medical Education Board – These two boards will be responsible for formulating standards, curriculum, guidelines, and granting recognition to medical qualifications at the undergraduate and post graduate levels respectively, 3. Medical Assessment and Rating Board (MARB): The MARB will have the power to levy monetary penalties on medical institutions which fail to maintain the minimum standards as laid down by the UGMEB and the PGMEB, 4. Ethics and Medical Registration Board: This Board will maintain a National Register of all licensed medical practitioners, and regulate professional conduct and only those included in the Register will be allowed to practice medicine.
- Section- 49 of the bill also allows the Practitioners of Traditional Indian Medicine System to be allowed to prescribe a pre-decided set of medicines for some common ailments after they do a bridge course for a period of six-months.
- There will be a uniform National Eligibility-cum-Entrance Test for admission to under-graduate medical education in all medical institutions regulated by the Bill.
- There will be a National Licentiate Examination for the students graduating from medical institutions to obtain the license for practice.

Source:
1.3 Private delivery of public health goals: Putting things in perspective

With increased dependence on the private sector for strategic investing in services that are not easily accessible such as diagnostic facilities and supply of drugs to remote communities in order to fill in the gaps of service provision, it has shifted the provision of certain diagnostic facilities and surgeries like cataract operation to profit making private sector companies and these are no longer provided at the government hospitals and primary health care facilities which creates grounds for manipulation of its services and prices. Juxtaposed against this is the fact that health care costs are one of the biggest causes for impoverishment in India where the share of private spending is higher than the government spending, and out of pocket payment forms a large share of the same. 7% of families (11.88 mn households or 63.22 mn individuals\(^3\)) were pushed Below Poverty Line (BPL) due to their health care expenditure in 2004\(^4\).

The private players are expected to fill supply gaps in the public sector over the provision of primary, secondary and tertiary health care services as well as further enabling research on health care practices and lowering the costs of health care. Whether local and small private providers will be able to bid for the contracts and create a competitive environment lacks clarity. While the policy looks towards universalising health care facilities, the private players have been found wanting in terms of pitting their services at high rates and making it accessible to only a select populace while leaving the lower income groups out of its ambit of care. In the absence of a strict enforcement of the Clinical Establishments Act, it has been found that the private hospitals are prone to charge their patients for services that are not required as well as producing fake documents to get extra money from the patient.\(^5\) For a country where the majority of the healthcare expenditure is borne by the private sector (82.3%), this speaks a lot in terms of achieving universality of its health services\(^6\).

Moreover, wherever countries have gone towards privatizing its health care services, it has been observed that these become more unaffordable and inaccessible due to the profit motive of the private companies in question like in the USA where in the market led model of American medical care came under severe criticism during the 80’s which essentially focused on the rising costs of medical care, excessive emphasis on curative and high technology care, the dominance of the medical technology and pharmaceutical industries in medical care.\(^7\) Even in Chhattisgarh, public–private partnership (PPP) model of MMUs shows that they are expensive and less sustainable endeavours when compared to strengthening of existing government system\(^8\). While a framework for privatisation has been put in place, the enforcement of regulatory frameworks remains a big bone of contention. Companies have been questioned by price regulatory mechanisms for overcharging on their drugs thereby violating the drug price control norms. Despite having been served two notices for drug price overcharging, some companies have failed to pay up for the penalties imposed on it and are now contesting the claim, reigning in further delays.\(^9\)

The move to privatising also works towards increasing the in formalisation of the healthcare workforce – increase the male health worker cadre – at the cost of marginalising ground level women workers such as the ASHA, the ANMs who had played a pivotal role in providing quality health care services\(^9\).

\(^3\) NSSO
\(^4\) Berman PA, Ahuja R &Bhandari L (2010) The impoverishing effect of healthcare payments in India: new methodology and findings; Economic and Political Weekly, 45, 65–71
\(^6\) http://timesofindia.indiatimes.com/city/kolkata/Privatisation-no-remedy-for-health-sector/articleshow/586610285.cms
\(^7\) Rama Vaidyanathan Baru, Privatisation Of Health Care In India : A Comparative Analysis Of Orissa, Karnataka And Maharashtra States, Available at: http://cmdr.ac.in/editor_v51/assets/mono-43.pdf
\(^8\) Roy, B: Aspiring for Universal Health Coverage through Private Care: Economic and Political Weekly; April 2017
The private companies are sometimes also found wanting in terms of adhering to safety practices of its various facilities set up across the country as also for unethical practices such as conducting trials on people without their knowledge or selling drugs that are highly substandard. There are no strict provisions for checking on the violations of the labour rights either of those employed in the private companies, especially of those employed on a contractual basis who face poor working conditions, lower wages and delays in getting their wages. Their protests and plea’s for raising wages are not given much importance either.

For a country where about 80% of the OPD and 60% of its in patients care is sourced through the private sector\(^\text{10}\), one wonders at the need for further synergizing with the private sector in the face of its non compliance to the already existing rules and regulations.

Thus, in terms of policy intent, the Policy is a comprehensive piece - it amalgamated within its targets, all the SDG targets, across goals, related to health. The point of departure vis-à-vis previous policies is with respect to the role of private sector. The National Health Policy, 2002, also from the previous National Democratic Alliance Government (1999-2004), observed, “Private health services are perceived to be financially exploitative, and the observance of professional ethics is noted only as an exception” and thereby prescribed, “the implementation of statutory regulation, and the monitoring of minimum standards of diagnostic centres / medical institutions becomes imperative”.

Incidentally, the new policy just stops short of putting the private sector in the driver’s seat, but surely the envisioning is in the form that by end of the policy duration, the private sector would have become central to health policies even in primary health care delivery. It aims to “enable private sector contribution to making health care systems more effective, efficient, rational, safe, affordable and ethical. Strategic purchasing by the Government to fill critical gaps in public health facilities would create a demand for private health care sector, in alignment with the public health goals”. The disbelief is the faith that the policy has put on the private health service providers; despite its own analysis of health-related information of the last two decades show the opposite.

\(^{10}\) [https://thewire.in/118615/indias-new-national-health-policy-is-ambitious-on-paper-but-lacks-clarity/](https://thewire.in/118615/indias-new-national-health-policy-is-ambitious-on-paper-but-lacks-clarity/)
Chapter 2: Pharmaceutical Companies: How amenable to regulation are they?

- Pragya Shah and Mary Abraham

The strengthening of private sector in the health sector has been gradually occurring for a couple of decades now. In fact, successive governments have not only receded a large extent from health delivery but also have actually invested in private take over of the sector. For example, the Situation Analysis report, does state, “The Government has invested heavily in the last 25 years in building a positive economic climate for the health care industry. Amongst these measures are lower direct taxes; higher depreciation in medical equipment; income tax exemptions for 5 years for rural hospitals; and custom duty exemptions for lifesaving equipment. Other forms of assistance are - preferential and subsidized allocation of land, subsidized professional education in government institutions; and provision for 100% FDI. This active policy enabled the private health care industry attract over 2 billion dollars of FDI in 2012-13, which as per market sources was mostly as venture capital”. Similarly, the Comptroller and Auditor General’s Audit Report No. 5 of 2015\(^\text{11}\) stated that the Government provides support to Pharmaceutical sector by way of various area based tax exemptions, weighted deductions on expenses towards Research and Development (R&D) and other deductions against business profits in the Income Tax Act 1961 (Act), concessional rate of excise duties, State VAT etc.

A presumptive calculation by CAG in the report indicates that the revenue foregone by the Government due to tax concessions on only “expenditure on scientific research”, which mostly pertain to Pharmaceutical sector, is about Rs 16,443 crore in 2013-14, which itself was about 11.8 per cent more than the previous year. The Government has contributed to building a robust health care industry, which is valued at $40 billion and is projected to grow to $ 280 billion by 2020 as per market sources. The current growth rate of the healthcare industry, at 14% is projected to be 21% in the next decade. It is pertinent to note that the prescriptions of the new Health Policy, that is, the strategic buying of services from the private health care industry, aligns with this kind of growth projections. In other words, there is a healthy private health care industry today, which is capable of selling health care to the people. The challenge for the Government is to streamline the regulations such that the health objectives of the country are realized.

2.1 Making Marketing Practices of Pharmaceutical Companies ethical: Government efforts

The draft of the Uniform Code of Pharmaceutical Marketing Practices (UCPMP) was issued by the Department of Pharmaceuticals in the year 2012, it became effective from 1\(^\text{st}\) January 2015. It was initially proposed to be voluntary on the condition that the Government would make it a statutory code if not implemented properly by Pharmaceutical Associations and Companies. This would follow a review of the policy after a period of six months from the date of enforcement of the code. The code provides for certain provisions that govern the activities of the companies and other related bodies, with regard to the following:

1. Product related claims and comparisons
2. Free Samples
3. Textual and Audio, Video Promotional materials
4. Medical Representatives
5. Gifts and freebies to health care professionals
6. Relationship with health care professionals
7. Complaint redress mechanisms
8. Formation of the Ethics Committee
9. Certification by CEOs/Managing Director

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Few of the provisions that are relevant to our study have been briefly explained below:

1. **Medical Representatives**\(^{12}\): The code defines medical representatives and elaborates the norms to be followed by them in their dealings with the health care professionals such as maintain a standard ethical code of conduct as well as not use inducements to gain interviews in their favour (health care professionals) and must be conversant and compliant with the code procedures.

2. **Free Samples, Gifts and Freebies (relationships with Health care professionals)**\(^{13}\): The Code specifies the qualified personnel to whom samples of medicinal products can be supplied to along with certain conditions to be followed while distributing these samples. The code prohibits benefits either in cash or kind to any person qualified to prescribe medicines or to whom the concerned pharmaceutical company may supply medicines. However, it allows for provision of reasonable assistance for the purpose of continuing education of the healthcare professionals, subject to certain conditions.

3. **Formation of Ethics Committee**: The Code lays down for the formation well as the constitution of an Ethics Committee for Pharma Marketing Practices (ECPMP) for handling complaints filed. The code further provides for the formation of the Apex Ethics Committee for Pharma Marketing Practices (AECMPM) for reviewing the decision of ECPMP in cases where the company is not satisfied with the decision of ECPMP, while notifying the same to the Head of Association.

4. **Penalties Provisions and Certification Process**: Wherever a breach of code is established, the code lays down four penalties to be imposed on the company for the perceived violation. The penalty can be proposed by the head of the Association to the concerned company. The code makes the Managing Director/CEO of the company responsible for adherence to the code and demands for a self-declaration to be submitted by the Executive head of the company with a stipulated time frame and the same must be uploaded on the website of the company.

**Government Notifications**: The first notification forwarded to the Associations by the Department of Pharmaceuticals on 12\(^{th}\) December 2014 brought into effect the guidelines of the UCPMP from 1 January 2015, for a period of six months and which was further up for extension until further notice. The department also issued a notification on 9 March 2015 for including the medical devices industry as well under the ambit of UCPMP. The table below elaborates on the notifications that were sent thereafter:

<table>
<thead>
<tr>
<th>Timeline</th>
<th>Notifications Issued</th>
</tr>
</thead>
<tbody>
<tr>
<td>12/12/2014</td>
<td>Implementation Notification from 01/01/2015</td>
</tr>
<tr>
<td>09/03/2015</td>
<td>Extending UCPMP to include medical devices industry as well</td>
</tr>
<tr>
<td>26/06/2015</td>
<td>Extended for next 2 months (till 31/8/2015)</td>
</tr>
<tr>
<td>28/09/2015</td>
<td>Extended for next 4 months (till 31/12/2015)</td>
</tr>
<tr>
<td>18/12/2015</td>
<td>Extended for next 3 months (31/03/2016)</td>
</tr>
<tr>
<td>17/03/2016</td>
<td>Extended for next 3 months (30/06/2016)</td>
</tr>
<tr>
<td>30/06/2016</td>
<td>Extended until the further orders</td>
</tr>
</tbody>
</table>

**Response by Industry Associations**: The government has taken efforts to make the code effective by imposing certain responsibilities on the “Eleven Associations” mentioned below to ensure that the member companies adhere to the code. These eleven Associations being:

1. The Indian Pharmaceutical Association (IPA),

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\(^{12}\) Section 4

\(^{13}\) Section 6 and 7
2. Organization of Pharmaceutical Producers of India (OPPI),
3. Indian Drug Manufacturer’s Association (IDMA),
4. Confederation of Indian Pharmaceuticals Industry (CIPI),
5. Federation of Pharma Entrepreneurs (FOPE),
6. Southern Petrochemical Industries Corporation (SPIC),
7. Association of Indian Medical Device Industry (AIMED),
8. Federation of Indian Chamber of Commerce of India (FICCI),
9. Confederation of Indian Industry (CII),
10. PHD Chamber of Commerce and Industry (PHD CCI),
11. Associated Chamber of Commerce and Industry India (ASSOCHAM).

Chart 2.1 below details the compliance level of the eleven associations to the various components of the Uniform Code of Pharmaceuticals Marketing Practices.

**Chart 2.1: Status of Pharmaceutical Manufacturer Associations vis-a-vis key UCPMP Provisions (n=11)**

- **1. Website provided (10)**
- **2. UCPMP uploaded (3)**
- **3. Disclosed names of member company (3)**
- **4. Complaints procedure given (1)**
- **5. Creation of ECPMP (0)**
- **6. Complaints received and disbursed (0)**
- **7. Any self declaration made (0)**
- **8. Consultations conducted on UCPMP (0)**
- **9. Workshops organised (0)**
- **10. Creation of apex ECPMP (0)**

**Website Link:** From the chart, it can be inferred that out of total eleven associations, only ten have provided links to their website. While the website of Federation of Pharma Entrepreneurs (FOPE) is not available, the website of Association of Indian Medical Device Industry (AIMED) is available, though not accessible.

**UCPMP uploaded:** Out of the total of eleven associations, only three have uploaded UCPMP on their website, while the rest haven't. The three associations are OPPI, CIPI and IDMA.

**Disclosure of Name of member companies:** Only two associations i.e. Organization of Pharmaceutical Producers of India (OPPI) and Confederation of Indian Pharmaceuticals Industry (CIPI) have disclosed the name of the member companies, while the rest of the nine companies have not made any disclosure.

**Creation of ECPMP:** Only one association i.e. Indian Drug Manufacturer’s Association (IDMA) has mentioned about the creation of Ethical Committee for Pharmaceutical Marketing Practices (ECPMP) while the other ten haven't mentioned anything. The association responded to the circular only on
10th March 2017 and then uploaded the UCPMP and other related information. This information was received as a response to an RTI filed on 3/03/2017.

Complaint’s Procedure: Out of the eleven associations, only one association i.e. Organization of Pharmaceutical Producers of India (OPPI) has mentioned of the procedures of complaint in its Code of Pharmaceutical Practices which has been in effect from 31/12/2012.

Creation of Apex ECPMP: None of the associations have mentioned anything about the creation of Apex ECPMP in their website.

Complaints received and disbursed: None of the associations have mentioned about any complaints received, the nature of the complaints received and the status of the same. The RTI also made an enquiry with regard to the complaints, if any, received by any of the associations but no record was found of the same.

Self-Declaration Made: None of the associations have disclosed anything about any self-declaration made by any of the member companies with regard to compliance with UCPMP code.

Any Information on consultation conducted on UCPMP: None of the associations have given any information on any consultation conducted on UCPMP.

Any workshop organized: None of the associations have conducted any workshop or other related events on UCPMP.

An RTI was filed on 2 March 2017 to the Department of Pharmaceuticals in order to ascertain whether any of the 11 associations thus formed had responded to the circular issued by the Department on 30th August 2016. It further tried to gauge whether any complaints had been filed to the ethics committee, and if so, of the status of that complaint.

1. How many out of the 11 associations have replied to the circular issued by the Department of Pharmaceutical?
2. Has there been any complaint filed to the ethics committee?
3. If any, what is the status of the complaint?

Through the reply to the RTI, we were informed that only two out of the 11 associations had responded to the Department of Pharmaceuticals as mandated by the circular namely Organisation of Pharmaceutical Producers of India (OPPI) and Indian Drug Manufacturers Association (IDMA). OPPI had also replied to the Department that towards the compliance of UCPMP, the monthly Ethics Committee (EC) meeting includes an agenda item on any matter relating to ethics and compliance, where any concern/complaint relating to OPPI are tabled before the President, OPPI. The OPPI Secretariat addresses the concerns and complaints of OPPI member companies with well-established procedures, to arrive at a satisfactory conclusion.

Before the RTI had been filed, only two associations had uploaded UCPMP on their websites and after the filing of the RTI, we were informed that OPPI, being one of the partners with Department of Pharmaceuticals, had also mentioned about their willingness to adhere with such business practices in pharmaceutical industries.

It was also found that the IDMA had responded to the concerned notification of the Department on 10th March 2017, after the filing of the above mentioned RTI. In its response, it submitted that they had already uploaded the code on their website on 24th December 2014 requesting their members that though the Code was voluntary in nature, it would be appreciated if the same was followed in order to ensure ethical and transparent marketing practices. They had further submitted that they had formed the ECPMP as well as the AECPMP, while elaborating on their composition.
No response was received through the RTI for the second and third questions concerned with the complaints, if any filed to the ethics committee

2.2 Respecting Medical Council of India’s Guidelines

In the year 2015, the CAG released its report, *Performance Audit on Assessment of Assessee in Pharmaceuticals Sector for the year ending 2013-14*. They audited 2,868 assessment records pertaining to Central Board of Direct Taxes assessments of Pharmaceutical companies. The Audit pointed out that there were 246 cases with deficiency in the system or in the compliance with the laid down provisions involving total tax effect of Rs.1,348.44 crores. Among them, 36 cases pertain to such instances where the Assessment Officers have not disallowed such expenses, which are in the forms of gifts to doctors. The Audit report states, “As per explanation to Section 37(1) of the (Income Tax) Act, any expenditure for a purpose which is an offence or which is prohibited by law is not an allowable business expense. MCI vide its regulations, Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002, provided that medical practitioners should prescribe generic drugs as far as possible. It inter-alia prohibited them to solicit or receive any commission, gifts etc. for any approval or recommendation, endorsement of any medicine or drug for advertisement purpose or for referring or recommending any patient any medical, surgical or other treatment. Vide amendment dated 10 December 2009, Pharmaceutical companies were specifically prohibited to give any consideration in the nature of gifts, travel facilities, hospitality, cash or monetary grants etc. CBDT issued a circular in 2012 and clarified that such expenses would not be allowable. Judicial pronouncement, (Confederation of Indian Pharmaceuticals Industry Vs. CBDT (Himachal Pradesh High Court), also clarified that this circular had retrospective effect.” Incidentally in January 2017, the pharmaceutical companies won the case on grounds that the MCI regulations are not mandatory for pharmaceutical companies (DCIT versus PHL Pharma Ltd as described in the box below). While the case may go up the higher courts, it is clear that the companies would not adhere to the spirit of the laws of the land, on voluntary basis, unless the law is made very specific.

Box 1: Tribunal Ruling on DCIT vs. PHL PHARMA LTD.

**FACTS**

The concerned company is engaged in the business of providing Pharma Marketing Consultancy thereby developing a mass market for pharmaceutical products. During the year 2010-11 the tax officer disallowed the expenses incurred on the ground that the expenses are in such nature as violating the MCI guidelines as well as Section-37 of Income Tax Act. The expenses were incurred for the purpose of gifts, sponsoring seminars, conferences etc.

**CONTENTIONS MADE BY THE COMPANY**

The company contended the validity of the expenses by stating that the gifts given were of such nature that would remind the doctors of the brands of the pharmaceutical companies and hence built a trust amongst the doctors of their products. The company therefore emphasized on the nature of such expenses and clarified that the expenses were meant for the sales and business promotion. The company also relied on the judgment of the Himachal Pradesh High Court and further highlighted that the concerned company acted responsible by satisfying the Assessing Officer that the expenditure was not in violation of MCI regulations. The company further highlighted on the non-applicability of Section- 37 (1) as well as the MCI regulations as both the provisions does not monitor and regulate the pharmaceutical companies. The company also further stated that the CBDT not being retrospective in nature would not regulate the activities of the concerned company.

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14 See more at: http://www.epw.in/journal/2017/23/insight/pricing-cardiac-stents.html#sthash.IbUCaFFD.dpuf
OBSERVATIONS MADE BY ASSESSING OFFICER:
The Assessing Officer observed and further stated that such expenses were prohibited by MCI regulations read with CBDT circular. The Assessing Officer highlighted upon the amended MCI notification 2009, which restricts the Medical Practitioners from receiving any kind of grants, gifts, travels from the pharmaceutical industries or allied health care sectors.

TRIBUNAL’S RULING:
The Tribunal observed and held that:
The tribunal placed reliance in the ruling of the Delhi High Court in the case of Max Hospital vs. MCI and further reiterated that MCI regulations was limited to medical practitioners alone and hence the pharmaceutical or other allied health sectors were not covered under the same therefore they couldn’t be held accountable. The tribunal also stated that the CBDT circular enlarged the scope of MCI regulations and made the pharmaceutical companies also liable under the same however such step of CBDT was not in consonance of any of the provisions of Income Tax Act. The tribunal also noted that the expenditure incurred by the concerned company was purely in the nature of business promotion, sales and thus such expenses were allowed. The Tribunal also noted that the gifts given by the company were cheap in nature and clearly indicated that they were meant only for the purpose of business promotion. The Tribunal for this purpose referred to the case of Liva HealthCare, which defined what would fall under the category of gifts meant for business or sales promotion and the other category which are disallowed under various provisions governing the same. 15

2.3 Pricing of Heart Stent devices: Lessons

One significant achievement for the health advocates of the country is the recent Government order against the backdrop of a court petition on the prices of heart stents. On 13 February 2017, the National Pharmaceutical Pricing Authority (NPPA) slashed the price of cardiac stents by 85%. “The data put out by the NPPA on 16 January put them to rest. It showed that the margin on stents ranged from 270% to 1,000%. The data showed that hospitals extracted the highest margin—11% to 654%". The assessment report by the Government itself, submitted in May 2016, “concluded that...the MRP in many cases was 10 times the landed cost, the bulk of the margins accounted for by distributors/hospitals and promotional costs. It added that in the case of most stent companies, the mark up over the import price ranged from about 300% to 1,200%. In PPP (purchasing power parity) terms, stents are 10 times costlier in India than in the US and the United Kingdom (UK), said the report, adding that government covered only 45% of angioplasties involving stents and private insurance covered 15%, leaving 40% of patients bearing the cost themselves". The massive inflation of prices of the product itself indicates how far the companies are from looking at ethical sales, let alone public health outcomes as their responsibility. While the government order did reduce the prices, there have been allegations that the private hospitals have now increased the cost for all allied services and procedures associated with heart stents! The idea that the private health sector will align their business with the public health goal agenda, without strong law, is absolutely impossible. Even on this issue of the cardiac stent pricing, “The NPPA asked such companies, including Abbott, Boston Scientific, Zimmer India, Johnson & Johnson and Medtronic to submit details of price revisions during the previous two years for each type of device. It asked for the information “within three days” as it was required “in connection with issues raised during the ongoing parliament session”. No information was provided.” 17

16 https://economictimes.indiatimes.com/industry/healthcare/biotech/healthcare/profit-on-stents-ranges-from-270-to-1000/articleshow/5667008.cms
17 http://www.epw.in/journal/2017/23/insight/pricing-cardiac-stents.html#sthash.lbUCaFFD.dpuf
Chapter 3: Pharmaceutical Companies: An Analysis of Business Responsibility Reports

- Dheeraj

A significant development in the context of Business Responsibility Guidelines in India was in 2011 when National Voluntary Guidelines on Socio-Economic and Environmental Responsibilities of Business (NVGs) were adopted. The NVGs were brought out by the Ministry of Corporate Affairs to help the corporate sector in their efforts towards inclusive development and help them evolve into a global leader in responsible business. The Guidelines emphasise that businesses have to endeavour to become responsible actors in society, so that their every action leads to sustainable growth and economic development. In this chapter, the focus would be on mapping commitments made by top pharmaceutical and healthcare sector companies vis-à-vis key NVG principles.

Keeping with the NVGs' demands of transparency and accountability among businesses and by the investor community in general, Securities and Exchange Board of India (SEBI) has amended the listing agreement and made Business Responsibility disclosure mandatory for top 100 companies – based on market capitalization – listed on Bombay Stock Exchange and National Stock Exchange. Other listed companies can voluntarily disclose Business Responsibility Reports as part of their annual reports.

NVGs have been articulated in the form of nine (9) Principles with the Core Elements to actualize each of the principles. The 9 principles are:

1. Principle 1: Businesses should conduct and govern themselves with Ethics, Transparency and Accountability
2. Principle 2: Businesses should provide goods and services that are safe and contribute to sustainability throughout their life cycle
3. Principle 3: Businesses should promote the wellbeing of all employees
4. Principle 4: Businesses should respect the interests of, and be responsive towards all stakeholders, especially those who are disadvantaged, vulnerable and marginalised.
5. Principle 5: Businesses should respect and promote human rights
6. Principle 6: Business should respect, protect, and make efforts to restore the environment
7. Principle 7: Businesses, when engaged in influencing public and regulatory policy, should do so in a responsible manner
8. Principle 8: Businesses should support inclusive growth and equitable development
9. Principle 9: Businesses should engage with and provide value to their customers and consumers in a responsible manner

The Section below analyses the Business Responsibility Reports of top 12 pharmaceutical companies and health sector companies (2015-16). The 12 companies are Cipla, Sun Pharma, Zydus Cadila, Lupin, GSK Healthcare, GSK Pharma, Dr. Reddy’s, Glenmark, Aurobindo Pharma, Divis Laboratories, Torrent Pharma and Apollo Hospitals. They together have market capitalization of around Rs 4,71,689 crores.

Whether Companies have formulated Policies on these 9 Principles?

The initial sections of the BRR provides for the tool for knowing the preparedness of the companies for implementing the systems related to key NVG principles. As per this self-reported information, most of the companies claimed presence of policies related to all the nine principles as detailed in National Voluntary Guidelines. However, they fell short at the level of commitment towards creation...
of grievance redressal mechanism as well as carrying out evaluation of the functioning of the related policies. On some of the crucial principles such as Ethics & Transparency, Human Rights and Customer Value, only 8 out of 12 companies had responded in affirmative on carrying out any evaluation of the functioning of the same as part of their Business Responsibility Reporting (BRR) disclosures.

**Distribution of Pharmaceutical and Healthcare Companies claiming to be following the implementation mechanism processes as detailed in BRR format (n=12)**

![Graph showing distribution](image)

**Whether Policies commit to Socially Responsible Business?**

Pharmaceutical and Healthcare sector has been growing at exponential rate in last few years and it is critical to understand if this growth has also translated in the form of better working conditions for the workers. The figure below details the number of companies that have made policy commitments on the elements, with details on implementation mechanisms:

**Pharmaceutical Companies (n=12)**

- Disabled friendly workspace: 7
- Existence of Sexual Harassment Policy as per law: 3
- Explicit prohibition child labour (including supply chain/contractors/service providers): 2
- Recognise workers Right to Association: 0

**Top-100 listed companies (n=100)**

- Disabled friendly workspace: 22
- Existence of Sexual Harassment Policy as per law: 74
- Explicit prohibition child labour (including supply chain/contractors/service providers): 38
- Recognise workers Right to Association: 68
- Contractual employees (directly or through contractors) are provided with the social benefits (PF and medical insurance): 9
The analysis of commitments made by companies depicts that there is a long way to go. None of the pharmaceutical companies had disclosed about mechanisms for creating disabled friendly workspace. Same is the case with extension of social benefits to the contractual employees hired directly or through contractors. In fact, the number of companies detailing mechanisms for prohibition of child labour in their supply chain is dismally low, as only three companies have detailed the same.

**Responsible Business guidelines with respect to workers and supply chain**

<table>
<thead>
<tr>
<th>Pharmaceutical Companies (n=12)</th>
<th>Top-100 listed companies (n=100)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Company policy recognises the need for Impact Assessment for assessing negative and positive impacts that its services/products or business operations would have on key stakeholders such as communities. (0)</td>
<td>Impact assessment system provides for Public hearing/community consultation (72)</td>
</tr>
<tr>
<td>Company policy recognises the need for community development projects in backward region (1)</td>
<td>Impact assessment system provides for Communicating project impacts with community (6)</td>
</tr>
<tr>
<td>Company policy has monitoring mechanism for CSR projects (8)</td>
<td></td>
</tr>
</tbody>
</table>

In addition to workers another category of important stakeholders is communities, particularly living in vicinity of production units. Exposure to production as well as disposal processes in pharmaceutical and healthcare sector do expose these communities to high risks. It was found that none of pharmaceutical and healthcare companies in top 100 detailed the mechanism that they had in place for assessing negative and positive impacts of their business operations on key stakeholders such as communities. Further, only 1 company recognised the need for community development projects in backward region as part of their Corporate Social Responsibility (CSR) policy while 8 out of 12 pharmaceutical and healthcare companies detailed mechanisms for monitoring their CSR projects.

**Equal Opportunity**

Diversity within workforce is an area of concern. 5 out of 12 companies as part of their policies had not recognised women as an identity to proactively focus on as part of recruitment process to provide for equal opportunities while recruiting. The analysis of information from public domain also disclosed that 6 companies did not mention PWDs in their recruitment policy. It is the case with non-discrimination on account of religious identity too.

As a positive step two companies had recognised Sexual Minorities as part of their recruitment policy. Scheduled Castes and Tribes in resonance with their position in society seemed to be on the margins in the pharmaceutical and healthcare sector too. Only 3 companies have mentioned Scheduled Castes as part of their policy of which only 2 have also delineated the mechanism for their inclusion. Scheduled tribes are totally absent from policy narrative. None of the companies had
disclosed commitment for creating a system for handling grievances related to discriminatory employment.

**Distribution of Pharmaceutical and health care sector companies vis-à-vis commitment towards equal opportunities in recruitment (N=12)**

<table>
<thead>
<tr>
<th>Status of policy recognition</th>
<th>Not available</th>
<th>Mentions only</th>
<th>Mentions and mechanism</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>A Women</td>
<td>5</td>
<td>4</td>
<td>3</td>
<td>12</td>
</tr>
<tr>
<td>B Persons with Disability</td>
<td>6</td>
<td>3</td>
<td>3</td>
<td>12</td>
</tr>
<tr>
<td>C Sexual Minorities</td>
<td>10</td>
<td>0</td>
<td>2</td>
<td>12</td>
</tr>
<tr>
<td>D Scheduled Castes</td>
<td>9</td>
<td>1</td>
<td>2</td>
<td>12</td>
</tr>
<tr>
<td>E Scheduled Tribes</td>
<td>12</td>
<td>0</td>
<td>0</td>
<td>12</td>
</tr>
<tr>
<td>F Religious identity</td>
<td>6</td>
<td>3</td>
<td>3</td>
<td>12</td>
</tr>
</tbody>
</table>

The analysis done as part of India responsible Business Index (IRBI) which incorporated five elements, of which four are focused on core business issues, presented an insightful trend regarding generally lower commitment of companies on core business issues as compared to CSR which is largely focused on “adopted” communities. The average element scores for pharmaceutical and healthcare sector companies are lower than average scores for top listed companies. Also, top-scoring companies had far positive results compared to average scores of these companies. This points to the huge gap in terms of commitments by pharmaceutical and healthcare sector companies in the domain of social inclusion and points to the dire need to strengthen such mechanisms.

**Average IRBI scores for the 12 pharmaceutical/healthcare companies and top 100 companies along with highest scores vis-a-vis respective IRBI elements**
Another issue, well within the realm of social responsibility is the accountability to customers and a core aspect of this is the issue of pricing of drugs. The National Pharmaceutical Pricing Authority (NPPA), is authorised to regulate and recover the amount for the controlled drugs. NPPA on a yearly basis publishes on its website the status of overcharging and recovery of those medicines which are subjected to price control under Drugs Price and Control Order (DPCO) 1995 and 2013. Under Drugs Price and Control Order 1995 seventy four drugs were subjected to control order however the new order of 2013 has expanded its horizon and covers three hundred forty eight drugs. The figure below details the overcharged amounts including interest (in lakhs) as per DPCO 1995 and 2013 respectively:

While 6 of the ten companies have not overcharged as per the Drugs Price and Control Order 2013, every one of them has some amount that they have overcharged as per DPCO 1995.
Chapter 4: Corporate Social Responsibility: Nature of Activities Organised by Pharmaceutical Companies

- Pragya Shah, Ekta Verma and Akoijam Surjit Singh

The National Health Policy, 2017 talks about Corporate Social Responsibility (CSR) as an instrument of financing public health care. The interpretation of this by some pharmaceutical companies is an adjustment of "marketing" expenses related to organising health camps for promoting their products, as CSR expenses. This trend points to a clear interest in creative accounting, to ensure that not a single pie of the company’s income be diverted to achieving larger national development goals.

An analysis of CSR reports for 2015-16 of forty companies - including twelve pharmaceutical companies and twenty-eight other companies - was done. The analysis was done to identify and understand the CSR expenditure of these companies across various sectors. Chart 1 below details expenditure of the 40 companies across the twenty-five permissible sectors. Sectors with less than one per cent CSR spend have not been included.

A further analysis of the twelve pharmaceutical companies (from this sample of 40) yield the results as detailed in chart 2 below:

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18 This sample of 40 companies all fall within the top-100 based on market capitalization as of 31st March 2016

19 Sectors with less than one per cent CSR expenditure include: women’s empowerment (0.6%); safe drinking water (0.38%); community development (0.36%); salary of CSR staff (0.36%); people with disabilities (0.33%); SC/ST welfare (0.25%); infrastructure (0.14%); children’s welfare (0.05%); urban slums (0.04%); elderly (0.01%) and national security (0.01%)
The sectoral spending trends by the 40 companies overall and just the pharmaceutical companies seem to be similar – the top three sectors include health, education and rural development – making up nearly 70 per cent of CSR spend.

Given that health related CSR spend makes up for close to 30 per cent of the 40 companies and a little over 50 per cent of the pharmaceutical sector, a close look was taken at the nature of health expenditure. This is presented in Chart 3 below:

**Chart 4.3: Expenditure on CSR activities within the health sector by 40 companies (on the left) and 12 pharmaceutical companies (on the right)**

Free medical health check ups and camps with a combination of similar activities emerge as the most popular type of CSR health sector activity among the 40 companies and the 12 pharmaceutical companies. This begs the question of whether health camps are actually being leveraged as a marketing tool or whether they genuinely serve the purpose of corporate social responsibility.
Marketing personnel from pharmaceutical firms are often seen screening people and conducting various diagnostic tests at 'free health camps' in return for prescriptions from doctors for their company's medicines, a report in the British Medical Journal\(^2\) has revealed. In these camps and clinics, it was found that the medicines being prescribed were mostly of the company whose representatives were doing the tests and many sales representatives told the BMJ that such camps helped them achieve their sales targets. “Some camps take place at temples or schools near slum areas and tend to attract hundreds of visitors, while smaller 'patient camps' can be at a hospital or in the waiting room of a doctor's office.”\(^2\)

“Boosting drug sales through screening programmes that look like charity is a common practice in India. Not only does it create new customers and capture market share, but insiders say that it allows companies to influence prescribing, despite regulations that prohibit doctors from accepting gifts from drug companies,” stated the BMJ article.

Cipla acknowledged that its employees test patients, reports Joelving. A Roche spokesperson said that Roche Diabetes Care India donates testing supplies to diabetes education camps, but added that "people with diabetes who attend the camp test on their own, after having signed a written consent."\(^2\) Ransom D'Souza, a GlaxoSmithKline India spokesperson, said: "Our sales representatives are not permitted to perform tests on patients in India" But Pinaki Dutt, a GSK sales rep from Bankura, West Bengal, told Joelving in 2013 that he and his colleagues were required by 'company policy' to do blood sugar tests at regular health camps.\(^3\)

The Medical Council of India (MCI) has declared this practice unauthorised stating that only a registered medical practitioner can perform screening and diagnostic tests. The BMJ report says it has evidence that unlicensed employees from several pharmaceutical companies - both Indian and multinational - including Abbott, Bayer, GlaxoSmithKline, Roche and Sanofi have tested patients at health camps.

\(^{20}\) Source: [http://www.bmj.com/content/351/bmj.h6413](http://www.bmj.com/content/351/bmj.h6413)
\(^{22}\) Available at: [https://doi.org/10.1136/bmj.h6413](https://doi.org/10.1136/bmj.h6413)
Chapter 5: Towards a Human Rights-based approach to the Pharmaceutical and Health Care sector (especially Drug companies)  

- Viraf Mehta

In considering roles for private pharmaceutical and health care companies (P&HC) in the country’s National Health Policy (NHP) it is an imperative to analyse their suitability and preparedness from a Human Rights perspective. It is insufficient to refer merely to the philanthropic and voluntary CSR activities by P&HC companies, however laudable such efforts may be, as indicators of their commitment and performance on issues stemming from the Right to the (highest attainable standard of) Health. Whilst a traditional assessment of a company’s performance in the marketplace, workplace, environment, supply chain and community can certainly provide useful indicators about its commitment to sustainable development, this cannot be a replacement for scrutiny under the lens of human rights. Additionally, whilst most activists and researchers have focussed on the adverse human rights impacts of companies in their sourcing and manufacture of their products - the upstream side of global value chains-, the significant challenges for pharmaceutical companies lie in the way in which they market and distribute their products - the downstream side of global value chains. Within these, whilst attention has primarily focussed on intellectual property, international trade law and pricing, several other key dimensions of the pharmaceutical industry’s influence and impact have been neglected.

All businesses have an obligation to respect all human rights as outlined by the authoritative UN Guiding Principles for Business and Human Rights (UNGPs), under whose 3-pillar prescription-“Protect Respect, Remedy”, the State has a duty to protect people from any adverse human rights impacts by business, and to provide access to effective remedy, when these occur. In this context, the Right to Health places, under international human rights law, a legal obligation upon States to ensure that essential medicines (EM) are available, accessible, affordable, acceptable, and of appropriate quality, and to develop a Lists of EM using the WHO Model List for guidance.

Whilst the debate on the responsibility of pharmaceutical companies have been hotly debated and considered for years by NGOs, it was the landmark submission to the UN General Assembly, in 2008, by the UN Special Rapporteur on the Right to Health, of his report on the “Human Rights Guidelines for Pharmaceutical Companies in relation to Access to Medicine” (UN HRGPC), that brought these into sharp focus and prominence. These Guidelines are comprehensive in the scope and coverage of issues relevant to pharmaceutical companies, and in conjunction with the aforementioned UNGPs, constitute the most authoritative guidance in respect of their human rights responsibilities: whilst the former focus upon the issues most relevant to the Access to Medicines, the latter provide detailed guidance on the operational aspect of Human Rights that companies are required to integrate into their management processes. The UN HRGPC in its Preamble, notes that ‘nearly two billion people lack access to essential medicines, and that improving access to existing medicines could save ten million lives each year, and further notes that the achievement of several Millennium Development Goals (reiterated in the SDGs) depend upon improving access to medicines. The UN HRGPC then proceeds to outline and provide commentary on issues including:

- Transparency
- Corruption
- Management, monitoring and accountability
- Pricing, discounting and donations
- Public policy influence, advocacy and lobbying
- Ethical promotion and marketing
- Quality
- Clinical trials
- Patents and licensing
- Disadvantaged individuals, communities and populations
- Neglected diseases

In addition to the above-mentioned areas there is additional guidance to companies participating in Public-Private Partnerships for health-related projects and for the conduct of associations of pharmaceutical companies.
At the international level, it is encouraging to note that the influential OECD have focussed recent attention to the application of key principles of the UNGPs to business, and have developed industry specific guidance on the critical process of a human rights due diligence for their supply chains. The work done by organisations such as the Access to Medicine Foundation in producing reports that rank 20 of the largest pharmaceutical companies in the world on the basis of their performance against over 70 indicators is an important contribution to the agenda of assessing their performance. It perhaps unsurprising that a recent report by the Business & Human Rights Resource Centre found that amongst all the company respondents invited to participate in an assessment of their human right actions, the pharmaceutical sector was the only one in which all companies had adopted a human rights policy.

<table>
<thead>
<tr>
<th>S.No.</th>
<th>Aspects related to HR commitment</th>
<th>No of companies (n=12)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Developed stand-alone Human Rights Policies</td>
<td>4</td>
</tr>
<tr>
<td>2</td>
<td>Companies reporting zero human rights violations</td>
<td>10</td>
</tr>
<tr>
<td>3</td>
<td>Companies not reporting data on human rights violations</td>
<td>2</td>
</tr>
<tr>
<td>4</td>
<td>Companies extending human rights principles to communities</td>
<td>2</td>
</tr>
<tr>
<td>5</td>
<td>Included grievance redressal for any violation as part of it’s human rights commitment</td>
<td>1</td>
</tr>
<tr>
<td>6</td>
<td>Mentioned about extending the HR principles to their supply chain</td>
<td>5</td>
</tr>
</tbody>
</table>

In the Indian context, the NVGs, released by the Ministry of Corporate Affairs in 2011, make explicit reference to the Human Rights-related expectations of Business through a separate Principle (P5). Additionally, the SEBI mandate for a Business Responsibility Report based upon the NVGs, provides us with a domestic framework well-aligned with the International ones previously referred to. An examination of BRR disclosures for 2016-2017 reveals that of the 12 Pharma and Health Care companies feature in the top 100 listed companies, only 4 report having developed stand-alone Human Rights Policies, less than half (5) extending HR principles to their supply chain, and with only a single one reporting having a grievance redressal mechanism for Human Rights. Whilst a beginning has been made in India with regards to transparency and disclosure of non-financial reporting, it is still some time away for most Indian Pharma companies, especially family-owned ones, to achieve the maturity of western multinational ones with regards to human rights systems.
Chapter 6: Strengthening Public Health Systems: The Way Forward  
- Pradeep Narayanan and Sowmyaa Bharadwaj

In the background paper to the National Health Policy, the Government’s own analysis of facts and evidence diagnosis present the reasons of poor health performance as (a) inequity in health access, (b) increased out of pocket expenses on health by households, (c) presence of unethical pricing by private health care providers and poor regulatory system; and (d) much reduced public health care expenditure compared to many other countries. The NHP 2017 aims to achieve universal access to health care by ensuring improved access and affordability to healthcare services while emphasising the need for strategic partnerships with the non-governmental sector and the private sector. In the new policy, there is a stated shift from providing primarily public services to new, strategic partnerships with private health providers, which it is believed, will further open up opportunities for the best treatments with the prospect to fill the gaps in public and private services in health care. What is ironic is that despite data that demonstrates that private players are not public spirited, policies are still dependent on these very players.

In this study, we assessed how the pharmaceutical companies are responding to three instruments that are largely of voluntary nature but have emanated from the Government of India: UCPMP, National Voluntary Guidelines and CSR under the Companies Act, 2013. It is clear that the pharmaceutical companies are very distant from voluntarily adhering to these guidelines - to an extent that they would be trusted to achieve public goals as stated under NHP 2017. To a large extent, even the Government has started considering using the mandatory legislation route to rope in Pharmaceutical companies. The example is the form that UCPMP is presently taking.

1. Strong Law on Pharmaceutical Marketing Practices, a Must

The government recently evolved a draft regulation - proposed Order, Essential Commodities (Control of Unethical Practices in Marketing of Drugs) Order, 2017. In its object and reasons, interestingly, the State acknowledges the presence of an “unholy nexus between certain companies and medical practitioners to create a virtual monopoly at the cost of general public and patients”. Further, the draft order acknowledges also the absence of any regulation to govern the unethical practices, which are in fact ‘criminal’ practices that require penalties. For the very same issue, way back in the year 2002, the Medical Council of India introduced a code of conduct for doctors in terms of their relationship with the Pharmaceutical industry. In 2009, the Council introduced regulations to prohibit doctors from accepting various kinds of gifts from any pharmaceutical companies. Despite the above regulations, the scenario still exists almost in the same form, requiring state intervention. The expectation was that the Government would draft a strong regulation, knowing very well that the unholy nexus is capable of circumventing different regulations! However, the draft order is found wanting in many aspects.

It is also significant to see that the Government prefers to take the ‘regulation’ route rather than follow Parliamentary law. It could be perceived as urgency of the Department to have some regulation very soon and it is encouraging to see a demonstration of administrative willingness to curb the nexus. The first set of voluntary codes was issued way back in 2011. The UCPMP in the current form was notified in 2012. Since 2015, the UCPMP notification is actually in force. Despite repeated notifications, the associations and the companies have ‘voluntarily’ ignored the voluntary code! In fact, only two out of eleven industry associations actually uploaded the UCPMP guidelines in their websites, let alone taking action to enforce the code. This clearly demonstrates the respect that the companies have for the State. Laws will far longer but the importance of parliamentary law cannot be undermined. It would facilitate greater discussions in Parliament and in the public domain. Regulations appear as ‘ad-hoc solutions’, while the issue needs a comprehensive legislation, including the creation of appropriate institutions which would include the role of the Ministry of Health as well as the Ministry of Consumer Affairs.
The Section 3 of the proposed Order on essential commodities lists the unethical practices. They pertain to two parts:

(i) Making false claims and inappropriate promotion (sub-section a,b,c and d) and
(ii) Building nexus relationship with medical practitioners (sub-section e,f,g and h).

Other laws relating to the Drugs and Cosmetics Act, 1940 and the Drugs and Magic Remedies Act, 1954, in any case, deal with the first part. This draft order does not have direct provisions for penalty on these sub-sections. To that extent, the proposed order literally ignores the enforceability of unethical practices with respect to promotion of drugs by the pharmaceutical companies. However, the draft order does prohibit clearly the following four practices (sub-section e, f, g and h) for which penalty have been prescribed:

- Offering free samples to any medical practitioners
- Offer gift, cash card, hampers or anything, which generates monetary benefit or allows gains in kind to medical practitioners, retail chemists, or pharmacists or their family members.
- Make available any travel facility, stay or food cost, registration fee or paid vacation to medical practitioner or family for even seminar, scientific writing or continuing medical education.
- Extend grant or funds for medical research or clinical trials, except through approved institutions subject to any law in force.

However, there are a number of provisions that make exceptions to the above prohibitions. With respect to offering free samples, the order provides for four conditions, but the one glaring miss, when compared to UCPMP, is that the latter prohibits supplying a sample of a drug which is an anti-depressant, hypnotic, sedative or tranquilizer. Similarly, while UCPMP does not state exceptions for the gift clause, the draft order has come out with exceptions, allowing pharmaceutical companies to sponsor events organised by Medical Associations. Further, it allows the companies to organize screening camps or awareness campaigns even in the hospitals and health centres. Moreover the Order allows the company to even ‘compensate’ a medical practitioner for attending the screening camps in commensuration with their average daily incomes. It just prohibits companies from using such camps for surrogate advertisement of their products, without explaining various scenarios that could come under surrogate advertising. Are these exceptions stated in the draft order not taking away the core essence of the provision itself? More than prohibition, the draft Order seems to be legitimating the nexus relationship by accepting certain kinds of engagement. These provisions are watered down ones, when we compare it with the UCPMP, which does not provide these exceptions.

2. Penalty: Will it be deterrent enough?

Firstly, the most important aspect of penalty is that it actually legitimizes offering of gift of value less than Rs. 1000/- because a penalty is prescribed only when the value of gifts exceeds this ceiling. Further, it does not even talk about gifts that could not be monetized. Secondly, there has not been much ingenuity while prescribing penalty. The only penalty that the State could think of is "suspension of marketing”, irrespective of the nature of violation, with difference being only the period of suspension. It is important to understand whether the amount of punishment is sufficient to be a deterrent? However, it is pertinent to say here that the Order is progressive to specify that the marketing would be suspended for the highest selling product of the company. Finally, the Order is generous to provide for commutation of penalty of suspension of marketing on deposit of a specified amount, which is as less as Rs. 5 lakhs to a maximum of Rs. 10 crore. With respect to the procedure for penalty, while it is creating a set of new Officers - Ethics Compliance Officer and an Additional Ethics Compliance Officer, there is an absence of clarity on the presence of a team to investigate the compliant. It seems that the onus of producing evidence for the compliant is with the complainant. While it rightly provides for opportunity for the company of being heard, there is no mention of any time period by which the officer has to dispose the compliant.
Sometimes, an absence of regulation is better than a scenario, where the regulations, more than prohibiting, provide escape routes for the companies to organize the same ‘unethical’ practices now in a legitimate way. A poor regulation could silence the voices of proactive citizens who represent the interests of general public and patients. This Order actually has the potential to formalise unethical practices, given that penalty and enforcement - both are weak. Especially, when one knows that the industry is well knows to play with the words of the Order than the spirit. If the pharmaceutical industry has the intent to go by the spirit of the law, the MCI codes would have been enough to mend their ways. As usual, the Department just wants check off an item on the list, rather than addressing the real issue of the unholy nexus.

3. Strengthening Public Health Care System Must

The question on whether the private sector would be able to address inequity issues related to the Universal health care agenda continues to persist. Over the last few decades, the Situation Analysis report reiterates, that the out of pocket expenditure by households has increased and led to impoverishment of people. While the health justice movement looks at this with concern, the health neo-liberals see the emerging health care industry as an opportunity. Despite the appalling situation of increasing impoverishment, households and patients being trapped in the hold of the private sector. This is being exploited thoroughly, led by corporate hospitals. The irony is that if one dilutes the Government health care system and forces households to spend, it is only logical that there is going to be an increase in household expenditure on health, further impoverishing people!

While focusing on private health care, the urgent need is actually to arrest the weakening of the public health care system. The facilities and quality was never improved. In fact, many even argue that the public health care system was ‘actively’ ignored forcing people to shift to private health care. In the same era, there was also active support by the Government for the private health care service provider - companies selling pharmaceuticals, medical devices, diagnostics as well as corporate hospitals - with tax concessions and subsidized land. This helped these companies to grow and spread its role and significance, more than the government hospitals. Today their growth has led to a significant contribution to the gross domestic product, to an extent that it has become the government's priority to build and sustain them or else suffer negative consequences on the national economy. It is in this context, one has to carefully examine the revision in the health policy, which proposes, “strategic purchasing of services from the private sector” through public funds. In other words, now the Government itself will take on the role of a customer, and thus facilitate the private administration (and take over) of the health sector. The health neoliberal may actually see these stages as logical and natural and find this course of action by the Government progressive and contemporary. However, the fear is the very diagnosis that the situation report has done- “the growing out of pocket expenses on health by the people have impoverished them.”

For once, it is not that there is not adequate information on the reasons why the health system is not evolving to cater to the needs of the population. The very need for recognising health as an entitlement to every citizen, especially the marginalised communities, does not require elaborate research - it requires a government that listens to people, and makes policies accordingly. The National Health Policy-2017 has very rigorously done background papers that provide significant inferences, which the NHP itself seems to ignore. When the prominence of facts and evidence takes a back seat and policy making affirms a policy prescription which is not substantiated by facts, but goes along with an approach that likens increased dependency on the private sector, one can easily conclude that this kind of policy making does not appreciate facts, and, in fact, they sideline facts – as Michael Deacon says, "Facts are negative. Facts are pessimistic. Facts are unpatriotic."
Chapter 7: Case Studies

Case Story 1: Apollo Hospitals by Jhumki Dutta

Snapshot

BACKGROUND
Apollo Hospital was India first corporate hospital launched in Chennai in 1983. Over the years, it has included Hospitals, Pharmacies, Primary Care & Diagnostic Clinics and Telemedicine units across 10 countries, Health Insurance Services, Global Projects Consultancy, Colleges of Nursing and Hospital Management and a Research Foundation with focus on Global Clinical Trials, epidemiological studies, stem cell and genetic research. It implements social initiatives and impactful programmes such as SACHI (Save a Child’s Heart Initiative), SAHI (Society to Aid the Hearing Impaired) and the CURE Foundation (focused on cancer screening, cure and rehabilitation for those from a financially challenged background).

<table>
<thead>
<tr>
<th>Positive News Stories</th>
<th>Negative News Stories</th>
</tr>
</thead>
<tbody>
<tr>
<td>・ Won the top 4 positions across categories in the Times All India Lifestyle Hospital and Clinic ranking survey 2017</td>
<td>・ Unethical practices: Case of extortion and fake documents</td>
</tr>
<tr>
<td>・ Launched India’s first heart disease prevention and reversal programme</td>
<td>・ Violation of bio waste disposal norms in Tamil Nadu</td>
</tr>
<tr>
<td></td>
<td>・ Medical negligence and failure to take consent</td>
</tr>
<tr>
<td></td>
<td>・ Rape of an ICU patient at a hospital</td>
</tr>
<tr>
<td></td>
<td>・ Organ trade scam</td>
</tr>
</tbody>
</table>

RESPONSIBLE BUSINESS

・ Policies on all nine principles of National Voluntary Guidelines exist and policies are available online
・ 6979 customers concerns were received in 2015-2016 of which 95% were resolved
・ Code of Conduct for Board Members helps in recognizing and dealing with ethical issues and to help foster a culture of honesty and accountability
・ Code of Conduct for Senior Management Personnel helps the Company to maintain the Standard of the Business Ethics and ensure compliance with the legal requirements
・ Whistle Blower Policy for directors and employees is a policy for reporting concerns of unethical behaviour, actual or suspected fraud or violation of the Company’s Code of Conduct

UCPMP

・ Apollo Hospitals is not expected to comply with the UCPMP, as is mandated by the Government but since the hospitals comprise of.medical practitioners, their role in ensuring the success of UCPMP is critical.
・ The code of conduct at first glance appears to be drawing its core meaning from the guidelines enumerated in UCPMP.
・ Code mentions that acceptance of “modest gifts” is acceptable as long as the intention of such act is not to influence a person or is against the interest of the Company. It however, is silent on the meaning of the word “modest”
・ In the absence of clear directives regarding benefit extended to HCPs, it appears that the hospital may have left a gap in understanding, thereby allowing for opportunities leading to unethical practices
・ Apollo hospitals, does not have a comprehensive marketing policy available for public review. It has a separate marketing team in each hospital, which engages with corporate for tie ups, doctor interactions, health camps and advertising through brochures, pamphlets, leaflets, television and hoardings.

CORPORATE SOCIAL RESPONSIBILITY

・ Spent Rs. 8.64 crore on CSR in 2015-16 to meet the CSR mission of creating meaningful and lasting impact on the communities in remote areas
・ Thrust areas include socio-economic development in rural areas, develop the skills of the youth through high quality education and research in healthcare services and extending comprehensive Integrated healthcare services to the community
・ It conducts impact assessments for all of its CSR initiatives.
・ It mentions measuring change from its social initiatives by regularly monitoring and evaluating the outcomes by setting key performance indicators.
Detailed Case Study

1. Background

Founded in 1983, by Dr. Prathap C Reddy Apollo Hospital was India first corporate hospital launched in Chennai. Over the years, it has transformed itself into an integrated healthcare services provider, the group’s presence includes Hospitals, Pharmacies, Primary Care & Diagnostic Clinics and Telemedicine units across 10 countries, Health Insurance Services, Global Projects Consultancy, Colleges of Nursing and Hospital Management and a Research Foundation with focus on Global Clinical Trials, epidemiological studies, stem cell & genetic research. Apollo Hospitals was one among the first few in the world to leverage technology to build integrated healthcare delivery models, which facilitate seamless healthcare delivery through electronic medical records, hospital information systems and telemedicine-based outreach initiatives and pioneered medical innovations in equipment and therapy.

It was the first to invest in the pre-requisites that led to international Quality accreditation like the Joint Commission International and Indraprastha Apollo Hospitals was the first hospital in India to be accredited with this gold standard in 2006.

Apollo Hospitals also implements social initiatives and impactful programmes such as SACHI (Save a Child’s Heart Initiative - a community service initiative for providing quality paediatric cardiac care to children from underprivileged sections of society suffering from heart diseases), SAHI (Society to Aid the Hearing Impaired) and the CURE Foundation (focused on cancer screening, cure and rehabilitation for those from a financially challenged background).

Apollo Hospital in News

POSITIVE STORIES:

- Apollo Hospitals won the top 4 positions across categories in the Times All India Lifestyle Hospital and Clinic ranking survey 2017
- Apollo has launched India’s first heart disease prevention and reversal programme

NEGATIVE STORIES

- **Unethical Practice**: March 2017- As the state government cracks the whip on private healthcare facilities ahead of the implementation of the recently passed Clinical Establishments Act, police in Kolkata registered a criminal case against Apollo Gleneagles Hospitals, a unit of Apollo Hospitals Enterprise Ltd, for alleged extortion. The Hospital is likely face consequences for lapses and malpractices. The case was registered on account of severe negligence and accounting malpractices committed by the hospital, wherein not only did the patient die but also the family has to pay extra on account of fake documents prepared by the hospital to get extra money from the patient. Such misdeeds seem to have increased the bill amount of the treatment to Rs 7.23 lakh. A committee was formed to look into the matter, and fix accountability in the death of a patient, the committee found four senior doctors and some staff of Apollo Gleneagles Hospitals guilty and liable for punishment

- **Violation in Bio-Waste Disposal**: The National Green Tribunal’s (NGT) Southern Bench here has directed the Tamil Nadu Pollution Control Board (TNPCB) to initiate immediate action, including

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launching of prosecution, against 21 hospitals including Apollo Hospital in Chennai, after the board found that these hospitals had “committed gross violations” of Bio-Medical Waste (Management and Handling) Rules, 1998. According to the report of the TNPCB, 21 hospitals are maintaining records that do not tally with the quantum of waste maintained.

- **Medical Negligence**: In a case of gross medical negligence, National Consumer Disputes Redressal Commission (NCDRC) has directed Apollo Hospital in Hyderabad and one of its doctors to pay Rs four lakh as compensation to a man who lost his wife due to alleged medical negligence. According to the Commission “…The OP (Hospital and the doctor) failed to take informed consent. As per medical record, the patient was not willing to undergo such high risk procedure... Similarly the progress sheet reveals ‘patient and her husband not willing for surgery immediately’. Thus, in our view, in the instant case it was not an informed consent”. The complainant stated that in spite of repeated requests that she was already suffering from a lung disease and was under treatment with steroids, the doctor directly performed for Endoscopic Retrograde Cholangad Pancreotography (ERCP) P in a negligent manner without conducting necessary tests and taking consent of the patient or her husband.

- **Worker Rights**: Over 12 Doctors in Pakistan working on Long Term Visa (LTV) were asked to resigned after a Pakistani doctor and a ward boy were arrested for allegedly raping a dengue patient at the ICU of Apollo hospital in Gandhinagar.

- **Organ Trade**: Indraprastha Apollo Hospital, New Delhi, was recently caught in a Kidney Racket, wherein, Kidneys from poor people was transplanted after forging documents of the donors. These donors would impersonate as a family member of the recipient and the necessary identity documents like aadhar cards, marriage licenses etc. would then be forged. In June 2016, based on a tip-off, the police unearthed a massive scam at Apollo hospital where middlemen lured unsuspecting 'donors' – usually economically challenged people, to sell their kidneys at a price between two to four lakhs. These kidneys would then go to those patients who fit the requirement. Since, the laws governing organ donation is stringent, and there is intense scrutiny on donors who are not family members, the middlemen forged paperwork to establish familial relationship between the donors and recipients. Over 17 people, including personal assistants of senior doctors were arrested in connected with the case.

### 2. Responsible Business

In the company’s BRR 2015-2016, it gives a description of the level of compliance with the nine NVGs and also mentions the other codes and policies which the company complies to.

<table>
<thead>
<tr>
<th>Principle</th>
<th>Whether it states it has policy?</th>
<th>Whether it states it has disclosed in website?</th>
<th>Whether the link provided is functional?</th>
<th>Whether policies are actually available in public domain?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Principle 1: Business Ethics and Governance</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes: Whistle Blower Policy, CSR Polices</td>
</tr>
<tr>
<td>Principle 2: Product Responsibility</td>
<td>Yes</td>
<td>Yes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Principle 3: Well being of workers</td>
<td>Yes</td>
<td>No</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Principle 4: Stakeholder Engagement</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>Principle 5: Human Rights</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>Principle 6: Environment</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td></td>
</tr>
</tbody>
</table>

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Bitter Pill: How Inclined Are Companies to Deliver National Health Policy Outcomes?

<table>
<thead>
<tr>
<th>Principle</th>
<th>Whether it states it has policy?</th>
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<th>Whether policies are actually available in public domain?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Principle 7: Public Advocacy</td>
<td>Yes</td>
<td>Yes</td>
<td></td>
<td>Yes</td>
</tr>
<tr>
<td>Principle 8: Inclusive Growth and Equitable Development</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Principle 9: Providing Value to Customers</td>
<td>Yes</td>
<td>No</td>
<td></td>
<td>Yes</td>
</tr>
</tbody>
</table>

6979 customers concerns were received in 2015-2016 of which 95% were resolved. No case has been filed by any stakeholder against our group, regarding dishonest trade practices, irresponsible advertising and/or anti-competitive behaviour during the year.

Additional policies

<table>
<thead>
<tr>
<th>Policy</th>
<th>What does it capture</th>
<th>Who does it apply to</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Code of Conduct for Board Members</td>
<td>The Code is intended to provide guidance to the board members and help in recognizing and dealing with ethical issues and to help foster a culture of honesty and accountability. The Board members of the company are responsible for setting the standards of conduct contained in the Code and for updating these standards as appropriate to reflect legal and regulatory developments.</td>
<td>Board Members of the Company</td>
</tr>
<tr>
<td>2 Code of Conduct for Senior Management Personnel</td>
<td>This Code for the Senior Management Personnel of the Apollo Hospitals Enterprise Limited (the Company) helps the Company to maintain the Standard of the Business Ethics and ensure compliance with the legal requirements, specifically under Clause 49 of the Standard Listing Agreements of the Company with the Bombay and National Stock Exchanges. The Code is aimed to prevent any wrongdoing and to promote ethical conduct at the Board and Senior Management level.</td>
<td>Senior Management Personnel: all members of management one level below the Executive Directors including all functional heads.</td>
</tr>
<tr>
<td>3 Whistle Blower Policy</td>
<td>The “Whistle Blower Policy” for directors and employees is a policy for reporting concerns of unethical behaviour, actual or suspected fraud or violation of the Company’s Code of Conduct.</td>
<td>Directors and employees of the company</td>
</tr>
</tbody>
</table>

3. UCPMP: Where Apollo stands?

II.I Should Apollo Hospital be expected to comply with UCPMP in any way?
Apollo Hospitals is not expected to comply with the UCPMP, as is mandated by the Government. However, since the hospitals comprise of medial practitioners, their role in ensuring the success of UCPMP is critical.

II.II Is there a statement on compliance with UCPMP available on its website?
There are no declarations by the company that showcases its compliance with UCPMP

II.III What relevant policies does it have?
Apollo Hospitals, has a Code of Conduct both for board members and senior management, this code in a very comprehensive manner lays down the guidelines that board members and senior managerial personnel are expected to follow. It helps the board members and senior management, in recognizing and dealing with ethical issues and to help foster a culture of honesty and accountability. The Code ensures that Company maintains the Standard of Business Ethics and ensure compliance with legal requirements, especially Regulation 17(3) of the Listing Regulations. It also has a Whistle Blower Policy that covers serious ethical concerns and lays down guidelines for dealing with violations.

II.IV Does it recognise any of the principles of UCPMP in any of its company policies?

Apollo Hospitals has a comprehensive code of conduct both for board members and senior management that spells out details about ethical engagement by health care professionals. According to the code “No... shall (directly or indirectly) solicit, accept or retain any gift, entertainment, trip, discount, service, or other benefit from any organization or person doing business or competing with the Company, other than (i) modest gifts or entertainment as part of normal business courtesy and hospitality that would not influence, and would not reasonably appear to be capable of influencing, such person to act in any manner not in the best interest of the Company or (ii) acceptance of a nominally benefit that has been disclosed to the Company”. The principle at first glance appears to be drawing its core meaning from the guidelines enumerated in UCPMP. Its mentions that acceptance of “modest gifts” is acceptable as long as the intention of such act is not to influence a person or is against the interest of the Company. It however, is silent on the meaning of the word “modest” thereby leaving it open to interpretation. In the absence of clear directives regarding benefit extended to HCPs, it appears that the hospital may have left a gap in understanding, thereby allowing for opportunities leading to unethical practices.

II.V Does it support the observance of Indian Medical Council Regulations 2002 in any of its policies?

The Code of Conduct both for Boards Members and Senior Managerial Personnel does include a component about acceptance and soliciting gifts. According to the code “No... shall (directly or indirectly) solicit, accept or retain any gift, entertainment, trip, discount, service, or other benefit from any organization or person doing business or competing with the Company, other than (i) modest gifts or entertainment as part of normal business courtesy and hospitality that would not influence, and would not reasonably appear to be capable of influencing, such person to act in any manner not in the best interest of the Company or (ii) acceptance of a nominally benefit that has been disclosed to the Company”. Insofar as application of the article is concerned, because of definitional problems, the article is left to individual interpretation.

The Hospital also has a comprehensive policy regarding the Preservation of Document, which states that “documents and records of the Company are adequately protected and preserved as per the statutory requirements and to ensure that the records of the Company which are no longer needed or are of no value are discarded after following the due process for discarding the same”. The policy among other documents also includes preservation of medical records of patients. It also captures time-period for the preservation of the document and its disposal. The policy, however, does not mention the procedure that needs to be followed in case of inquiry about documents from patients. This aspect of the MCI guideline has often been violated like in the case of Apollo Hospitals Vs. M. Sathyanarayana & Ors.,(NCDRC Order dated 28th April, 2011 in RP No.2069 of 2010) and H. S. Sharma Vs. Indraprastha Apollo Hospital anr.,(2007 CPJ 21 NC). In both the above cases, the court had upheld the judgement in favour of the petitioners.

II.VI Are there any internal systems and mechanisms to uphold any of the principles of the UCPMP?

31 Case details - https://indiankanoon.org/doc/117161249/
32 Case details - https://indiankanoon.org/doc/629042/
Apollo Hospitals has a comprehensive whistle-blower policy that “covers serious concerns that could have grave impact on the operations and performance of the business of the Company”.

It covers all malpractices and events, which have taken place / suspected to take place which includes a whole variety of issues listed below:

- Any unlawful Act, whether criminal or a breach of the civil law.
- Breach of any Policy or Manual or Code adopted by the Company
- Abuse of power/authority (through physical, sexual, psychological or financial abuse, exploitation or neglect)
- Negligence causing substantial and specific danger to public health and safety
- Manipulation of company data/records
- Financial irregularities, including fraud, or suspected fraud
- Perforation of confidential/propriety information
- Deliberate violation of law(s)/regulation(s)
- Wastage/misappropriation of company funds/assets
- Breach of employee Code of Conduct or Rules; and
- Any other unethical or improper conduct

II.VII Are the marketing ethics consistent with that of a socially responsible company?

Apollo hospitals, does not have a comprehensive marketing policy available for public review. It has a separate marketing team in each hospital, which engages with corporate for tie-ups, doctor interactions, health camps and advertising through brochures, pamphlets, leaflets, television and hoardings. The hospital also conducts conference for doctors for encouraging them to join. In 2015-2016, the Company spent Rs. 1095.88 Million on advertising, publicity and promotion.

4. Corporate Social Responsibility Reporting

The company’s CSR Mission is to create a meaningful and lasting impact on the communities in remote areas by helping them transcend barriers of socio-economic development as well as to develop the skills of the youth through high quality education and research in healthcare services and extending comprehensive Integrated healthcare services to the community. As part of their intervention, the CSR intervention thrust areas include:

- **Rural Development:** A Model of Integrated Healthcare Service will be established to improve the health of communities through: access to quality education for youth, education and train ASHA workers etc.
- **Healthcare:** The Company intends to touch a billion lives by reaching out to people from every walk of life to help them stay healthy. The objective is to promote wellness and not treatment. In line with this, under its CSR focus the company will aim to promote preventive healthcare in the most remote corners of the country with the aim of making quality healthcare accessible & affordable for all.

**Amount Spent:** During the year 2015-2016 Apollo Hospital has spent Rs. 8.64 crore towards their CSR expenditure.

**Impact Assessment:** In its BRR, Apollo Hospitals agrees that it conducts impact assessment for all of its CSR initiatives. It mentions measuring change from its social initiatives by regularly monitoring and evaluating the outcomes by setting key performance indicators.
Case Story 2: GlaxoSmithKline Pharmaceuticals by Jhumki Dutta

Snapshot

BACKGROUND
GSK India works towards providing medicines that improve people’s quality of life and truly make a difference to patients. Over the years, GSK Pharma India has forayed into diverse segments and have developed a broad range of innovative products in three primary areas - Pharmaceuticals, Vaccines and Consumer Healthcare and this critical success factors for the company

Positive News Stories
- GSK has been lobbying to ensure “sensible pricing” policy to enable access to decent healthcare
- Digitisation is a key agenda and it has developed apps for providing information about various ailments and to enable companies provide product information

Negative News Stories
- Unethical clinical trials of the cervical cancer vaccine
- Substandard drugs accusation along with 17 other pharma companies
- Two cases of misleading advertising
- Trading violation in bidding practices for provision of meningitis vaccine

RESPONSIBLE BUSINESS
- Policies on all nine principles of National Voluntary Guidelines Exist
- Facilitative polices include:
  - Code of Conduct which provides a working guide for the way in which they should apply their values across all their business practices and working styles
  - Global Code of Practice for Promotion and Customer Interactions which applies mainly to vaccines and pharma and excludes consumer healthcare
  - Anti bribery and anti corruption policies

UCPMP
- Not a member of IDMA or any other medical association and therefore no self-declaration by the Executive Head of the company indicating compliance with the UCPMP
- The Code of Practice and Code of Conduct quite adequately captures most of the critical aspects stated in the UCPMP, however, it does not include any reference to the said Code
- Marketing ethics – it has cut the link between sales volume and pay for its sales reps and is working towards removing a potential risk for employees engaging in unethical marketing practices. The new sales force incentive model gives sales staff bonuses based not on the number of prescriptions reported but on their professional medical knowledge and their skills in communicating this.
- GSK strives to provide complete and evidence-based product information to healthcare professionals and consumers. Most of its products include information about the key ingredients or composition of the items including its generic name

CORPORATE SOCIAL RESPONSIBILITY
- Corporate Social Responsibility (CSR) is seen an investment in the social asset of the country, and is an integral part of the ethos of the Company
- Focus is on access to healthcare; affordable healthcare, awareness regarding healthcare, promoting education related to healthcare and employment and vocational skills building related to the field of healthcare
- In 2015-16 Rs. 14.70 crore was on CSR
Detailed Case Study

1. Background

GSK India works towards providing medicines that improve people’s quality of life and truly make a difference to patients. It aims at leveraging the power of science through new innovations in both preventive and curative healthcare and provide sustainable and effective healthcare solutions. Over the years, GSK Pharma India has forayed into diverse segments, creating products people value, making them widely accessible and operating efficiently. In India, they have developed a broad range of innovative products in three primary areas - Pharmaceuticals, Vaccines and Consumer Healthcare and this critical success factors for the company.

Pharmaceuticals: GSK India is one of the leading pharmaceutical companies in the country today. They have a consolidated position in the therapy areas where GSK provides healthcare solutions to patients, with a wide range of prescription medicines across areas covering anti-infectives, dermatology, gynaecology, diabetes, oncology, cardiovascular disease and respiratory diseases.

Vaccines: GSK’s vaccines business is one of the largest in the world, producing paediatric and adult vaccines against a range of infectious diseases. In the area of preventive healthcare, GSK continues to be the No. 1 vaccines company in the private vaccines market in India. Their global vaccines portfolio includes products that help fight some of the most critical diseases like pneumococcal disease, meningitis, hepatitis, rotavirus, whooping cough, small pox and influenza.

Consumer Healthcare: GSK’s portfolio includes products that aim at promoting healthy living through consumer products. Some of the products include Horlicks, Boost, Sensodyne, etc.

GSK in news

POSITIVE STORIES:
- Pricing Policy: As the government in India, is working towards dismantling the drug pricing regulator, NPPA, and delinking price control from essential medicines, GSK has been lobbying to ensure that “sensible pricing” policy is followed to ensure that people get access to decent healthcare.
- Digitisation: GSK is one of the frontrunner pharmaceutical companies currently involved in digitisation to gear up for the introduction of the proposed uniform code of pharmaceutical marketing practices. The company reportedly plans to develop apps for providing information about various ailments. Digitisation will enable the companies provide product information and create awareness for the benefit of the end users.

NEGATIVE STORIES:
- Unethical Clinical Trials: In February 2017 GSK came under scanner for unethically conducting trials under Bill and Melinda Gates Foundation’s vaccination campaign on tens of thousands of young girls throughout India back in 2009-2010 for its vaccines for cervical cancer. The vaccines in question are Cervarix by GlaxoSmithKline (GSK), which are marketed as protecting against the human papillomavirus (HPV), which is claimed to have a link to cervical cancer. The vaccines come with extreme side effects, and evidence shows that GSK essentially teamed up with the Gates Foundation to take advantage of young Indian girls and use them as human guinea pigs in

trials of the vaccine. According to reports these trials resulted in thousands of injuries and hundreds of deaths that were eventually traced back to the vaccine.\textsuperscript{35}

- **Substandard Drugs**: GSK along with 17 other Drug manufacturing companies have come under scanner in the recent times for “substandard” quality of its products, citing grounds such as false labelling, wrong quantity of ingredients, discoloration, moisture formation, failing dissolution test and failing disintegration test. Its worm infection drug Zentel, worm infection drug and Phexin, an antibiotic used to treat respiratory infections, which has been tested by drug regulators of Maharashtra, Karnataka, West Bengal, Goa, Gujarat, Kerala and Andhra Pradesh, were found deficient in one or more count. While Zentel, was found to be substandard, Phexin, which records an annual sale of Rs. 71.22 crore was reported having wrong quality of key ingredient, Cephalexin (present only 63% in the drug). The company has challenged this report citing reasons including incorrect testing methodology and no “labelling requirement” as drug batch was meant for the World Health Organisation.\textsuperscript{36}

- **Advertisements**: On October 216, ASCI banned 98 advertisements for being misleading and miscommunicating consumers. Of the 98, 2 belong to that of GSK Consumers Limited\textsuperscript{37}. These two include:
  1. *GlaxoSmithKline Consumer Healthcare Ltd. (Horlicks)*: The advertisement’s claims, “Horlicks now has two times higher immune-nutrients, that helps support your child’s immunity and make him taller, stronger, sharper”, “Strong inside. Taller, Stronger, Sharper outside”, were inadequately substantiated (in the context of immunity related claims) and are misleading by implication of enhancement of immunity. The advertisement was also misleading by ambiguity and omission of clear demarcation of two separate disclaimers for two distinct claims.
  2. *GlaxoSmithKline Consumer Healthcare Ltd. (Horlicks Growth)*: It was observed that the advertisement uses the word “naturally” (“New Horlicks Growth+ naturally enhances bone growth*......”) and “Naturally” implies “Natural” growth without any artificial inputs. The use of this word “naturally” for an artificially composed drink supplemented in overall food intake is likely to mislead the consumers by ambiguity.

- **Trading Violation**: In June 2015 the Competition Commission of India ordered GlaxoSmithKline Pharmaceuticals Ltd. and Sanofi SA to pay nearly $10 million in fines for colluding in 2011 in their bidding practices for supplying a meningitis vaccine to the government for use among approximately 200,000 pilgrims going to visit Mecca, Saudi Arabia. The companies violated India’s Competition Act by acting as a cartel for supplying the vaccine to the government and by mutually agreeing both to quote higher prices and to share in the total tendered quantity.

## 2. Responsible Business

In its Business Responsibility Report, 2015-2016 it gives description of policies on the basis of nine NVG principles as below:

<table>
<thead>
<tr>
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</tr>
</thead>
<tbody>
<tr>
<td>Principle 2: Product Responsibility</td>
<td>Yes</td>
<td>Yes</td>
<td></td>
<td>Yes</td>
</tr>
<tr>
<td>Principle 3: Well being of workers</td>
<td>Yes</td>
<td>No</td>
<td></td>
<td>Yes</td>
</tr>
<tr>
<td>Principle 4: Stakeholder Engagement</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
</tbody>
</table>

\textsuperscript{35} http://medicine.news/2017-02-14-india-tosses-out-gates-foundation-due-to-conflicts-of-interest-with-big-pharma.html


With regards to principle 9, as on March 31, 2016, from a quality perspective, 44 complaints that were made directly to the company are pending, and GSK’s response is awaited. Investigation is in progress in these cases. As on March 31, 2016, there are 8 consumer complaints pending in different consumer forums.

There are also some policies as detailed in the table below that guide their responsible business practices:

<table>
<thead>
<tr>
<th>Policy</th>
<th>What does it capture</th>
<th>Who does it apply to</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 GSK Code of Conduct</td>
<td>Our Code of Conduct embodies the Spirit of GSK and brings together a number of company policy principles. It provides a working guide for the way in which we should apply our values across all our business practices and working styles.</td>
<td>GSK Employees, the Complementary Workforce (consisting of Agency Workers, Statement of Work (SOW) Workers, and Outsourced Workers) and Suppliers,</td>
</tr>
<tr>
<td>2 Global Code of Practice for Promotion and Customer Interactions</td>
<td>This code provides our global standards for promoting prescription medicines and vaccines (referred to as medicines in this code) and engaging about our science and our prescription medicines in a non-promotional manner. It applies to Vaccines and Pharma (including Pharma R&amp;D). It excludes ViiV Healthcare and Consumer Healthcare who have separate codes.</td>
<td>GSK Staff, Medical officers, managers, business development department, heads of various units and business owners engaging with the firm including suppliers, consultants, market research agencies, advertising agencies, medical communication agencies, and public relations agencies</td>
</tr>
<tr>
<td>3 Anti-Bribery and Corruption (ABAC) Policy</td>
<td>This Policy covers GSK’s general principles and standards on anti-bribery and corruption (ABAC) and maintenance of business documentation and financial records</td>
<td>GSK employees, officers, or third-parties acting for or on behalf of the GSK</td>
</tr>
</tbody>
</table>

### III. UCPMP: Where GSK stands?

#### III.1 Should GSK be expected to comply with UCPMP in any way?
GSK Pharmaceuticals India Limited is not a member of IDMA or any other Medical Association in India, however, being a pharmaceutical company with operations in India, it will be required to adopt the code once it is made mandatory by the government.

#### III.2 Is there a statement on compliance with UCPMP available on its website?
There are no declarations by the company that showcases its compliance with UCPMP.
II.III What relevant policies does it have?
Having been accused of the unethical practice of incentivising doctors for prescribing GSK drugs in the past, GSK has drafted two policies that set out the fundamental principles that the company values and that employees should apply in their daily work. These policies, namely GSK Code of Conduct and Global Code of Practice for Promotion and Customer Interactions, clearly states the policy principles and guidelines that people associated with GSK need to follow for conducting business ethically. It provides information to stakeholders about the various responsible and ethical practices that are in accordance with applicable regulatory and legal requirements. This code is applicable for GSL Staff, Medical officers, managers, business development department, heads of various units and business owners engaging with the firm including suppliers, consultants, market research agencies, advertising agencies, medical communication agencies, and public relations agencies.

II.IV Does it recognise any of the principles of UCPMP in any of its company policies?
The Code of Practice and Code of Conduct quite adequately captures most of the critical aspects stated in the UCPMP, however, it does not include any reference to the said Code. It has in most cases provided adequate safeguards to ensure ethical practices by its staff and people it engages with. The documents are universal in nature and applicable to all GSK subsidiaries, with enough space to adaptation and modification as per local laws. The code also clarifies that “Local laws, regulations and applicable industry codes are followed (where local or regional industry codes do not exist the IFPMA Code of Practice is applicable). In addition to these local standards, the global requirements provided in this code are followed unless a stricter approach is adopted due to:
- Local, regional or business unit specific GSK standards or restrictions.
- Local laws, regulations or applicable industry codes.

The principles of UCPMP that find mention and adequately covered in the code include;

**Interaction and Engagement with HCPs**
Both Code of Conduct and Global Code of Practice for Promotion and Customer Interactions quite vehemently demonstrate the changing the manner of GSK’s interactions and engagement with HCPs. As of January 2016, GSK stopped payments to the HCPs to speak to other prescribers about company prescription medicines and vaccines. With regard to prescribing medicines to patients the Code of Practices states that, “Nothing is offered or provided in a way that has an inappropriate influence on the recommendation, prescription, purchase, supply, dispensing or administration of our medicines”. The code states that ‘Gifts for the personal benefit of HCPs/OHS are not permitted. Provision of cash or cash equivalents as gifts is prohibited. Except for the items expressly permitted in this code no gift, benefit in kind, or financial advantage may be offered or given to HCPs/OHS’. Even with regard to gifting courtesy items, the code quite adequately states that cultural courtesy items are not permitted, other than by exception in some countries in EMAP and Japan where it is considered respectful of local customs and permitted under local laws and regulations and provided it is done in a fully transparent way. And even in these cases, it should be documented and approved by the local or area Risk Management and Compliance Board (RMCB) with the rationale for respecting the relevant holiday(s), together with the permitted frequency and cost limits (minimal/modest and proportionate within the country) for the items. The limits for cultural courtesy items in any country are consistent across business units in that country.

With regard to participation at scientific congresses, GSK provides funding to independent professional bodies who will allocate funding to individuals, thereby working towards cutting down the incentive system for the doctors. The Code of Practice categorically states that GSK does not make payments to HCPs/OHS for speaking about the products of the company with other HCPs/OHS. The code however mentions provision of fees like subsistence, travel costs (e.g. airfare) and accommodation for providing services. These payments are governed by rigorous controls and are
based on fair market value. The code is, however, silent on what can be categorised as medical services, leaving much to interpretation by individuals.

**Promoting marketing values through sales representative and executives**
Under the policy, the company has withdrawn target-linked incentives for its 3,000 strong sales force, and stopped direct payments to doctors for speaking engagements, while also putting in place an "aggressive growth model to get back being one of the fastest growing MNCs in India by 2020". By cutting the link between sales volume and pay for its sales reps, GSK is working towards removing a potential risk for employees engaging in unethical marketing practices. The new sales force incentive model gives sales staff bonuses based not on the number of prescriptions reported but on their professional medical knowledge and their skills in communicating this.

In India, under the 'Patient Focused Selling' programme, the company will evaluate its sales force on scientific knowledge, technical skills and customer evaluations, rather than meeting sales targets. The company is investing in a new-age business model and will leverage digital capability to improve delivery of information to HCPs and doctors. Under the 'Veeva' platform, information will be shared with sales staff in a more systematic and consistent manner.

**Advertising and Promotion**
The code of practice quite comprehensively covers areas with regard to advertising and promotion of medicines through textual and audio visual channels. It covers areas like what information on promotional material, seminars and publication of research works and papers. The code also allows for modification and adaptation of the artwork, illustration or photograph in order to comply with local laws, regulations or applicable industry codes.

**Product Information**
GSK strives to provide complete and evidence-based product information to healthcare professionals and consumers. Most of its products include information about the key ingredients or composition of the items including its generic name. This specific aspect finds mention in the Code of Conduct. The code states that “We can only gain our patients’ and consumers’ respect and trust by focusing on their needs. That means always thinking from their perspective. We must always put their safety first, provide them with clear and up to date information and always promote our products appropriately and ethically. Our values demand that we think about and protect their interests at all times”. The code also states that incase concerns arise about a side effect, adverse reaction, or other potential issue with the effectiveness of a GSK product, the same can be reported Central Safety Department (CSD), or your Local Operating Company (LOC) medical department within 24 hours. The company also states that it provides regular reports and discuss actions with regulatory authorities and takes further actions, which includes modifying prescribing information or patient leaflets, carrying out additional clinical trials, design new studies to further investigate the risk, or withdraw the product from sale or initiate a product recall.

**Product Samples**
The Code of Practices details out the guidelines regarding samples. The code states that samples of medicines, excluding vaccines, in small supplies can be provided to HCPs to familiarise them with a particular medicine and its use in patients, and/or to facilitate patient experience with the medicine. Samples of other medicines can be given to HCPs/OHS authorised to prescribe or supply that medicine provided this meets local laws, regulations, applicable industry codes and any global, regional or local GSK requirements for specific medicines. These are not provided for clinical studies or compassionate use or to address issues of patient access to medicines.
Such supplies should be well-documented and should include information about:
• The rationale for providing samples.
• An approved list of medicines and presentations, which can be offered as samples (pack size are not larger than the smallest presentation available within that country).
• Acceptable volumes
• Duration of sample distribution
• Distribution requirements including storage requirements where needed (e.g. appropriate refrigeration if required, security of samples, inventory management).
• Labelling (each sample is to be marked ‘free product sample – not for resale’ or words to that effect and accompanied by prescribing information or other approved product information).
• Processes to monitor and track sample distributions, enable recall and audit.
These aspects are governed by local and country specific rule and regulations.

II.V Does it support the observance of Indian Medical Council Regulations 2002 in any of its policies?
Being a multinational, GSK has universal policies that are applicable across its subsidiaries in all countries. GSK India also follows the same guidelines to ensure highest degree of medical ethics. While doing so GSK India, does not demonstrate commitment to the Indian Medical Council Regulations 2002 in any of its policies. However, both the codes to ensure that the said guidelines and policies are in tandem and adaptable to the local laws and do not over ride them states that “Code ... sets the GSK minimum standard. If local laws, industry codes or GSK policies set higher standards, the strictest requirement must always be applied. Be aware that additional requirements may also apply if healthcare professionals are government employees.” The robust and comprehensive nature of the policy allows for adaptations and modification of various critical elements like promotions and advertising to suit to context of the country.

II.VI Are there any internal systems and mechanisms to uphold any of the principles of the UCPMP?
GSK has set a comprehensive mechanism to ensure that the code of conduct is not violated and if in any event such violation happens, the same is reported through proper channels. GSK has set up speak up channels or integrity line in areas of its operation to report violation of the policy. Also, the Code of Conduct is supported by Global Ethics and Compliance team. This team is responsible for fostering a positive, ethical work environment as well as providing oversight and guidance to ensure compliance with applicable laws, regulations, and company policies. Any complaints made regarding violation is treated with utmost confidentiality and investigated fairly, cooperate with governments and comply with legal obligations, including discovery in litigation. The Code, while specifying the mechanism also states persons who could be investigated for violation and these include “employees, complementary workers, consultants, vendors, and partners with whom we jointly do business (including co-promote entities)”.

II.VII Are the marketing ethics consistent with that of a socially responsible company?
GSK has a comprehensive and robust policy to ensure ethical practices in its marketing and promotional activities. The Code of Practice for promotion and scientific engagement (prescription medicines) while focusing on the core values of Patient focus, Integrity, Respect for people and Transparency, specifies global standards for promoting prescription medicines and vaccines (referred to as medicines in this code) and engaging about our science and our prescription medicines in a non-promotional manner.

The past history of accusations against GSK for its unethical conduct, especially with regard to payment to doctors, has been a major driving force for drafting of this code in January 2016. The policy quite comprehensively includes critical aspects of UCPMP, without mentioning the same. It states that while setting global standards they are minimum ethical expectations from GSK staff and wherever, stricter laws exists the same maybe adhered to for all practical requirements. The Code

39 https://www.tnwgrc.com/gsk/
provides detailed view of what promotional activities can be undertaken and in what manner, such as content of printed and electronic material, promotional meetings, role of sales representative, sample distribution, etc. It has attempted to explain and address most of the critical areas where ethical concerns may arise, leaving less room for individual interpretation. In terms of compliance, the Code was published in January 2016, therefore reasonable time would need to be given to understand the practicability and application of the code and how it helps to keep a check on unethical practices.

4. Corporate Social Responsibility Reporting

GSK India is a values-based business, which believes that Corporate Social Responsibility (CSR) is an investment in the social asset of the country, and is an integral part of the ethos of the Company. This CSR Policy intends to demonstrate the Company’s commitment to social welfare by creating robust processes and replicable models for delivery of social sector services. The CSR themes for GSK include:

Access to Healthcare including mobile medical clinics and/or static clinics in urban slums and rural areas as well as training of community health workers

Affordability of Healthcare including infrastructure and facility upgradation of healthcare facilities, subsidies for life saving/ life altering treatments and product donations

Awareness regarding healthcare, which includes an awareness building programmes for children on communicable diseases and screening and awareness for major non-communicable diseases

Promoting Education related to Healthcare

Employment enhancing vocational skills related to the field of healthcare

Amount Spent: The Amount spent for CSR for the year 2015-2016 has been Rs.14.70 crores.
Case Story 3: Sun Pharma Laboratories Limited by Shireen Kurian and Pragya Shah

SNAPSHOT

BACKGROUND
Sun Pharma Laboratories Private Limited was incorporated in 1997 in India and after changes in 2012 it became a wholly owned subsidiary of Sun Pharmaceutical Industries Limited. Their total workforce accounted for 14,747 permanent employees

Positive News Stories
- Dilip Shanghvi, promoter of Sun Pharmaceutical Industries received the 2016 US-India Business Council leadership award
- Mr. Dilip Shanghvi received a Padma Shri in 2016 from Government of India
- It received Community Care Award by ASSOCHAM

Negative News Stories
- Pending wages case and unfair labour practices
- FMRAI alleged that Sun Pharma had violated the directions given by the court related to transferring senior medical sales representatives
- USFDA found violations in good manufacturing
- Ethical malpractice: non-compliance of procedures for giving incentives to pharmaceutical firms and this resulted in under assessment of income to the effect of Rs. 228 crore ad Rs. 193 crore in two years

RESPONSIBLE BUSINESS
- Has been reporting their content related to responsible business in a inter-connected manner based on the NVG module since past four years.
- Policies on all nine principles of National Voluntary Guidelines exist but these are not in the public domain
- Grievance mechanisms exist as follows:
  - Sexual harassment: no complaints
  - Human rights violations: no complaints
  - Child labour/bonded labour: no complaints
  - Consumer complaints: does not mention about grievance redress mechanism with regard to consumer complaint neither in their annual report nor in their business responsibility report.

UCPMP
- Despite being the members of three associations IPA,CII,IDMA there has not been any self-declaration nor any statement on compliance with the UCPMP is available on their website
- Whistle blower policy to ensure the highest level of honesty, integrity and ethical behaviour in all its operations
- ‘Fair code of disclosure’ and ‘SPIL global code of conduct’ are quite comprehensive by way of adherence to the UCMPM code
- Product and packaging - no specific or direct reference but mentions ethical advertising with standards of commercial fairness in devising, using and selecting advertisements and trademarks
- Gifts, not in cash, consistent with customary business practice, does not violate laws and cant be construed as a bribe are acceptable
- Global Code of Conduct does not talk about marketing Ethics specifically it however mentions ethical conduct and fair dealing interactions.

CORPORATE SOCIAL RESPONSIBILITY
- The average net profits of the Company for last three financial years is negative and is not obligated to spend on CSR despite which it spent Rs. 11.65 crores
- CSR focus is on serving/ giving back to the community, focus on quality and ensuring sustainability
- Thrust areas are healthcare (mental health, primary health, school health and hygiene, de-addiction); environment (waster management and water conservation), education and livelihoods for youth and women
- The company does not have an impact assessment tool at present but is developing one
Detailed Case Study

1. Background

Sun Pharma Laboratories Limited ("SPLL" or "Company") was incorporated on January 17, 1997 and is a pharmaceutical company with a registered office in Mumbai, Maharashtra. The Company manufactures and markets pharmaceutical products in India. On March 9, 2012, it became a wholly owned subsidiary of Sun Pharmaceutical Industries Limited (SPIL). The Domestic Formulation Undertaking of SPIL was transferred to the Company with effect from March 31, 2012, pursuant to the Scheme of Arrangement between Sun Pharmaceutical Industries Limited and the Company. The shares of the Company are not listed on any of the Stock Exchanges.

As per their disclosure in the Business Responsibility Report for the year 2015-2016, the total workforce accounted for 14747 permanent employees.

Sun Pharma in the News

POSITIVE STORIES:

- Dilip Shanghvi, promoter of Sun Pharmaceutical Industries received the 2016 US -India Business Council leadership award in Washington. He was presented the award at the 40th annual general meeting of the US India Business Council by the visiting Prime Minister. USIBC represents about 350 American companies having footprint in India.40
- Mr. Dilip Shanghvi received the civilian honour of Padma Shri in 2016 by the Government of India
- The company has also been felicitated with Community Care Award by ASSOCHAM and DIANA (Distribution Industry Award for Notable Achievements) Award in the USA.

NEGATIVE STORIES: Sun Pharma has been in negative news as well for the following alleged violations:

- Worker’s Rights: When it comes to the issue of employee well being and workers rights Sun Pharma has had its fair share of controversy. In the past, India’s largest drug maker Sun Pharmaceutical Industries Ltd in its tussle with the FMRAI, had to release the pending wages of 86 employees, who joined Sun Pharma after its merger with Ranbaxy Laboratories Ltd, on the order by the Maharashtra Industrial Court in Mumbai. The FMRAI, the largest grouping of medical sales representatives in the country, had filed a lawsuit against Sun Pharma in June, alleging that the company was indulging in unfair labour practices after it withheld salary and expenses of 86 sales representatives. At the same time, the court also directed India’s largest drug maker to pay the staff and directed the company not to terminate employees without following the due procedure of law.41
- The Federation of Medical and Sales Representatives Associations of India (FMRAI), the largest grouping of medical sales representatives in the country, filed a petition against Sun Pharmaceuticals in the Punjab and Haryana high court. In the petition, FMRAI alleged that Sun Pharma had violated the directions given by the court at the time of the merger approval by transferring senior medical sales representatives of Ranbaxy. The petition also alleged that trainee medical sales representatives, recruited by Ranbaxy Labs, were issued probation letters

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41 http://www.livemint.com/Companies/dp2jW0cYI3yVUGycG3LT1H/Mumbai-court-directs-Sun-Pharma-to-pay-pending-wages-to-86-e.html
as sales executives in an illegal manner. The salary paid to sales executives is much lesser than what is paid to medical sales representatives, FMRAI alleged in the petition.\textsuperscript{42}

- Quality: During an inspection of Sun Pharmaceutical Industries Ltd’s Halol unit in Gujarat last November, the US Food and Drug Administration (USFDA) found lapses in testing methods, quality control processes and other standard operating procedures. USFDA had made nine observations relating to violations of good manufacturing practices in its Form 483 issued to Halol plant following the inspection, but did not reveal details on the nature of the observations. In a copy of the Form 483 seen by Mint, the US regulator said it had found inadequate testing methods, delay in submission of field alert reports for batches of bupropion HCl tablets, inappropriate stability data for drugs, inadequate laboratory control mechanism and laxity in adhering to standard operating procedures.\textsuperscript{43}

- Ethical Malpractices: In 2015, Comptroller and Auditor General came down heavily on the Income Tax department, as the non-compliance of procedures for giving incentives to pharmaceutical firms, including Ranbaxy, Dr Reddy’s and Piramal, resulting in a Rs.1,348.44 crore loss to the exchequer. CAG pointed out in the report containing 246 cases that there was a “deficiency in the system or in the compliance with the laid down provisions involving total tax effect of Rs.1,348.44 crore”.

According to a CAG report, assessing officers (AOS) allowed expenses on freebies and gifts to doctors despite such a practise being illegal. In doing so, the IT department allowed forms to claim benefits on R&D expenses without verification. The public accounts auditor in the assessment report completed during the period from 2010-11 to 2013-14 also pointed out that the I-T Department did not maintain proper data on incentives given to the sector. On the practice of freebies and gifts to doctors, CAG said AOs allowed expenditure on gifts, travel facilities, hospitality, cash or monetary grant despite the practice being prohibited by Medical Council of India, CBDT/judicial pronouncements. CAG in its report said that there were 21 cases in five states in which the AO had allowed expenses which were in nature of freebies given to doctors involving tax effect of Rs.45.43 crore. Citing examples of how due procedures were not followed, the CAG said Ranbaxy Laboratories had claimed weighted deduction on R&D expenditure of Rs.670.8 crore and Rs.645.5 crore for assessment years 2008-09 and 2009-10 respectively. “The claim deduction had been allowed without the confirmation of approved expenditure,” CAG said, adding that it “resulted in under assessment of income to the same extent involving tax effect of Rs.228 crore and Rs.193 crore” for the two assessment years respectively.\textsuperscript{44}

### 2. Responsible Business

As disclosed in their Annual Report they have been reporting their content related to responsible business in a inter-connected manner based on the NVG module since past four years. In its BRR it claims that it has policies for all the nine NVG principles as seen in the table below:

<table>
<thead>
<tr>
<th>Principle</th>
<th>Whether it states it has</th>
<th>Whether it states it has disclosed in</th>
<th>Whether the link</th>
<th>Whether policies are actually</th>
</tr>
</thead>
</table>

\textsuperscript{42} [http://www.livemint.com/Companies/16nb5DovelGsDRVjOofjnM/Petition-against-Sun-Pharma-for-allegedly-violating-merger-n.html](http://www.livemint.com/Companies/16nb5DovelGsDRVjOofjnM/Petition-against-Sun-Pharma-for-allegedly-violating-merger-n.html)

\textsuperscript{43} [http://www.livemint.com/Industry/Lb8feeDFxuIqGsPy8D36uN/USFDA-finds-lapses-in-testing-methods-quality-control-at-Su.html](http://www.livemint.com/Industry/Lb8feeDFxuIqGsPy8D36uN/USFDA-finds-lapses-in-testing-methods-quality-control-at-Su.html)

\textsuperscript{44} [http://www.livemint.com/Politics/Nd6DUBS2Q7TkeUQ37FgmFK/CAG-blames-IT-dept-for-Rs1348-crore-tax-loss-in-pharma-sect.html](http://www.livemint.com/Politics/Nd6DUBS2Q7TkeUQ37FgmFK/CAG-blames-IT-dept-for-Rs1348-crore-tax-loss-in-pharma-sect.html)
Bitter Pill: How Inclined Are Companies to Deliver National Health Policy Outcomes?

<table>
<thead>
<tr>
<th>Principle 1: Business Ethics and Governance</th>
<th>policy?</th>
<th>website?</th>
<th>provided is functional?</th>
<th>available in public domain</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>Copies will be made available on receipt of written request from shareholders</td>
<td>Not applicable</td>
<td>Not available</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Principle 3: Well being of workers</th>
<th>Yes</th>
<th>Same as above</th>
<th>NA</th>
<th>Not available</th>
</tr>
</thead>
<tbody>
<tr>
<td>Principle 5: Human Rights</td>
<td>Yes</td>
<td>Same as above</td>
<td>NA</td>
<td>Not available</td>
</tr>
<tr>
<td>Principle 8: Inclusive growth and Equitable Development</td>
<td>Yes</td>
<td>Same as above</td>
<td>NA</td>
<td>Not available</td>
</tr>
<tr>
<td>Principle 9: Providing value to customer</td>
<td>Yes</td>
<td>Same as above</td>
<td>NA</td>
<td>Not available</td>
</tr>
</tbody>
</table>

IRBI component has not been mentioned in the annual report neither in their business responsibility report.

On the issue of nature of grievance redress mechanism it has stated the following:

**Sexual Harassment:** During the year ended 31st March, 2016, no complaints pertaining to sexual harassment was received by the Company.

**Human Rights Violations:** In its BRR company states that “Not only are we compliant with all the statutory laws and regulations, we have grievance redress mechanisms in place for violations, if any”. During the reporting year, there were no human rights violation complaints, relating either to child, forced and involuntary labour or sexual harassment / discriminatory employment, against the Company.

**Child Labour/Bonded Labour:** In its BRR it has stated that “In the reporting year, there were no human rights violation complaints, relating either to child, forced and involuntary labour or sexual harassment / discriminatory employment, against the Company”.

**Consumer Complaints:** The Company does not mention about grievance redress mechanism with regard to consumer complaint neither in their annual report nor in their business responsibility report.

### 3. UCPMP: Where Sun Pharma stands?

#### II.I Should Sun Pharma be expected to comply with UCPMP in any way?
Sun Pharma is a member of IPA,CII,IDMA which are amongst the eleven association to whom the UCPMP circular was communicated to by the Ministry of Chemicals and Fertilizers. Sun Pharma is expected to provide a self declaration in their website indicating compliance to UCPMP.

#### II.II Is there a statement on compliance with the UCPMP available on their website?
Despite being the members of three associations IPA,CII,IDMA there has not been any self-declaration nor any statement on compliance with the UCPMP is available on their website.

#### II.III What relevant policies does it have?
It has been stated in the annual report of the company that it has “WHISTLE BLOWER POLICY/ VIGIL MECHANISM” to ensure the highest level of honesty, integrity and ethical behaviour in all its operations, the Company has a ‘Whistle Blower Policy’ for Sun Pharmaceutical Industries Limited.
(SPIL) and its Indian subsidiaries and a ‘Global Whistle Blower Policy’ for its Global subsidiaries, in addition to the existing Global Code of Conduct that governs the actions of its employees.

II.IV Does it recognise any of the principles of UCPMP in any of its company policies?
The ‘fair code of disclosure’ and ‘SPIL global code of conduct’ is available on Sun Pharma’s website. The code of conduct of Ranbaxy is also available on the company’s website. The policies are quite comprehensive by way of adhering to the UCPMP code.

i. Product and Packaging: There is no direct mention about product and packaging however the company mentions about ethical advertising. We observe the standards of commercial fairness in devising, using and selecting advertisements and trademarks, so that our products succeed on the strength of their own quality and our own reputation, rather than by imitation, misinformation or piggybacking on the goodwill of our competitors.

ii. Business Interactions:
   a. Gifts and Gratuities: The purpose of business entertainment and gifts in a commercial setting is to create good will and a sound working relationships, not to gain unfair advantage with third parties. No personnel must give, offer, promise to offer, or authorize the offer, directly or indirectly (proxy bribing), anything of value (such as money, shares, goods or service), any type of gratuity, kickback, bribe, payoff or advantage (whether in cash or any other form) to government officials, customers, potential customers, foreign officials including officials of any public international organisations which could be regarded as influencing any business decision or to obtain improper advantage, unless it a) is not a cash gift; b) is consistent with customary business practices; c) cannot be construed as a bribe, kickbacks or payoff; and d) does not violate any laws or regulations.
   b. Bribery and Corruption: The Company expects its employees to maintain good relationships based on high professional standards with its customers. An employee is not allowed to accept money, loans or any such benefit or privilege from the customers of the Company that undermine or compromise his position vis-à-vis discharge of his responsibilities and duties towards the Company. The employee shall not make any offer of any gift or entertainment of any value in contravention of any Anti Bribery Law as applicable in any jurisdiction. The Company prohibits any payment of money, gifts or anything of value to any Government officials for influencing any decision in favour of the Company or to obtain business in favour of the Company.

II.V Does it support the observance of Indian Medical Council Regulations 2002 in any of its policies?
Sun Pharma in its Legal Compliance Policy states that Sun Pharmaceutical Industries Ltd. (“SPIL” or “Company”) is committed to comply with the provisions of all applicable laws and conducts all business activities lawfully and in a manner that is consistent with SPIL’s compliance obligations.

II.VI Are there any internal systems and mechanisms to uphold any of the principles of the UCPMP?
The Global Code of Conduct provides for provisions monitoring and regulating Ethical Trading and Fair Dealing, Gifts and Gratuities which are some of the core components of UCPMP. The Global Code of conduct also provides for mechanism to redress violation of the code if any.

The code states that “Personnel are responsible for reporting in good faith to the Company any circumstances that they believe may constitute a violation of the Code or any other Company policies. Policy violations should immediately be reported in writing to the Global Human Resources Head or the Compliance Officer(s). Personnel may report violations of the Code using the Company’s Whistle Blower Policy. The Company will investigate any matter so reported and will take appropriate corrective action. All concerns and issues raised shall be treated in a confidential
manner except to the extent necessary to conduct a complete, fair and effective investigation. If Sun Pharma determines that corrective action is necessary to fix a problem and avoid the likelihood of its recurrence, Sun Pharma will promptly decide what steps to take, including legal proceedings when appropriate. Disciplinary Action: To the extent legally permissible under applicable law, appropriate disciplinary action will be taken, in relation to this Code or any related Sun Pharma standard, policy or procedure. Certification: All Personnel must certify, in writing or electronically, that they have received, read, understood and shall abide by this Code. There will be no retribution against an employee for reporting in good faith, policy violations. However, the employee will not be protected from possible disciplinary action if the matter reported is with a malicious intent (bad faith) or if the employee has otherwise engaged in misconduct. Unless authorized by the employee or required by law, the identity of the employee reporting a violation, a concern, or a complaint will not be disclosed. The Company will not retaliate nor tolerate retaliation or victimisation against any Personnel who raises an issue, complaint, or concern in good faith.”

**II.VII Are the marketing ethics consistent with that of a socially responsible company?**
The Global Code of Conduct does not talk about marketing Ethics specifically it however mentions about Ethical conduct and fair dealing. It states that “All Personnel should endeavour to deal honestly, ethically and fairly with the Company’s suppliers, distributors, customers, competitors, agents, independent contractors, consultants and shareholders. Statements regarding the Company’s products and services must not be untrue, misleading, deceptive or fraudulent”.

### 4. Corporate Social Responsibility Reporting

**Amount** The average net profits of the Company for last three financial years is negative, therefore the Company was not required to spend on CSR activities during the previous year. However, the Company has voluntarily spent on CSR activities and the Annual Report on CSR activities. The CSR expenditure for the year 2015-2016 has been Rs.11.65 crores

**CSR Policy**
Drawing from the CSR vision and mission statement of Sun Pharma Laboratories Limited (the Company) the CSR policy has been formulated with the following objectives:

1. Serving the community: Giving back to the community and addressing their needs is a key priority for the Company. The Company believes that the progress of the local community should go hand-in-hand with the growth of the Company. The Company therefore intends to concentrate on the communities immediately around its areas of operation and support their upliftment.
2. Focus on quality: The Company believes in delivering high quality support to meet the needs of the community.
3. Ensuring sustainability: The Company wishes to introduce interventions in the communities that address critical needs and can become sustainable over a period of time.

The key thrust areas activities/programme:

**Healthcare:**
- Psychiatry: mental health,
- Primary Health care services,
- School Health Services,
- Hygiene and Sanitation,
- De-Addiction,
- Diagnosis, Awareness and Treatment for Ophthalmology, Oncology, Epilepsy.

**Environment:**
- Waste Management,
- Water Conservation.
Education:
- School transformation and remedial education.

Livelihood:
- Vocational training to youth, women and Children.

Others:
- Any cause covered under Schedule VII of the Companies Act, 2013.

Impact Assessment: The company does not have an impact assessment tool at present however it mentions in the Business Responsibility report “To enhance productivity and impact, we periodically gather feedback regarding our programmes from beneficiaries, partners and implementers. Development of a formal impact assessment tool is in the pipeline.
Case Story 4: Lupin Ltd by Rohan Preece

Snapshot

BACKGROUND
Lupin Limited, headquartered in Mumbai, is one of the fastest growing generic pharmaceutical companies in the world. It has 28 international subsidiaries in 15 countries. In the financial year 2015-16, Lupin’s consolidated turnover and profit after tax was, respectively, Rs 13.7 crores and Rs 2.2 crore.

Positive News Stories
- 'Top Most Reputed Pharmaceutical Brand' in a study conducted by BlueBytes in 2016
- Entrepreneur of the year at Forbes India leadership awards 2016
- No. 1 biotech and pharma company at Thompson Reuters India Innovation award for research and development

Negative News Stories
- Health Camps: forcible prescription of 13 Lupin drugs at health camps and screening and testing not performed by registered medical practitioner
- Drug Quality: several global drug quality compliance issues over the years including with the United States and Brazil as well as within India

RESPONSIBLE BUSINESS
- Corporate Governance philosophy lays emphasis on timely disclosures, transparent policies, consistent value systems and integrity with a view to maximise long term corporate values and preserving shareholders trust
- Codes of Conduct have been adopted for Directors and Senior Management personnel as also for Independent Directors but not for employees or contract workers
- Whistle-blower policy and Prevention of Workplace Harassment lay down the rules and procedures, by way of which the employees of the Company can report any suspected wrongdoings or fraudulent business practices against any other employee, irrespective of their grade or management level
- 6% of the permanent employees are members of recognised employee associations and over 4,000 contract workers are not covered under this

UCPMP
- No self-declaration by the Executive Head of the company indicating compliance with the UCPMP
- While a Whistle-blower Policy does cover all employees, but since actual employees’ policies are not accessible online it is not possible to say whether there is a specific policy that binds an employee to ensuring that sound and trustworthy product information is displayed
- Product and packaging - no specific or direct reference to ensure that products carry true and accurate information, backed by evidence; there is reference in the Code of Conduct for Senior Management of the need to ensure that “product quality is maintained and process quality parameters are properly adhered to”
- Gifts: policy statement starts out saying that gifts are not acceptable but finishes by saying that they are, and even in volumes greater than Rs 1,000, provided they are reported, and provided that the intention was sound and that the Company did not appear to be compromised in the process.
- Marketing ethics not taken robust/unambiguous steps to cover promotional materials, and business interactions.

CORPORATE SOCIAL RESPONSIBILITY
- Engages mainly through Lupin Human Welfare and Research Foundation (LHWRF) which reaches out to 2.8 million living in 3,500 villages.
- Company had allocated Rs. 54.1 crores on CSR activities, of which a sum of Rs. 20.5 crore was spent
- This was spent largely on natural resource management and economic and social development; infrastructure development; rural industry and skill development; learn and earn programmes and on women’s health, empowerment and education
- Impact measurement: Lupin Foundation initiated GRI4 sustainability reporting; most programmes have their own monitoring mechanisms and they are evolving an internal guideline for monitoring and evaluation at all levels internally
Detailed Case Study

1. Background

Lupin Limited, headquartered in Mumbai, is one of the fastest growing generic pharmaceutical companies in the world. It has 28 International subsidiaries in 15 countries, including South Africa, Brazil and the United States and a joint venture in Japan. It is the 6th largest generic pharmaceutical company globally by market capitalisation. In the financial year 2015-16, Lupin’s consolidated turnover and profit after tax was, respectively, was Rs 13.7 crores (USD 2.09 billion) and Rs 2.2 crore (USD 347 million).

Lupin in the news

**POSITIVE STORIES:**

- In 2016, Lupin was seen as the 'Top Most Reputed Pharmaceutical Brand' in a study conducted by BlueBytes, in association with TRA Research.45
- In 2016, the Entrepreneur of the Year, Forbes Leadership award was given to Ms. Vinita Gupta, CEO and Mr. Nilesh Gupta, MD won the Outstanding Company of the Year, by CNBC TV18
- Lupin was ranked No.1 in the Biotech and Pharma, and No. 4 amongst large organisations in the list of top 100 – Great Place to Work in the Thomson Reuters India Innovation Award for Research & Development

**NEGATIVE STORIES:**

A) Health Camps: In a 2013 camp attended by sales representatives and technicians from four Indian pharma companies, including Lupin, representatives had brought a range of equipment including an electrocardiograph and a bone density scanner and one of the doctors running the camp had been specifically asked to prescribe 13 drugs made by Lupin. As conceded by a sales rep, the camps have a dual purpose: medical, and commercial. While one of the companies had clarified that doctors are free to prescribe whichever drugs they wish to, the doctors in this case would appear to have fallen foul of the Medical Council of India guidelines, which say that “screening and diagnostic tests... can be performed only by [a] registered medical practitioner.” Another issue is conflict of interest as a doctor’s recommendation of a certain drug may be a result from pressure from a particular company, not because it is the right drug. In such a scenario, the patient is at risk of either substandard or even inappropriate treatment. Clearly, doctors must be given all the support they need to work autonomously and scientifically, independent of any commercial pressure, which poses a threat to their freedom and to the integrity of the service they are able to deliver.47

B) Drug Quality: Despite having had some recognition as a reliable brand, Lupin has also been subject to certain quality concerns. The table below details these:

<table>
<thead>
<tr>
<th>Date</th>
<th>Case</th>
</tr>
</thead>
<tbody>
<tr>
<td>March 2016</td>
<td>The Food and Drug Administration (FDA) agency of the US Government observed 9 possible non-compliance issues at Lupin’s Goa plant. A form 483 was issued. According to a letter from a Lupin representative, the observations were on areas “such as inadequacy and adherence to SOPs.” (ref)48</td>
</tr>
</tbody>
</table>

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46 India’s “health camps”: the drug rep will see you now: BMJ 2015; 351 doi: https://doi.org/10.1136/bmj.h6415; Published 02 December 2015
47 A larger issue, of which the demand for such health camps is symptomatic, is the widespread and entrenched privatisation of health care in India. Private companies such as Lupin have been allowed to thrive in the context of massive and historic State neglect of healthcare.
In the light of these concerns that have been raised about the impacts of Lupin’s activities on the integrity of the medical profession and on patient health - due to doubts about drug quality and the quality of manufacturing processes, it is important to explore what kinds of systems the company has in place to ensure ethical practices.

2. Responsible Business

The Company firmly believes that good governance practices stems from a dynamic culture and positive mindset. The Company’s philosophy on Corporate Governance lays emphasis on timely disclosures, transparent policies, consistent value systems and integrity with a view to maximise long term corporate values and preserving shareholders trust. Codes of Conduct have been adopted for Directors and Senior Management personnel as also for Independent Directors. The said Codes have been hosted on the Company’s website (www.lupin.com). The Company is committed to uncompromising integrity in conduct of business and its value systems and ethical principles set the ground rules of the manner in which it interacts with employees and outside world.

Lupin Ltd in its Business Responsibility Report, Annual Report 2015-16 in response to ‘Does the policy relating to ethics, bribery and corruption cover only the Company?’ and ‘Does it extend to the Group/Joint Ventures/Suppliers/ Contractors/NGOs/ Others?’ shared a response but policy information is not in the public domain could not be considered. Whilst this is an omission, two points are relevant:

a) Certain worker-centric policies of Lupin are indeed available publically. Insofar as a policy area is not available publically, or a category of workers is not covered, it therefore raises questions as to the company’s commitment to the given policy area, or its expectations of the given category of workers

b) The majority of Lupin’s stakeholders – the consumers of their products – are outside the company space, and therefore unable to access internal policies. It is from their perspective, and with regard to their interests, that much of this case study is written

The brief analysis below considers three key and to some extent overlapping constituencies in Lupin’s domains of influence: workers, communities, and consumers.

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50. Lupin Ltd appears to have an intranet for its employees containing policy material. This is referred to in the BRR and when clicked it takes the user to the following website: https://remote.lupinworld.com/my.policy. Access to the website is password protected meaning that interested stakeholders outside of the Company are unable to reach it.
Workers: Whilst the Company has adopted codes of conduct for Directors and Senior Management these do not appear to exist for either employees or contract workers, and certainly not for suppliers. The Company has instituted an initiative encompassing three important policies viz. Code of Conduct, Whistle-blower Policy and Prevention of Workplace Harassment (which includes ‘The Sexual Harassment of Women at the Workplace’ (Prevention, Prohibition and Redressal) Act and Rules, 2013). The said policies lay down the rules and procedures, by way of which the employees of the Company can report any suspected wrongdoings or fraudulent business practices against any other employee, irrespective of their grade or management level. The policy states “all complaints received from employees are dealt with seriously and responded to in a prompt and professional manner by the Office of the Ombudsperson.”

Collective bargaining and other rights related to unionisation would appear to elude most of the Company’s employees, as only 6% of the permanent employees are members of recognised employee associations. The over 4,000 contract workers are obviously not covered under this area.

Lupin’s extent of engagement with human rights in relation to its workers and suppliers is a cause for concern; whilst the Company states that it “does not hire child labour, forced labour or involuntary labour” and “never discriminates between its employees” there is no evidence that it conducts any due diligence with respect to its suppliers, either to identify groups at risk, or to ascertain human rights issues that may arise within its supply chains. The table below summarises its policies on principles of labour rights and human rights in the workplace:

<table>
<thead>
<tr>
<th>Principle</th>
<th>Whether it states it has policy?</th>
<th>Whether it states it has disclosed in website?</th>
<th>Whether the link provided is functional?</th>
<th>Whether policies are actually available in public domain?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Principle 3 Employee well-being</td>
<td>Y</td>
<td>Y</td>
<td>N</td>
<td>N</td>
</tr>
<tr>
<td>Principle 5 Human Rights</td>
<td>Y/N</td>
<td>Y</td>
<td>Generic link only</td>
<td>Partial (in relation to workspace only)</td>
</tr>
</tbody>
</table>

Communities: Another inextricable dimension of a Company’s commitments to human rights lies in its attitude towards local communities. Broadly, there are two kinds of groups here: the first are those who are directly affected by Lupin’s core business operations, such as those who live in the vicinity of a Lupin factory; and the second include those who are targeted by Lupin as part of its CSR community development initiatives (now within the mandate of the 2013 Companies Act).

With regard to the first group, the only evidence of a commitment to this group came in the form of the Company’s environmental procedures. Lupin says that it conducts environmental impact assessments, which are important given the potential hazards that local communities can face due to pollution from factories. However, the fact that the company did not refer to local communities in its response to questions on human rights suggests that it has not fully committed itself to a consideration of just how their human rights can be threatened by Lupin’s operations, both directly and as a result of environmental violations. The absence of a public commitment to a grievance redressal mechanism that local stakeholders can access also creates potential for serious human rights oversights. The table details human rights amongst local communities with whom the Company interacts.

<table>
<thead>
<tr>
<th>Principle</th>
<th>Whether it states it has policy?</th>
<th>Whether it states it has disclosed in website?</th>
<th>Whether the link provided is functional?</th>
<th>Whether policies are actually available in public domain?</th>
</tr>
</thead>
</table>

|
More encouraging is Lupin’s reference to a recent initiative to report on the impact assessments of its community programmes using the GRI framework, as well as the reference to conducting impact assessments of its CSR initiatives through collection of qualitative feedback from project beneficiaries. We are also told that there are efforts in place to “establish a robust internal monitoring and evaluation system.” This is all very laudable, though we are entitled to enquire why comparable systems appear not to have been put in place for local communities impacted by Lupin’s operations or in relation to many of its own workers.

Consumers: Doctors and Patients: As flagged in the previous section, the Company has had a potential negative impact on the integrity of the medical profession and, most fundamentally, on the end users of a company’s products – the patients. In this regard it is notable that Lupin actually appears to regard doctors, but not patients, as critical stakeholders, since it reported\(^{51}\) having conducted consumer satisfaction surveys at doctor level but not at patient level. When commenting on engagement with vulnerable and marginalised stakeholders, the Company referred to various community development activities through CSR, such as free health camps, so clearly there is extensive direct engagement of Lupin with patients, some or many of whom are likely to be socio-economically disadvantaged. This then raises the question of why Lupin has not conducted consumer satisfaction surveys at patient level on these occasions, since they, not the doctors, are the actual consumers of the medicine the Company manufactures.

A twin area of concern, alluded to above, is the fact that the Company Codes of Conduct do not actually embrace the vast majority of Lupin workers. Applying only to Senior Management, Directors and Independent Directors, the rest of the Company’s employees and other categories of workers appear outside the scope of any formal system of accountability towards either medical professionals or patients. It is these very Codes of Conduct that govern, for example, gift-giving and other kinds of bribery. The table below details Commitments to consumers: medical professionals and patients

<table>
<thead>
<tr>
<th>Principle</th>
<th>Whether it states it has policy?</th>
<th>Whether it states it has disclosed in website?</th>
<th>Whether the link provided is functional?</th>
<th>Whether policies are actually available in public domain?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Principle 1: Ethics and Transparency</td>
<td>Y</td>
<td>Y</td>
<td>Generic link only</td>
<td>Yes</td>
</tr>
<tr>
<td>Principle 2: Product Responsibility</td>
<td>Y</td>
<td>Y</td>
<td>N</td>
<td>N</td>
</tr>
<tr>
<td>Principle 9: Customers and consumers</td>
<td>Y</td>
<td>Y</td>
<td>Generic link only</td>
<td></td>
</tr>
</tbody>
</table>

3. UCPMP: Where Lupin stands?

II.I Should Lupin be expected to comply with UCPMP in any way?
Lupin is a member of the Indian Pharmaceutical Alliance (IPA) and the Indian Drugs Manufacturers Association (IDMA), amongst other trade bodies, chambers and associations. Both IPA and IDMA were communicated to by the Ministry of Chemicals and Fertilizers regarding UCPMP in 2012. As such, we would expect Lupin to provide a self-declaration on compliance with UCPMP on its website.

\(^{51}\) Business Responsibility Report
II.II Is there a statement on compliance with UCPMP available on Lupin’s website?
Despite being members of these two Associations, no self-declaration by the Executive Head of the company indicating compliance with the UCPMP was in evidence on the Lupin website.

II.III What relevant policies does Lupin have
While there is a Code of Conduct Senior Management, it does not directly cover Directors, Independent Directors, or employees, and does not apply at all to contract workers. It covers employees and all other workers, including contract workers, through the Whistle-blower Policy, according to which any employee who fails to uphold the Company’s code of conduct or ethic employees are liable to having a complaint registered against them; but as the actual employees’ policies are not accessible online it is not possible to say whether there is a specific policy that binds an employee to ensuring that sound and trustworthy product information is displayed.

II.IV Does Lupin recognise any of the principles of UCPMP in any of its company policies?
Lupin’s recognition of UCPMP principles in terms of product and packaging, and business interactions, are considered below.

i. Product and packaging
There is no specific reference within any of the Codes of Conduct to ensuring that products carry true and accurate information, backed by evidence. However, in the Business Responsibility Report of Lupin, there is a statement, “Company follows all legal statutes with respect to product labelling and displaying of product information.”

In terms of product quality, which is a necessary prerequisite of appropriate packaging, there is reference in the Code of Conduct for Senior Management of the need to ensure that “product quality is maintained and process quality parameters are properly adhered to” by the concerned officials of the Company.

ii. Business Interactions
a. Gifts
Senior Management will not offer, give or receive gifts from/to persons or entities that deal with the Company in those cases where any such gift is being made in order to influence the actions or where acceptance of the gifts could create the appearance of a conflict of interest. In any case, where gifts exceeding about Rs.1000 in value is offered, given or received, the details thereof should be provided to the Compliance Officer, who in turn will make a suitable report to the Managing Director.

- Code of Conduct, Senior Management, Lupin

At first glance, Lupin’s policy on gifts has some commonalities with the position of the UCPMP, although closer reading reveals some substantive differences. Both Senior Management and the Directors of Lupin are instructed that they must not offer or receive gifts to persons in order to influence the actions of the other entity, “or where the gifts could create the appearance of a conflict of interest.” This introduces two important qualifiers to the injunction not to give gifts: (1) that it is acceptable if the intention is not to influence the actions of the other party and (2) that it is acceptable as long as it does not appear to generate a conflict of interest. As intention is difficult if not impossible to prove, and as appearances are typically subjective, it is clear that Lupin’s policy is allowing for the possibility of gift-giving. Any doubt about this is promptly extinguished by the addition of a third qualification, which is that whenever gifts larger than Rs 1,000 are offered, the details should be shared with senior internal authorities. Thus a policy statement that starts out saying that gifts are not acceptable finishes by saying that they are, and even in volumes greater than Rs 1,000, provided they are reported, and provided that the intention was sound and that the Company did not appear to be compromised in the process.
Significantly, perhaps, there is no such condition set on Independent Directors or employees. Senior Management is instructed to “oversee fair dealing by employees and officers” with “customers” and other stakeholders, but this point is neither specific enough to be categorically applicable to the area of gift-giving, nor, by focusing on the supervisory role of Senior Management, does it place the responsibility not to give gifts on the employee herself. Given that one cannot expect Senior Management to constantly supervise a staff of over 16,000, it would appear that the conditions exist for employees to give gifts without fear of the consequences.

Those who work on contract, meanwhile, would appear to be free to give gifts with impunity. Significantly too, there is also no mention within either of these aforementioned Codes of Conduct specifically of healthcare providers amongst the potential recipients of gifts.

b. Bribery and corruption
Lupin’s Codes of Conduct for Senior Management and Directors on bribery and corruption are more categorical, disallowing the offering of “any undue pecuniary or other advantages” in order to further the business. In these strong statements against bribery, these two Codes of Conduct are consistent in spirit both with Clause 6 of the UCPMP (on Gifts) and also with Clause 7 (On Relationship with Healthcare Professionals, which forbids provision of Travel Facilities, Hospitality and Cash or Monetary Grants).

As with the issue of gifts, however, the fact that employees themselves are not specifically enjoined not to indulge in bribery and corruption does raise serious questions as to whether the Company has done all it can to ensure to ensure Compliance with clause 6 and 7 of the UCPMP.

II.V Does Lupin support the observance of Indian Medical Council Regulations 2002 in any of its policies?
There is no specific mention about the observance of provisions of IMCR,2002 however some of the provisions of the code of conduct align to the provisions of IMCR,2002. This includes the clauses on gifts which prohibits offering, giving and receiving of gifts in the Code of Conduct as well as on fair dealing and professionalism.

II.VI Are there any internal systems and mechanisms to uphold any of the principles of the UCPMP?
The Company is committed to uncompromising integrity in conduct of business and its value systems and ethical principles set the ground rules of the manner in which it interacts with employees and the outside world. The Company has instituted an initiative encompassing three important policies viz. Code of Conduct, Whistle-blower Policy and Prevention of Workplace Harassment (which includes ‘The Sexual Harassment of Women at the Workplace’ (Prevention, Prohibition and Redressal) Act and Rules, 2013). The said policies lay down the rules and procedures, by way of which the employees of the Company can report any suspected wrongdoings or fraudulent business practices against any other employee, irrespective of their grade or management level. All complaints received from employees are dealt with seriously and responded to in a prompt and professional manner by the Office of the Ombudsperson.

II.VII Are the marketing ethics of Cipla consistent with that of a socially responsible company?
In its marketing ethics and, therein, commitments to the integrity of the medical profession and ultimately to optimum patient health, Lupin has not taken robust and comprehensive steps either to ensure that key domains of the UCPMP, covering product and packaging, and business interactions, are complied with. In particular, in terms of product packaging, there appears to be very little in the way of specific guidance regarding truthfulness and integrity, which are key hallmarks of social responsibility. Whilst these principles may be well understood within the Company, the fact that
they are not spelt out in relation to packaging inevitably raises questions about the Company’s products.

Most of all, by not ensuring that employees and other workers are directly covered by its own Codes of Conduct, the Company offers hope, but little assurance, of being a socially responsible marketer.

### 4. Corporate Social Responsibility Reporting

**CSR Statement:** The Company is one of the pioneers in the CSR field having been engaged in social welfare activities for over 30 years. It has been implementing its CSR activities mainly through the Lupin Human Welfare and Research Foundation (LHWRF). LHWRF has a well-set implementation mechanism at the grass-root level, with an objective of transforming rural lives. LHWRF reaches out to 2.8 million living in 3,500 villages.

**Amount:** Pursuant to the provisions of Section 135 of the Companies Act, 2013 (‘the Act’) read with Companies (Corporate Social Responsibility Policy) Rules, 2014, during the year, the Company had allocated Rs. 54.1 crores on CSR activities, of which a sum of Rs.20.5 crore was spent

**Thrust Areas:** The key focus of Lupin’s CSR programme is:
- Economic and Social Development and Natural Resource Management
- Rural Infrastructure development at various locations (including areas near the plant locations of the Company)
- Learn and earn programmes with a view to provide opportunities and monetary support to needy students, particularly in small towns and rural areas to enable them to pursue higher studies
- Rural Industry and Skill Development and
- Women’s Health, Empowerment and Education

**Impact Assessment:** During the year under review, Lupin Foundation initiated the GRI 4 sustainability reporting process and the report is awaited. The Company conducts impact assessments of its CSR initiatives through qualitative feedback collected from the beneficiaries of the projects undertaken. Various projects are undertaken in partnership with government as well as quasi-government agencies that have their own monitoring mechanisms and impact assessment systems. Efforts are on to establish a robust internal Monitoring & Evaluation (M&E) system. This year the Company developed guidelines for effective M&E process at all the levels internally.
Case Story 5: Cipla by Krishnamoorthy Perumal

Snapshot

**BACKGROUND**
Chemical, Industrial & Pharmaceutical Laboratories (CIPLA) is a leading global healthcare company that uses technology and innovation to meet everyday needs of all patients. It was incorporated in 1935 and now boasts of annual turnover of about USD 2 Billion of which India contributes 40%.

<table>
<thead>
<tr>
<th>Positive News Stories</th>
<th>Negative News Stories</th>
</tr>
</thead>
<tbody>
<tr>
<td>nominee at Pharma Leaders 2016</td>
<td>Workers: Protests in Kashmir, ill-treatment and delayed wages</td>
</tr>
<tr>
<td>Sir P C Ray Award for inhouse technology for indigenous medicine products</td>
<td>Consumer Court: Fines for overcharging</td>
</tr>
<tr>
<td>Forbes Asia's Best Company Under a Billion Company List from Forbes Magazine.</td>
<td><strong>Ethical Malpractices</strong>: poor quality medicines and non-compliance to manufacturing norms; data integrity violations; patent infringement</td>
</tr>
<tr>
<td>Recognised by Fortune magazine in a list of global firms changing the world for the good</td>
<td></td>
</tr>
</tbody>
</table>

**RESPONSIBLE BUSINESS**
- Cipla has submitted BRRs for four years since 2012-12.
- Policies on all nine principles of National Voluntary Guidelines Exist
- **Grievance mechanisms exist as follows:**
  - **Sexual harassment:** A total of 14 cases were reported and 2 under investigation at the end of the year
  - **Human rights violations:** no complaints made in 2014-15
  - **Child labour/bonded labour:** it does not employ child labour as of 2014-15
  - **Consumer complaints:** There were 988 complaints received in 2014-15 of which only 15 are pending at the end of the financial year

**UCPMP**
- No self-declaration by the Executive Head of the company indicating compliance with the UCPMP
- Vigil Policy - serves as a mechanism for its directors and employees to report genuine concerns about unethical behaviour, actual or suspected fraud or violation of the Code of Conduct without fear of reprisal. Also provides for direct access to the Chairman of the Audit Committee in appropriate and exceptional cases. Nature of unethical behaviour, actual or suspected fraud or violation of the Code of Conduct not fully explained
- **Product and packaging** - no specific or direct reference to ensure that products carry true and accurate information, backed by evidence; **Gifts**, not intended or perceived to obtain business and uncompetitive favours, are acceptable
- Marketing ethics not taken robust/unambiguous steps to cover promotional materials, and business interactions.

**CORPORATE SOCIAL RESPONSIBILITY**
- Spent 20.6 crores, out of which 13.95 crores spent of health, Rs 2.95 crores for education and 0.15 crores for environment whereas in the BRR Report 2014-15 it says that it has environment policy as per the requirement of ISO 14001 but spending under CSR is negligible. It also spent Rs 0.61 crores for skill development and 0.29 crores for community development.
- CSR policy guided by ‘Caring for Life’, which has been at the forefront of Cipla’s business philosophy and remains the principal purpose of doing business.
- Initiatives taken by the Company as part of CSR programmes effectively contribute to developing a sustainable and resilient community and are across five broad thematic areas
- Over the last three decades, the Company has carried out various CSR activities directly and through its trusts.
Detailed Case Study

1. Background

Chemical, Industrial & Pharmaceutical Laboratories, now known as Cipla, is a global pharmaceutical company with a registered office in Mumbai, and a goal to ensure that no patient shall be denied access to high quality & affordable medicine and support. Cipla’s mission is to be a leading global healthcare company, which uses technology and innovation to meet everyday needs of all patients. It was incorporated in the year 1935, has been running successfully ever since and now boasts of annual turnover of about USD 2 Billion. Cipla has a total of 24,034 employees with over half (13,003) contractual employees and 2,663 women permanent employees as per the 2015-16 Business Responsibility Report.

The India business contributed to 40 per cent in the overall revenue of the company. It has been listed in the Bombay Stock Exchange (BSE Limited) and National Stock Exchange (NSE) of India Limited and Global Depository Receipts: Luxembourg Stock Exchange. It has a presence in over 100 countries, produces over 1,000 products across various therapeutic categories, with 50+ dosage forms. The average net profit for the last three years is Rs 17,98.89 crores, out of which Rs 35.8 crore have been allocated for CSR in 2015-2016.

Cipla in the news

POSITIVE STORIES: Cipla has been in news for the following awards for recognition or achievement for developing indigenous generic medicines and innovations.

- Top Pharma Company Cipla, is one among final nominees at Pharma Leaders 2016:Investments, merger and acquisitions - Cipla Limited plans to invest around Rs. 600 crore (US$ 90 million) to set up a biosimilar manufacturing facility in South Africa for making affordable cancer drugs and growing its presence in the market. Cipla Ltd, one of the major pharmaceutical and biotechnology companies in India, has acquired two US-based generic drug makers, InvaGen Pharmaceuticals Inc. and Exelan Pharmaceuticals Inc., for US$ 550 million, which is expected to strengthen Cipla’s US business.

- Sir P C Ray Award for developing in-house technology for indigenous medicine products.

- Forbes Asia’s Best Company Under a Billion Company List from Forbes Magazine.

- Cipla also won the Most Profitable Company overall among those companies under a Billion in the Region from Top 200 Small and Mid -Size companies from Forbes Magazine

- Cipla Bags Express Pharma Pulse Award-after supplying AIDS-combating drugs to HIV-ravaged African countries at a fraction of the price at which other multinational pharma companies supplied the drug. Moreover, the award has come at a time when Cipla’s name has been included as the only generic manufacturer for supplying of AIDS/HIV drugs to the United Nations’ agencies.

- Cipla Quality Chemical Industries Ltd (QCIL) emerged as the winner in the biggest category of Transformational Business of the year in the 2012 Africa Awards for Entrepreneurship. The function was dubbed ‘Africa’s Oscars of Business.

- Cipla has been recognised by Fortune magazine in a list of global firms changing the world for the good and having a positive social impact through their activities.

NEGATIVE STORIES: In the last few years, Cipla has been in news for the following kinds of alleged violations as well:

(A) Workers: Dozens of employees of Cipla Limited, staged a protest against the company’s ill treatment with its field employees in Kashmir. The protesting employees alleged that the company

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was violating labour laws by not releasing salary on time and offered no other privileges while carrying its trade in Kashmir province. “Cipla Ltd, runs only a franchise, we want ethical operation of company in the Valley,” Tahir Ahmad Maqdoomi, President Kashmir Field Force of Cipla said. He alleged that despite the tall claims of Government for boasting of private sector in the state, the companies were violating its norms while operating in the state53.

(B) Consumer Court: Even as a Supreme Court ruling is pending on a drug price overcharging case involving drug maker Cipla Ltd the country’s drugs price regulator national pharmaceutical pricing authority or NPPA has asked the company to pay up a fresh penalty of Rs 27.30 crore on new charges of price rule violation. This is the second notice that NPPA is serving on Cipla for alleged drug price control norms violation in the last nine months; it was fined Rs748 crore in April 2007. Cipla is contesting that claim too54.

Cipla’s DPCO 1995 Overcharging Case: The Supreme Court delivered a Judgment in DPCO 1995 in the overcharging cases of Cipla. This judgment may not have any direct implications for the industry (as the price-fixation notifications are fixed under DPCO 1995 and the issues were restricted to Conversion Charges and Packaging Cost norms which were a part of the cost based pricing system), however it would have ramifications in setting a judicial trend with respect to challenging a price-fixation notification. The Supreme Court has observed that High Courts must be circumspect while granting interim orders in price fixation cases.

Pharmaceutical companies are gearing up to challenge the Centre’s populist move to slash prices of essential medicines through the new drug pricing policy. According to sources, drug makers Cipla and Alembic have approached the Delhi High Court and Gujarat High Court, respectively, challenging the provisions of the new Drug Price Control Order (DPCO), 2013, notified by the government55.

Cipla Ltd. was also fined 24 crores for over pricing the Cipro injections and 81 crores for Ciplox.

(D) Drug quality and Ethical Malpractices

In a drug overcharging case, the Supreme Court directed Cipla to pay Rs 175.07 crores in a case related to alleged overcharging in certain drugs as per the provisions of Drug( Price Control Order), 199556. The Drug Controller General of India has launched inspections against Cipla and 200 other drug companies for allegedly selling poor quality medicines and non-compliance to manufacturing norms57.

The FDA found nine deviations in Cipla’s manufacturing processes during an inspection of its plant in Bangalore, in 2009. It is a very old case. FDA issues warning letter to Actavis regarding violations at a US58.

There is an accusation that Cipla is infringing Roche’s patent in a lung cancer drug, according to Delhi High Court. It refused to issue any injunction against Cipla restraining it from manufacturing the medicine, after observing that the life of the patent granted to Roche was ending in March 2016. The Delhi high court held that Cipla was infringing on the Swiss pharmaceutical company Hoffman-La Roche’s patent in lung cancer drug erlotinib hydrochloride, sold under the name of Tarceva. In a

53. www.dailyexcelsior.com/cipla-pharma-employees-stage-protests
54. http://www.livemint.com/Companies/M2FnmNOUJqgHA1gP0yhuQuI/Cipla-gets-fresh-notice-on-drug-price-violation.html
setback to the Indian drug major, a division bench of Justices Pradeep Nandrajog and Mukta Gupta ruled in favour of Roche after noting that Cipla's lung cancer medicine, Erlocip, was one polymorphic form of the erlotinib hydrochloride compound, which may exist in several forms, and Roche's patent claim was not limited to any one such version.\(^5^9\)

According to EvaluatePharma, based on the forecast for the 500 leading pharmaceutical and biotechnology companies, the market for prescription drugs is expected to grow 6.1 per cent over 2015–22 and drug sales are expected to thus reach USD1.1 trillion by 2022. The Indian pharmaceutical sector is estimated at USD39.5 billion (including exports) as of 2015–16. It is in this context of growth, issues of quality have surfaced against Cipla. NPPA (National Pharmaceutical Pricing Authority) has fined Cipla, Ranbaxy and Dr Reddy's Laboratories as many as 871 times in the last seventeen years.

Cipla’s four different medicines — Fixobact, Ciploric, Omecip D and Dilvas — were alleged to be substandard by the drug regulators of West Bengal, Andhra Pradesh, Gujarat and Kerala respectively.

### 2. Responsible Business

Based on the National Voluntary Guidelines, the top 100 companies must submit their Business Responsibility Reports (BRR). Cipla has submitted BRRs for four years since 2012-12.

**Policies on NVG principles**

In BRR 2014-15, it claims, it has policies on the principles relating to all NVG principles 1-9, and additionally it says that it has an Environment policy as per the requirement of ISO 14001 and on independent assessment, it has plans to conduct these in due course without specifically mentioning the time line. The table below details information that was publically available:

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<thead>
<tr>
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<tbody>
<tr>
<td>Principle 1 - Corporate governance and ethics</td>
<td>yes</td>
<td>yes</td>
<td>yes</td>
<td>Yes Vigil policy has been disclosed</td>
</tr>
<tr>
<td>Principle 3 - Wellbeing of workers</td>
<td>yes</td>
<td>no</td>
<td>no</td>
<td></td>
</tr>
<tr>
<td>Principle 5 - Human rights</td>
<td>yes</td>
<td>no</td>
<td>no</td>
<td></td>
</tr>
<tr>
<td>Principle 8 - Inclusive growth and Equitable Development</td>
<td>yes</td>
<td>Only CSR report as a part of annual report</td>
<td></td>
<td>no</td>
</tr>
<tr>
<td>Principle 9 - Providing value to customer</td>
<td>Yes-SOP</td>
<td>no</td>
<td>no</td>
<td></td>
</tr>
</tbody>
</table>

It also states that all 10 key components of IRBI have been recognized by it.

On the issue of the nature of grievance redressal systems it has, it stated the following:

**Sexual harassment:** A total of 17 cases were reported under the Prevention of Sexual Harassment Policy during FY 14-15, out of which 3 cases were under investigation at the end of financial year.

\(^5^9\) [Link](http://timesofindia.indiatimes.com/business/india-business/Cipla-infringing-Roches-cancer-drug-patent-HC/articleshow/49956000.cms)
**Human rights violations:** In its BRR 2014-2015 it stated Cipla’s philosophy towards respecting human rights and upholding the dignity of every individual associated with the company. It was also stated that no stakeholder complaints pertaining to Human rights entertained in 2014-2015.

**Child labour/bonded labour:** In the Business Responsibility Report 2014-2015 it stated that it does not employ child labour.

**Consumer complaints:** There were 988 complaints received in 2014-2015 of which only 15 are pending at the end of the financial year. These complaints were either on product quality or drug safety (144 cases), of which 12 were pending. A structured customer complaint system is in place and these are referred to the Individual Unit where a CAPA-Corrective Action Preventive Action is generated.

### 3. UCPMP: Where Cipla stands?

**II.I Should Cipla be expected to comply with UCPMP in any way?**
Cipla had quit from its membership of the Indian Pharmaceutical Alliance (IPA) in 2002 due to patenting issues. Cipla is also a member of the Indian Drugs Manufacturers Association (IDMA), amongst other trade bodies, chambers and associations. The Ministry of Chemicals and Fertilizers communicated with both IPA and IDMA regarding voluntary adherence of UCPMP in 2012. Cipla is expected to provide a self-declaration on compliance with UCPMP on its website.

**II.II Is there a statement on compliance with UCPMP available on Cipla’s website?**
Despite being member of Indian Drug Manufacturers Association (IDMA), no self-declaration by the Executive Head of the company indicating compliance with the UCPMP was in evidence on Cipla’s website.

**II.III What relevant policies does Cipla have**
In the Director’s report, it said, “the Company believes in upholding professional integrity and ethical behaviour in the conduct of its business. It claims that to uphold and promote these standards, the Company has formulated a Vigil Policy which serves as a mechanism for its directors and employees to report genuine concerns about unethical behaviour, actual or suspected fraud or violation of the Code of Conduct without fear of reprisal. It also has a Code of Conduct for Directors and Employees.

**II.IV Does Cipla recognise any of the principles of UCPMP in any of its company policies?**
Cipla’s recognition of UCPMP principles in the following areas are considered:

- **i. Product and packaging**
There is no specific or direct reference within the Codes of Conduct and Vigil Policy to ensuring that products carry true and accurate information, backed by evidence.

However, in the Business Responsibility Report of 2015-2016, it says that Cipla shall never engage in any unfair trading practices, irresponsible advertising and anti-competitive behaviour. The company follows properly laid-down guidelines for producing any promotional materials. The Code of Conduct says that all directors and employees of the Company shall at all times ensure compliance with all the relevant laws and regulations affecting operations of the Company. They shall keep abreast of the affairs of the Company and be kept informed of the Company’s compliance with relevant laws, rules and regulations. In the event that the implication of law is not clear, eminent legal counsel whose opinion should be documented must support the course of action chosen. But there is no specific reference to product quality and packaging.
On ethical conduct, all directors and employees shall deal on behalf of the Company with professionalism, honesty, integrity as well as high moral and ethical standards. Such conduct shall be fair and transparent and be perceived to be as such by third parties.

ii. Business Interactions
a. Gifts

| Relationships with Suppliers and Customers: The directors and employees of the Company during the course of interaction with suppliers and customers, shall neither receive nor offer or make, directly and indirectly, any illegal payments, remuneration, gifts, donations or comparable benefits which are intended or perceived to obtain business or uncompetitive favours for the conduct of its business. However, this is not intended to include gifts of customary nature. |

Prima facie, Cipla’s Code of Conduct on Relationships with Suppliers and Customers, specifically on “Directors and employees of the Company during the course of interaction with suppliers and customer shall neither receive nor offer or make directly and indirectly any illegal payments, remuneration, gifts, donations or comparable benefits” perfectly align with the Principles of UCPMP. However, it appears to be with caveat that gifts, which are not intended or perceived to obtain business and uncompetitive favours, can be acceptable. This totally contradicts the principles of UCPMP.

b. Bribery and corruption
This Vigil Policy provides a secure framework to all the directors and employees of Cipla to report genuine concerns about unethical behaviour, actual or suspected fraud or violation of the Code of Conduct by providing for adequate safeguards against victimization of the person making such a report. This Vigil Policy also provides for direct access to the Chairman of the Audit Committee in appropriate and exceptional cases. But what is not unambiguously explained is the nature of unethical behaviour, actual or suspected fraud or violation of the Code of Conduct and none of the above directly corresponding with the UCPMP.

II.V Does Cipla support the observance of Indian Medical Council Regulations 2002 in any of its policies?
Cipla clearly says in the Code of Conduct on Relationships with Suppliers and Customers that the directors and employees of the Company during the course of interaction with suppliers and customers, shall neither receive nor offer or make, directly and indirectly, illegal payments, remuneration, gifts, donations or comparable benefits which are intended or perceived to obtain business or uncompetitive favours for the conduct of its business. However, this is not intended to include gifts of customary nature.

II.VI Are there any internal systems and mechanisms to uphold any of the principles of the UCPMP?
The Vigil policy enables formalisation of the Ethics Committee to make complaints by sending a completed Protected Disclosure Form. It says that “Any Director or Employee who becomes aware of an unethical behaviour, actual or suspected fraud or a violation of the Code, as further mentioned in the Scope of this Policy hereinafter, is encouraged to bring such behaviour, fraud or violation to the Company’s notice by sending a completed Protected Disclosure Form to the Ethics Committee. Protected Disclosures received directly by the Chairman of the Audit Committee may be forwarded to the Ethics Committee for investigation, or he may choose to investigate the matter at his own discretion.

Any Protected Disclosures involving Directors - the senior management, or any member(s) of the Ethics Committee, or any other appropriate and exceptional cases - which any employee believes

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cannot be resolved in accordance with the aforesaid procedure and the Ethics Committee, can be addressed directly to the Chairman of the Audit Committee.

The Vigil Policy of Cipla lists a number of areas such as an unethical behaviour, actual or suspected fraud or a violation of the Code. Though unethical behaviour is corresponding generally with the precise contents of the UCPMP, there is a scope for interpretation of such unethical behaviour.

### Grievance Redressal System of Cipla

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<table>
<thead>
<tr>
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</thead>
<tbody>
<tr>
<td>1.</td>
<td>The Ethics Committee shall maintain a log of all Protected Disclosures received by it and shall report the status of the Protected Disclosures along with the action taken/recommended to the Chairman of the Audit Committee.</td>
</tr>
<tr>
<td>2.</td>
<td>The Chairman of the Audit Committee will place the aforesaid log/report before the Audit Committee on a periodic basis.</td>
</tr>
<tr>
<td>3.</td>
<td>The Audit Committee shall oversee the implementation of this Policy.</td>
</tr>
<tr>
<td>4.</td>
<td>The Audit Committee shall be free to amend this Policy from time to time.</td>
</tr>
</tbody>
</table>

**II.VII Are the marketing ethics of Cipla consistent with that of a socially responsible company?**

In its marketing ethics, Cipla has not taken robust and unambiguous steps either to ensure that key domains of the UCPMP, covering promotional materials, and business interactions, are complied with. It clearly articulates about ethical business as to carry on Cipla’s legacy to provide patients and physicians with a service hallmarked by integrity, quality and care. These are aligning with the UCPMP.

### 4. Corporate Social Responsibility Reporting

**Amount**

The average net profit for the last three years is Rs 1798.89 (crores), out of which Rs 35.8 crores have been allocated for CSR in 2015-2016. Out of CSR, it spent 20.6 crores, out of which 13.95 crores spent of health, Rs 2.95 crores for education and 0.15 crores for environment whereas in the BRR Report 2014-15 it says that it has environment policy as per the requirement of ISO 14001 but spending under CSR is negligible. It also spent Rs 0.61 crores for skill development and 0.29 crores for community development.

**Policy**

Cipla has a CSR policy guided by ‘Caring for Life’, which has been at the forefront of Cipla’s business philosophy and remains the principal purpose of doing business. This philosophy is seamlessly integrated into Cipla’s people, products and processes. The initiatives taken by the Company as part of CSR programmes effectively contribute to developing a sustainable and resilient community. Being a good corporate citizen is an integral part of Cipla’s core values. Over the last three decades, the Company has carried out various CSR activities directly and through its trusts.

Making quality medicines at affordable prices has always been Cipla’s focus. The corporate responsibility vision of Cipla is to achieve the distinction of being acknowledged as an admirable and trusted Company. Sustainable development and creating value for the stakeholders are two missions that will drive the company to realize its corporate responsibility vision which will be built on four strategic pillars of the corporate responsibility framework – ‘safe & quality products at affordable cost’, ‘valuing our people’, ‘helping the environment & sustainability’ and ‘empowering our communities’.

The Key thrust areas Activities/ Programmes
1. Health
- Palliative care for terminally ill patients
- Creating awareness on health
- Improving sanitation
- Providing easy access of medical support to vulnerable communities
- Supporting Cancer/ HIV/ Thalassemia patients
- Mobile Medical Units

2. Education
- Setting-up/ Developing infrastructure for schools
- Arranging training and awareness programmes for adolescents.
- Promoting e-learning
- Enhancing reading culture
- Awarding scholarships for meritorious/ needy students
- Providing vocational skills

3. Address Social Inequalities
- Supporting old age homes
- Supporting orphans and differently abled

4. Environment
- Promoting environmental sustainability
- Promoting conservation of natural resources
- Promoting of Renewable Energy Resources

5. Rural development projects
- Enhancing livelihood
- Undertaking Sustainable Rural Development Projects

6. Others
- Undertaking disaster management
- Supporting NGOs & trusts for conducting various programmes/activities
- Any other permissible activity under Schedule VII of the Act

Impact assessment: Not done
Case Story 6: Dr. Reddy’s by Krishnamoorthy Perumal

SNAPSHOT

BACKGROUND
Dr. Reddy’s Laboratories is an Indian multinational pharmaceutical company based in Hyderabad, Telangana, India. With more than 21,669 employees worldwide and a commercial presence in 26 countries, Dr Reddy’s values the importance of working together with employees, communities and partners to identify issues that matter to all.

<table>
<thead>
<tr>
<th>Positive News Stories</th>
<th>Negative News Stories</th>
</tr>
</thead>
<tbody>
<tr>
<td>4th Most Reputed Pharmaceutical Brand, 2016 as per the report by BlueBytes</td>
<td>Workers: industrial strikes across various locations in Andhra Pradesh for management indifference</td>
</tr>
<tr>
<td>Entered into a strategic collaboration agreement with Turkey-based TR-Pharm</td>
<td>Overpricing: Fined for over pricing their Asthma drug and 871 violations over the last 17 years</td>
</tr>
<tr>
<td>award, recognition or achievement for developing Indigenous generic medicines and innovations</td>
<td>Ethical Malpractices: For oncology formulation facility, repeat warnings from the US drug regulator</td>
</tr>
</tbody>
</table>

RESPONSIBLE BUSINESS
- Dr. Reddy has been regularly submitting sustainability reports since 2004
- Policies on all nine principles of National Voluntary Guidelines Exist
- All 10 components of the India Responsible Business Index have been recognized by Dr Reddy’s.
- It reported zero fatality for two consecutive years
- Grievance mechanisms exist as follows:
  - Sexual harassment: A total of 8 cases were reported in 2014-15 and all cases have been addressed.

UCPMP
- No self-declaration by the Executive Head of the company indicating compliance with the UCPMP
- The Code of Business Conduct and Ethics (COBE) serves as a mechanism for its directors, officers and employees with a commitment to doing the right things, the right way. Dr Reddy’s has unambiguously highlighted a set of values that they must adhere at all times are: Integrity and transparency; safety; quality; productivity; respect for the individual; collaboration and team work and finally sustainability.
- **Product and packaging** - no specific or direct reference to ensure that products carry true and accurate information, backed by evidence; **Gifts**, if not intended or construed as improper, are acceptable. Additionally, if it is legal in countries to give or to offer to give anything of value to influence a person to recommend or to purchase a healthcare product or service, it is acceptable to give or offer.
- Marketing ethics state that false or misleading advertisements or promotion are prohibited and fair dealing with all customers and suppliers will be ensured, relying on the merits of products, services and people - these are aligning with UCPMP.

CORPORATE SOCIAL RESPONSIBILITY
- CSR allocation Rs. 41.88 crore of which it spent Rs. 41.81 crores. Rs.17.8 crore was spent on education; 0.3 crore on health, 0.2 crore on safe drinking water and 0.1 crore on rural development. It also spent Rs 2.12 crores for skill development and 0.1 crores on common CSR activities. The total beneficiaries of CSR were 32,749 persons
- CSR policy guided by the principles of empathy and dynamism, which has enabled Dr Reddy’s to address core needs and widen outreach at a faster pace.
- The key thrust areas include education work in Telengana, livelihoods provision for young adults through skill building and healthcare provision in rural areas
Detailed Case Study

1. Background

Dr. Reddy's Laboratories is an Indian multinational pharmaceutical company based in Hyderabad, Telangana, India. Dr. Reddy's manufactures and markets a wide range of pharmaceuticals in India and overseas. The company has over 190 medications, 60 active pharmaceutical ingredients (APIs) for drug manufacture, diagnostic kits, critical care, and biotechnology products. In 2014, Dr. Reddy Laboratories was listed among 1200 of India's most trusted brands according to the Brand Trust Report 2014, a study conducted by Trust Research Advisory, a brand analytics company. With more than 21,669 employees worldwide and a commercial presence in 26 countries, Dr Reddy's values the importance of working together with employees, communities and partners to identify issues that matter to all.

Dr. Reddy’s in the news

Positive Stories: Dr.Reddy's has been in news for the following award, recognition or achievement for developing Indigenous generic medicines and innovations.

- Dr.Reddy’s Laboratories is India’s 4th Most Reputed Pharmaceutical Brand in 2016 as per the report by Bluebytes. (There were 41 Domestic and 17 International pharmaceutical brands listed in the study by BlueBytes conducted in association with TRA Research (both part of the Comniscient Group) which released ‘India’s Most Reputed Pharmaceutical Brands 2016’)
- Dr Reddy’s Laboratories, has entered into a strategic collaboration agreement with Turkey-based TR-Pharm, to register and subsequently commercialise three biosimilar products in Turkey.61
- Dr. K. Anji Reddy, Founder and Chairman of Dr. Reddy's Laboratories Ltd., has been honoured with the Lifetime Achievement in Health award in the Asian Voice Political & Public Life Awards for 2012 at London for his lifetime commitment to medical research, and improving the lives of others. Voted by a committee of MPs in Britain, this award is an annual event hosted by The Asian Voice, a weekly.
- Other awards include:

<table>
<thead>
<tr>
<th>Award</th>
<th>Division</th>
<th>Awarded By</th>
</tr>
</thead>
<tbody>
<tr>
<td>T USER AWARD 2008</td>
<td>Dr. Reddy’s Pharmaceutical Vertical</td>
<td>NASSCOM-CNBC IT USER AWARDS 2008</td>
</tr>
<tr>
<td>Unichem Generics Supplier for 2008</td>
<td>Dr. Reddy’s UK</td>
<td>Industry’s largest wholesaler / retailer in the UK</td>
</tr>
<tr>
<td>BEST Company in Class with sales under $100 M USD, 2009</td>
<td>Dr. Reddy’s North America Generic Team</td>
<td>HDMA Annual Leadership Forum in Washington DC by its customers</td>
</tr>
<tr>
<td>Five coveted awards, 2009</td>
<td>HR practices - Dr. Reddy’s HR division</td>
<td>World HRD Congress</td>
</tr>
<tr>
<td>Five awards including Overall Excellence Award for Communications Collaterals, 2009</td>
<td>Communications Collaterals - Dr. Reddy’s Corporate Communications -</td>
<td>Annual Public Relations Council of India (PRCI) Corporate Collateral competition</td>
</tr>
<tr>
<td>3 Awards for Best All India House Journal, Websites, Photography, 2009</td>
<td>Communications Collaterals - Dr. Reddy’s Corporate Communications -</td>
<td>Public Relations Society of India (PRSI)</td>
</tr>
<tr>
<td>Best Imperative Content, 2009</td>
<td>Elixir, Dr. Reddy’s house magazine</td>
<td>At the Inaugural edition of In-house Communications Excellence</td>
</tr>
</tbody>
</table>

61. [https://www.ibef.org/industry/pharmaceutical-india.aspx](https://www.ibef.org/industry/pharmaceutical-india.aspx)
Bitter Pill: How Inclined Are Companies to Deliver National Health Policy Outcomes?

<table>
<thead>
<tr>
<th>Prestigious AIF – Annual Spring award, 2009</th>
<th>Visionary leadership in business and philanthropy through Dr. Reddy’s Foundation and Naandi Foundation</th>
<th>American India Foundation (AIF)</th>
</tr>
</thead>
</table>

Negative Stories: In the last few years, Dr Reddy’s has been in news for the following kinds of alleged violations:

A) Workers: An industrial strike in Pydibhimavaram, Andhra Pradesh in November 2011, turned violent when agitating workers tried to forced their way into Dr. Reddy’s Laboratory (DRL) alleging that the management had been indifferent to their problems despite their struggle for the last three months. Police lobbed teargas shells and resorted to a lathi charge to quell the unrest but could not restore normalcy in the vicinity of the factory. Several workers, three constables and reporter of a television news channel, were injured in the tussle and were rushed to the hospital. As many as 10,000 workers of 25 factories in the industrial belt of Etcherla, Ranasthalam and Pydibhimavaram participated in the protest to express solidarity with contract workers and regular staff of DRL.62

600 workers at Srikakulam Plant of Dr Reddy’s laboratories staged a strike for 4 days by shutting production for demanding better wages (August 2011).63

The Directorate of Factories, Andhra Pradesh, has filed a second case against pharma major Dr Reddy’s Laboratories over alleged safety-related lapses at its US FDA-certified manufacturing facilities at Bollaram, in Medak District of Andhra Pradesh. Two persons were charred to death in fire at DRL’s Bollaram plant on 17 March 2011. The fire broke out in the material-handling lift area at G Block in the unit’s API manufacturing facility at around 10 pm.64

B) Overpricing and not following good manufacturing practices: Dr. Reddy’s was fined for over pricing their Asthma drug. NPPA (National Pharmaceutical Pricing Authority) fined Dr Reddy’s, and Dr Reddy’s Laboratories as many as 871 times in the last seventeen years.

Another violation common to most of them was export of sub-standardized medicines to the United States. Dr. Reddy, and Dr Reddy’s are facing charges for not following good manufacturing practices. Some of the products of Dr. Reddy were banned from the US on the basis of contamination of the products or non-adherence of quality of the products. Dr. Reddy’s Laboratories recalled 58,656 bottles of heartburn drug lansoprazole in the United States due to contamination.

C) Tax related: The Comptroller and Auditor General of India (CAG) has pulled up the income tax (I-T) department for giving undue exemption to pharmaceutical companies, including Ranbaxy Laboratories, Dr. Reddy’s Laboratories and Piramal Life Science, which led to a Rs 1,348.44-crore loss to the national exchequer.65

64 http://timesofindia.indiatimes.com/business/india-business/Safety-issue-Case-against-Dr-Reddys/articleshow/8741387.cms
D) Ethical malpractices: The US drug regulator issued the observations for its oncology formulation facility at Duvvuda in Visakhapatnam’s SEZ. The site is important given Dr Reddy’s focus on complex generic filings. The US Food and Drug Administration (FDA) issued 13 observations for its Duvvuda oncology formulation facility. It also reported that the 13 observations received by Dr. Reddy’s for its Duvvada oncology formulations plant from the US FDA on 8 March, 2017 contained some repeat warnings from a letter issued in 2015, indicating the company had failed to resolve the issues.

2. Responsible Business

Dr Reddy’s published their first Safety, Health and Environment (SHE) Report in 2001, and have been regularly publishing Sustainability Reports since 2004. They shared that with the guidance from their senior management, they have gone for third party assurance for our Sustainability Report of FY 2013-15 and they continued to do that in FY 2015-16.

Policies on NVG principles
In BRR 2014-15, it claims, it has policies on the principles relating to all NVG principles 1-9. The table below details information that was publically available:

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<td>Principle 2 – Product cycle</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
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<td>Yes</td>
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<td>No</td>
<td>No</td>
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It also states that all 10 key components of IRBI have been recognized by it.

On the issue of safety it reported zero fatality for two consecutive years.

On the issue of the nature of grievance redressal systems it has, it stated the following:

**Sexual harassment**: Dr Reddy’s prohibits any form of harassment including demeaning, insulting or intimidating remarks or behaviour, related to gender, age, physical or mental disability, religious creed, sexual orientation, racial background, pregnancy, national origin, caste, political affiliation, or regional origin directed at any employee. There are 8 cases have been filed in the year 2014-2015 and all cases have been addressed as per BRR Report NVG principle 3- worker’s wellbeing.

3. UCPMP: Where Dr Reddy’s stands?

It is not clearly mentioned about UCPMP but since Dr Reddy’s membership in OPPI, it has to oblige voluntarily to submit the declaration.

II.I Should Dr Reddy’s be expected to comply with UCPMP in any way?
One would expect Dr Reddy’s to provide a self-declaration on compliance with UCPMP on its website.
II.II Is there a statement on compliance with UCPMP available on Dr Reddy’s website?
Despite being members of Associations, no self-declaration by the Executive Head of the company indicating compliance with the UCPMP was in evidence on the Dr Reddy’s website.

II.III What relevant policies does Dr Reddy’s have?
Dr Reddy’s Laboratories has a Code of Business Conduct and Ethics- COBE and an Ombudsperson Procedure. COBE applies to all Reddy’s Directors, officer and employees, regardless of their position, business affiliation and location.

The CEO G.V. Prasad has clearly articulated in the introduction to the Code of Business Ethics, “as we continue to build our future in an even more demanding regulatory environment, we must continue to uphold the highest ethical standards both in our operations and in our behaviour. But this is not just about compliance, it is more about doing the right things, the right way”. Dr Reddy’s has unambiguously highlighted a set of values that they must adhere to at all times are: Integrity and transparency; safety; quality; productivity; respect for the individual; collaboration and team work and finally sustainability. The code is intended to comply with the ethical provisions but does not mention UCPMP.

II.IV Does Dr Reddy’s recognise any of the principles of UCPMP in any of its company policies?
Dr Reddy’s recognition of UCPMP principles in the following areas are considered:

i. Product and packaging
There is no specific or direct reference within the COBE to ensuring that products carry true and accurate information, backed by evidence.

ii. Business Interactions

a. Gifts
No employee should offer or agree to provide a gift, entertainment, or payment, directly or indirectly, to any party conducting or with which Dr Reddy’s seeking to conduct business if it could be construed as an improper inducement. No employee may offer a gift, entertainment or payment or anything of value in contravention of any applicable anti-bribery legislation or any applicable code of practice. On the face of it, Dr Reddy’s COBE-Code of Business Conduct and Ethics states specifically for employees of the Company conducting or seeking to conduct business that if it could be construed as an improper inducement, it is barred. However, it is vague and one could infer that if it is not to be construed as an improper inducement, it can be allowed. This is contradicting the basic ethics that we articulated in the UCPMP.

b. Bribery and corruption
Dr Reddy’s is committed to dealing fairly with its business partners, relying on the merits of the products, services and people. In dealing with business partners, employees are expected to not show any favour or any preference to any person or business based on anything other than the best interests of Dr Reddy’s.

Policy states that employees must not pay, offer, promise or authorize the payment of money, inducements, or anything of value to Government officials for the purposes of influencing any act or decision of such Government Official in favour of Dr Reddy’s, or inducing Government official to do or omit to do any act in violation of his or her lawful duty in order to obtain or retain business, direct business to any person or to secure any improper advantage to Dr Reddy’s Commitments to business Partners. The COBE says that in some countries, it is illegal to give or to offer to give
anything of value to influence a person to recommend or to purchase a healthcare product or service. Dr. Reddy’s prohibits illegal commercial bribes or kickbacks of any kind. But COBE said that if it is legal in countries to give or to offer to give anything of value to influence a person to recommend or to purchase a healthcare product or service, it is acceptable to give or offer. This is directly not corresponding with the UCPMP.

II.V Does Dr Reddy’s support the observance of Indian Medical Council Regulations 2002 in any of its policies?
Dr Reddy’s clearly says in the COBE that it will strictly adhere to all legal compliance and strives to be a good corporate citizen.

II.VI Are there any internal systems and mechanisms to uphold any of the principles of the UCPMP?
Systems at Reddy’s Laboratories include a Chief Compliance Officer is responsible for overseeing Dr Reddy’s compliance systems and Business Unit Heads and Heads of the Functions of the region, are responsible for implementing the principles. All violations are to be addressed to the Chief Compliance Officer and he/she will report to the Audit Committee through the Chief Ombudsperson.

II.VII Are the marketing ethics of Dr Reddy’s consistent with that of a socially responsible company?
In its marketing ethics, Dr Reddy’s highlighted in the COBE that fair dealing with all customers and suppliers will be ensured, relying on the merits of products, services and people. These are aligning with UCPMP.

4. Corporate Social Responsibility Reporting

Amount
The average net profit of the company is Rs. 20,944,406,795 and prescribed CSR allocation was Rs. 418,888,136 and spent about Rs 418,195,984 on education (Rs.178,188,088), health (Rs.3,969,282), safe drinking water (Rs.1,941,225) and Rural Development (Rs. 1,828,117). Rs. 21,270,000 was allocated for skill development and Rs.134374893 for common CSR activities. The total number of beneficiaries of their CSR programme is 32,749 persons. They have issued a responsibility statement from the CSR committee with regard to the implementation of their CSR policy in compliance with the CSR objective and policy of the company.

Policy
Dr Reddy's has a CSR policy for which 'empathy' and 'dynamism' are the two guiding principles define all their intentions, actions and decisions. While 'empathy' helps them learn about and act upon the needs of the communities, 'dynamism' drives them to seed community interventions with business-like speed, precision, innovation and aggression. This approach enables them to address core needs and widen outreach at a faster pace.

Activities
Key thrust areas Activities/ Programmes/ Projects
1. EDUCATION- supported 12,000 students in Telangana for their education.
2. LIVELIHOODS-secured for 7,000 young adults through skill building
3. HEALTHCARE-service provided to 75,000 villagers

Impact Assessment
Not done
Partners in Change (PiC), a Society registered in 1995 under the Societies Act (1860) to promote responsible business in India, aims to build partnerships with businesses, communities and governments to co-construct policies, practices and narratives that advance responsible financing, sustainable production and consumption and decent work. More information at www.picindia.org

National Foundation for India is an independent grant making and fundraising foundation with a core mandate to strengthen philanthropy in India. NFI was founded in 1992, by a group of eminent leaders including Dr. M S Swaminathan, Mr. Ratan Tata, late Shri C. Subramaniam and late Dr. Kamla Chudhury among others. In the last 20 years, it has supported more than 200 grassroots organizations in 14 states. Its annual fellowships have supported more than 400 individual change makers in the areas of development journalism and community leadership. More at www.nfi.org.in

Praxis – Institute for Participatory Practices is a development support organisation committed to mainstreaming the voices of the poor and marginalised sections of society in the quest for equity and governance. We believe that for development to be sustainable, the process must be truly participative. Praxis engages in participatory research, capacity-building and advocacy to ensure that the most excluded and vulnerable communities have a say in development. More at www.praxisindia.org