Study Report

Dr Arun Gadre
Dr Archana Diwate

Support for Advocacy
and Training to
Health Initiatives

Promotional Practices of the Pharmaceutical Industry and Implementation Status of Related Regulatory Codes in India

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साथी

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List of Abbreviations

WHO	-	World Health Organization
MR	-	Medical Representative
CIMS	-	Current Index of Medical Specialties
FDC	-	Fixed Dose Combinations
IFPMA	-	Federation of Pharmaceutical Manufacturers' Associations
CME	-	Continuous Medical Education
MCI	-	Medical Council of India
OPPI	-	Organization of Pharmaceutical Producers of India
UCPMP	-	Uniform Code for Pharmaceutical Marketing Practices
CAG	-	Citizen, Consumer and Civic Action Group
FMRAI	-	Federation of Medical Representative Association of India
BAMS	-	Bachelor of Ayurvedic Medicine and Surgery
BHMS	-	Bachelor of Homeopathic Medicine and Surgery
RMP	-	Rural Medical Practitioner
PCD	-	Propaganda cum Distribution Companies
MNC	-	Multinational Company

Executive Summary

Over the past decade in India, the Medical Council of India (MCI), pharmaceutical manufacturers and the government have instituted regulatory advisories to medical professionals and pharmaceutical and allied health sector industries for their conduct with the intention to curb unethical promotional practices. These are voluntary codes and anecdotal experience reveals that often these codes are not adhered to.

Taking a clue from the anecdotal experience, SATHI carried out a study with the aim of exploring ground level realities of promotional and marketing practices of the pharma industry and the implementation status of related regulatory codes in India. The study is qualitative in nature, 50 In-depth interviews were conducted with various key informants in six selected cities across the country. The study primarily focused on interviewing medical representatives because they are the ones who are involved as front-line key persons on the actual field to promote drugs to doctors.

The key findings are –

Changing Trends in Promotions Practices-Inducements and New Innovations of Temptations:

- Trends in promotional strategies have changed from providing scientific information to doctors to only focusing on generating business by any means.
- The ethics and values which were followed in the past are getting bypassed to achieve business.
- Tactics like an inducement, emotional appeals, persuasions, serving family members, sponsorships for national and international conferences, pampering doctors, etc. are used as a norm.
- New innovative mechanisms have emerged over the years such as - providing debit cards/credit cards, petro-cards e-vouchers for online purchasing on Amazon and Flipkart.
- Different strategies are used for different categories of doctors. Doctors are categorized as core doctors and secondary doctors, in which core doctors are those who give business to the company. Additional categories include

but not restricted to - specialists, doctors with a good reputation, opinion leaders. The doctors who set the prescription pattern in the field are sought after and looked after well.

- For the pharma company, the doctor's educational background doesn't matter as long as he or she gives business to the company.
- There is no hesitation to promote allopath drugs to the Bachelor of Ayurvedic Medicine and Surgery (BAMS), Bachelor of Homeopathic Medicine and Surgery (BHMS), Rural Medical Practitioners (RMP).
- In order to generate the prescription, the pharma companies conduct direct deals with the doctors.
- Over the years' the competition of companies is rising as anyone could enter the market freely. As a result, me-too drugs, irrational drugs, irrational Fixed Dose Combinations (FDC) are being poured in and hence the pressure on MRs to get business for his/her brand among many other competing ones.
- There is evidence that the roles have reversed now. Earlier Pharma companies used to induce/tempt doctors proactively. Now doctors are in driving seat. They demand and pharma companies succumb.
- Some Doctors who give huge business demand women for entertainment and these demands are met.
- There is influence of these promotional inputs on generating business as MR's clearly pointed out that in their work-experience they had observed that, based upon incentives, prescriptions get generated from the doctor.
- It was also observed that there were instances when despite incentives being provided to the doctors, the doctors did not generate business. The reasons for this were that the doctor could not fulfill or satisfy each company.
- In many deals involving high value offers such as installment on the purchase of a car; the company threatens the doctor of dire consequences if the targeted business is not achieved.
- Most common inducement is sponsoring doctors for national and international conferences.

The Regulatory Failure:

- MCI has laid down mandatory regulatory codes for medical practitioners; in practice they were not being followed. It was revealed by senior MR's that doctors do accept or demand incentives. According to some senior MR's, hardly 10 to 20 percent of doctors follow prescribed ethics.
- It is no wonder that when mandatory

codes from MCI are given a toss, voluntary regulatory codes like Uniform Code for Pharmaceutical Marketing Practices (UCPMP) prescribed by pharma industries are non-functional on the ground.

- It is no surprise that MR's are hardly given any information about regulatory codes in their training. Most of the MR's are not even aware about the regulatory codes.
- There are various ways to circumvent the regulatory codes. For example - appointing the doctor on the advisory board or on a research project of that particular company and thus paying him, offering in-kind like gold ornaments, gold coins; paying for talks by the doctor which never really take place.
- One of the innovative tools that have come in hands is Propaganda cum Distribution Companies (PCD) companies.

The Focus of the Training for MR's has Changed

The nature, duration and content/quality of the training of the MR have changed drastically since the 1990's. The trend shows that earlier the focus was on providing scientific knowledge about the product to MR, now it has shifted to train them to maximize market share through identifying doctor's needs and demands. The training period which used to be one and half month has been reduced to merely 7 to 8 days.

The MRs are Stressed

The working conditions of MR are highly stressful and they have to undergo continued pressure to perform in order to achieve targets. Such pressures from the management have serious implications on the very life of MR's and have led to road accidents and a few cases of suicides.

Patients Suffer from Irrational Practices and Pushing of High-Cost Brands

Promotional practices led to promote excessive, irrational drugs and pushes for high-cost brands. It came out that the drugs are being promoted to non –allopath doctors which are not allowed in practice and has led to prescribing non indicated doses of antibiotics as well as less adherence of the doctors to prescribe a full dose of antibiotics. This has serious implications for patients not only in terms of money, but also for quality of medicines, which are a risk to the life of the patient.

In Nutshell :

What emerges clearly is that the MR-doctor interaction actually involves less of information on new products and more of giving all kinds of gifts to influence, even induce or bribe the doctor to prescribe only

the company's products irrespective of its merits, and not that of any other company. MRs are at the lowest rung in the marketing hierarchy of the pharma industry and are just the medium to implement the strategies formulated and designed by the company. So, the promotional practices have to be placed in the larger context of the goals of the pharma industry. Given that the major activity of the pharma industry is production of medicines for treatment and cure and to keep people healthy, the implications of such promotional practices of the pharma industry and of the industry-physician relationship for the availability and affordability of medicines need to be understood from a larger health systems perspective. Health is a social good and basic right of populations, the means to remain healthy are also social goods and cannot be treated as commodities. Pharma products help cure and save human lives and in keeping them healthy, hence they should be considered as public goods.

The key issues which need to be addressed

The study has revealed the dark underbelly of the greed, competition, irrationality, in the field of medicine and pharmaceutical practices

This study corroborates earlier findings from similar studies and clearly highlights the increased intensity and changing forms of the promotional practices adopted by the pharmaceutical industry. Prominent among the changes is the co-operation and collusion of sections of the medical profession in such practices. This less widely known dark under-belly of irrationality in the field of medicine, driven by the profit-seeking, competitive behavior of the pharma industry raises serious concerns for patient care as well as for medical science and its ethics. Evidently, patients are out of the radar for the pharma manufacturing companies as well as the colluding sections of doctors, who seem least interested in the affordability and the burden of rising drug costs on people, and the effects on people of consumption of unnecessary drugs. Questions also arise over the lack of implementation of existing regulatory mechanisms, however inadequate they may be, and role of the government and the medical profession in such failures.

Would the government, doctors' associations, the pharma associations take these findings seriously? Would a robust regulation be framed that could address the various mechanisms to circumvent the boundaries? We do hope so and appeal for it.

Section I

Introduction, Literature Review and Methodology

Section –I

Introduction, Literature Review and Methodology

It is now an established fact that the health service system in India is dominated by the private sector, with the pharma industry, private medical colleges, private insurance companies and private and corporatized hospitals being major stakeholders in the system. The private health care sector itself is largely unregulated and that leaves scope and space for the pharma industry to collude with the private healthcare sector to promote high-cost branded medicines, push for irrational and un-indicated prescriptions. In the last ten years, policymakers and the Medical Council of India have taken note of the collusion of the pharma industry and private healthcare sector and has come out with voluntary codes to prevent unethical practices. Anecdotal experience is that on the ground often these codes are not adhered to by pharma industries nor by sections of the medical profession.

Hence, the detailed documentation of field level practices by the pharma industry to promote and market their products was taken up. The information and insights from such a study could contribute to regulating activities of the pharma industry as also in generating awareness and discussion among the medical professionals about the promotional activities of pharma manufacturers and their influence on medical care.

Background

Accessibility and Affordability of Medicines

According to the Department of Pharmaceuticals, the $32-billion Indian pharmaceutical industry is expected to touch $85 billion by 2020 (Jacob, 2015) The industry was growing at a rate of 14-15 percent per annum and expected to grow five-fold by 2025 (ibid). India is reported to enjoy an important position in the global pharmaceuticals sector. Leading Indian pharma companies export a substantial amount of medicines also to developed countries (Lofgren, 2012). India's pharmaceutical export stood at the US $16.4 billion in 2016-17 and was expected to grow by 30 percent to reach the US $20 billion by 2020. In short, there is substantial manufacturing capacity in India, and lack of technical capacity or of physical availability

of medicines is not an issue.

India has over 20 thousand drug companies, yet access to medicines and affordability of medicines is an important problem plaguing the health care system in India. According to WHO, almost 65 percent of the people in India have limited or no access to essential medicines. An estimated 649 million people in India lack access to essential medicines (WHO, 2004:63). Further, the cost of medicine accounts for a large share of all out-of-pocket health expenses incurred. At all-India level, around 72 percent in the rural sector and 68 percent in the urban sector of the total medical expenditure was for purchasing medicine for non-hospitalized treatment"(Government of India, 2014a: 42-43). Out of pocket expenditure on medicines has pushed 38 million people into poverty (Selvaraj, Farooqui and Karan, 2018).

On one hand, public health systems fail to provide essential drugs to patients while on the other over one lakh formulations are sold in the private drug market with a rich plethora of "me too" drugs, brands, irrational drugs, irrational fixed-dose combinations which are inappropriate and irrelevant to the public health needs of the country (Bhargava and Kalantri, 2013).

The organisation and activities of the pharmaceutical sector can have implications for what medicines are produced and their rational use, as well as availability, accessibility, affordability of medicines.

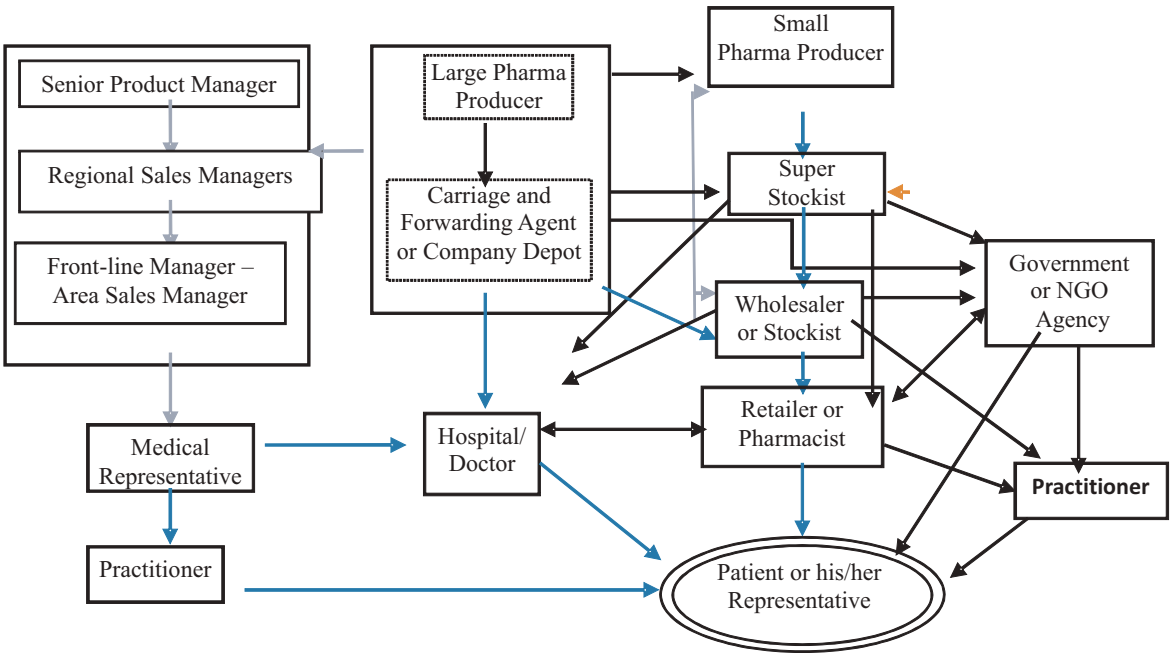
Pharma business is not like any other business

The business of pharma companies differs from that of other industries. Here the customer is not the king, the customer or the patient is not in a situation to choose or decide which medicine they should take.It is the doctor who decides the medicine to be taken by a patient. Hence, for pharma manufacturers creating awareness and promoting medicines amongst doctors is critical for profit generation and long-term survival. Thus, it is not the patients but physicians who are targets of pharmaceutical promotion and marketing, in which pharmaceutical representatives (PRs) or Medical Representatives (MRs) play a crucial role. WHO defines drug promotion as “all informational and persuasive activities by manufacturers, the effect of which is to induce the prescription, supply, purchase and/or use of medicinal drugs” (WHO 1988:5). Pharma manufacturing companies devote large amounts of money on drug promotion, given its importance for their business.

The Medical Representative: pivotal role in pharma promotion

Das and Jeffrey (2009) have identified the following channels for the flow of medicines from the manufacturer to the patient (Fig. 1)

Fig. 1: Channels for flow of Pharmaceuticals from manufacturer to patient in India



From the distribution chain it is obvious that the MR occupies a central role in the distribution channel, through whom the sales and marketing departments of the pharma manufacturer interact with the other key player: namely the medical professional. Every pharmaceutical company employs and trains medical representatives, popularly known as their "field force", to promote and sell drugs, using printed product literatures, drug samples and gifts. Besides the salaries, they also receive incentives for achievement of sales targets, which might tilt the balance in favor of aggressive drug promotion. In India, in 1993 there were an estimated 40,000 medical representatives (Bhatt 1993). According to industry estimates major pharma companies - Ranbaxy, Sun Pharma, Lupin, Dr Reddy's, Cadila, Glenmark - employ 3,000-5,000 MRs in the field, and up to 500 senior executives supervising these MRs, and a little over 60 per cent of a company's total promotional expenses is spent on MRs. Even smaller companies employ 2,000-2,500 MRs (Dey, 2013).

It is MRs who visit physicians to promote their company's products, through practices such as, gifting, drug detailing, providing drug samples, sponsoring Continuing

Medical Education conferences – all these are conveyed to the physician through the MR. While doctors are a major target, the pharmaceutical industry also maintains relationships with the organizations to which physicians belong and for which they work, as well as hospitals in which they work. Companies promote medicines to chemists as well, who are also offered bonuses on brands and hugely discounted prices on commonly used drugs (Roy, Madhiwalla, and Pai, 2007; Bhargava and Kalantri, 2013).

Drug promotion, the interaction between the MR and physician, and its impact on drug prescribing have all been an area of concern in public health, among medical professionals and non-governmental organisations, and hence have been well-studied since the 1960s (Morgan, et al. 2006; Brax, et al. 2017).. The industry invests enormous amounts of money in marketing. According to WHO, in 2017 one-third of the sales revenue of pharmaceutical companies was to be spent on marketing their products (WHO, 2014 as cited in Salmasi, Ming & Khan, 2016).

“Drug promotion has an important bearing on the rational use of drugs, on drug price control mechanisms, the manufacture, availability and use of essential drugs, on equity of drug distribution and the cost of health care all making it a central public health issue” (Roy, 2004:2).Current Index of Medical Specialties (CIMS) lists more than 100 irrational combinations which are not approved in any developed country but are being marketed in India (Gautam and Aditya, 2006). In 2016 the Government of India banned 344 Fixed Dose Combination drugs (FDCs) and issued a notice to the drug manufacturers. However, "pharma companies have teamed up to mount an intense battle to claim that the future of the industry and the government's slogan of *Make in India* are threatened but the industry, in fact, is doing everything in its power to prevent the government from acting in the public's interest now and in the future" (Srinivasan, Shiva and Aisola, 2016).According to ORG-IMS analysis of the yearly sales of 603 top-selling medicines during 2006, 134 medicines were irrational, and total sales of irrational medicines were Rs. 2901.71 million (Guha, 2009:117). "The real pushing factor of irrational and harmful medicines is unethical promotion. This very factor if neglected would allow a proliferation of more irrational medicines [sic]" (ibid:126). Other researchers have also documented the prescription of irrational and high-cost medicines by doctors under pressure of pharma marketing, as well as instances of pharma companies pushing allopathy drugs through non-allopathy doctors (Gadre and Shukla, 2016:36-37). In fact, the competition among a large number of private pharmaceutical companies has led them to depend on "the tried and tested 3Cs: convince if possible, confuse if necessary, and corrupt if nothing else works"(Gulhati, 2004:778; Guha, 2009).

Given the nature of this interaction of the MR and the medical professional for promotion of medicines of a particular company, there is scope for financial interests of pharma industries to creep in, at the cost of the patient's needs and interest. Hence what actually happens in these transactions on the ground assumes importance. However, in the discourse on regulation of medicines and on the pharma industry in India, the issue of drug promotion does not get as much attention and importance as it should.

Regulation of promotional practices of pharma manufacturers

Attempts have been made to control promotion through a combination of guidelines issued by government and WHO, and voluntary codes adopted by industry associations and medical organizations

A. The World Health Assembly and Government of India guidelines

In 1988 the World Health Assembly framed the 'WHO Ethical Criteria for Medicinal Drug Promotion' in order to support and encourage the improvement of health care through the rational use of medicinal drugs. According to this document, promotion should be in keeping with national health policies and in compliance with national regulations. Along with this, it lays down that all the claims made during promotion should be reliable, accurate, truthful, informative, balanced, up-to-date, capable of substantiation and in good taste. It should not contain misleading or unverifiable information. Scientific data in the public domain should be made available to those prescribing the medicines. Financial or material benefits should not be offered to or sought by health care practitioners to influence them in the prescription of drugs (WHO, 1988:5).

It also laid down some criteria pertaining to qualifications and qualities of an MR, namely: they should have an appropriate educational background and be adequately trained, with sufficient medical and technical knowledge, and integrity to present information on products in an accurate, unbiased, and responsible manner. It holds employers responsible for not only the basic and continuing training of their representatives, but also for the information they impart as well as their actions and activities; it further states that medical representatives should not offer inducements to prescribers and dispensers; and in order to avoid over-promotion, the main part of the remuneration of medical representatives should not be directly related to the volume of sales they generate (WHO, 1988:9-10).

In 2014 the Department of Pharmaceuticals, Government of India drafted a Uniform Code for Pharmaceutical Marketing Practices (UCPMP), with an explanation that this was a voluntary code of marketing practices for the Indian pharmaceutical industry and it would be made compulsory

if not it was not voluntarily adhered to by the pharmaceutical companies (Government of India, 2014b; Jacob, 2015).

B. Regulatory Codes of pharmaceutical manufacturers' associations

In recent years the global pharmaceutical industry has introduced some changes in the companies' interactions with healthcare professionals. At the international level, the 'Code of Pharmaceutical Practices' has been developed by the International Federation of Pharmaceutical Manufacturers' Associations (IFPMA) which is applicable to all member companies. IFPMA describes promotion as "any activity undertaken, organized or sponsored by a member company which is directed at healthcare professionals to promote the prescription, recommendation, supply, administration or consumption of its pharmaceutical product(s) through all methods of communications, including the internet" (IFPMA, 2012:4).The IFPMA Code has laid down the following codes for pharma promotion (IFPMA, 2012):

- There should be transparency in promotion.
- Product information should be consistent, accurate and it should not provide any misleading information.
- Promotion should be capable of substantiation with scientific evidence.
- Sponsorship of healthcare professionals should be limited to payment for travel, meals, accommodation and registration fees, and sponsorship provided to individual healthcare professionals must not be conditional upon an obligation to prescribe, recommend, purchase, supply, administer or promote any pharmaceutical product (IFPMA, 2012:8).
- No entertainment or other leisure or social activities should be provided or paid for.
- No payments should be made to compensate healthcare professionals for time spent in attending the event. The company should not pay any costs associated with individuals accompanying invited healthcare professionals.
- Financial support for Continuous Medical Education (CME) can be provided by the member companies in order to enhance medical knowledge of the medical professional.
- Payments in cash or cash equivalents must not be provided or offered to healthcare professionals. Gifts for personal benefit of healthcare professionals must not be provided or offered.
- Promotional aids of minimal value and quantity may be provided or offered to

healthcare professionals if relevant to the practice of the healthcare professional (IFPMA, 2012:9).

The Organization of Pharmaceutical Producers of India (OPPI) has also prepared a code of conduct which is applicable for the pharma producers and has to be followed by the member companies of the OPPI. It is largely based on the IFPMA code of conduct such as, Promotion must be ethical, accurate, balanced and must not be misleading. Information in promotional materials must support proper assessment of the risks and benefits of the product and its appropriate use. No financial benefit or benefit-in-kind may be provided or offered to a healthcare professional in exchange for prescribing, recommending, purchasing, supplying or administering products or for a commitment to continue to do so. Nothing may be offered or provided in a manner or on conditions that would have an inappropriate influence on a healthcare professional's prescribing practices or would influence their professional integrity and autonomy or will compromise patients' interest in any manner. Member companies or their representatives shall not give any travel facility inside the country or outside, including rail, air, ship, cruise tickets, paid vacations, etc. to healthcare professionals for self and family members for vacation or for attending conferences, seminars, workshops, CME programme, etc. as a delegate.(OPPI, 2012:1-10).

C. Professional self-regulation

In 2009 the Medical Council India (MCI), the regulatory body for medical professionals, included in its Indian Medical Council (Professional conduct, Etiquette and Ethics) Regulations, 2002, Clause 6.8.This Clause lays down the Code of conduct for doctors in their relationship with pharmaceutical and allied health sector industry. Some of the stipulations are:

a) Gifts:

A medical practitioner shall not receive any gift from any pharmaceutical or allied health care industry and their sales people or representatives.

b) Travel facilities:

A medical practitioner shall not accept any travel facility inside the country or outside, including rail, air, ship, cruise tickets, paid vacations etc. from any pharmaceutical or allied healthcare industry or their representatives for self and family members for vacation or for attending conferences, seminars, workshops, CME programme etc as a delegate.

c) Hospitality:

A medical practitioner shall not accept individually any hospitality like hotel accommodation for self and family members under any pretext.

d) Cash or monetary grants:

A medical practitioner shall not receive any cash or monetary grants from any pharmaceutical and allied healthcare industry for individual purpose in individual capacity under any pretext.

Funding for medical research, study etc. can only be received through approved institutions by modalities laid down by law / rules / guidelines adopted by such approved institutions, in a transparent manner. It shall always be fully disclosed.

Endorsement:

A medical practitioner shall not endorse any drug or product of the industry publicly. Any study conducted on the efficacy or otherwise of such products shall be presented to and / or through appropriate scientific bodies or published in appropriate scientific journals in a proper way".

The MCI lays down action to taken in case of violation of these codes, such as censure and removal of the name from the register for a certain period of time.

However, the actual impact of these codes on the regulation of marketing practices is unclear and needs to be studied.

Rationale and Objectives of this Study

As mentioned earlier drug promotion has been a public health concern andstudies havedocumented various features of promotional tactics of pharmaceutical companies' world over(Wazana, 2000; Moynihan, 2003; Morgan, et al. 2006; Fugh-Berman & Ahari, 2007; Katz, 2003; Brax, et al. 2017). Some studies on the situation in India have covered the following aspects:

a) Roy, Madhiwalla and Pai, (2007) undertook a study conducted around 2003-05, wherein interviews were conducted with 15 senior executives of drug companies, 25 chemists and 25 doctors; and focus group discussions held with 36 medical representatives in Mumbai. The study sheds light on some crucial promotional practices of pharma companies: providing gifts, sponsorships, trade practices among the manufacturers, chemist and Stockist. Additionally, misleading information, incentives and unethical trade practices were identified as methods to increase the prescription and sale of drugs.

b) Another study confined to collecting information from doctors showed that: promotional practices of pharma companies are one of the major factors influencing the prescription behavior of doctors; MRs were the most important source of CME for doctors (Phadke, et al. 1995: XIII). The study also found that a very high proportion of prescriptions of all types of doctors contain irrational / unnecessary /hazardous drugs or unnecessary

injections or more than three drugs (ibid: X).

c) A study by Citizen, Consumer and Civic Action Group (CAG) (2007), on the promotional practices of pharmaceutical industry in Chennai undertook a survey of around 274 different stakeholders which included doctors, lay public, laboratories, pharmacists, hospitals and MRs, corroborated the findings of Phadke, et al. and showed that for doctors major source of information on new drugs was the MR. This study shed light on gifts and incentives offered by pharma industries and doctors' perspective regarding the same. A majority of doctors felt that it was acceptable for pharma companies to sponsor CMEs organized by doctors' associations. All MRs felt that giving benefits / sponsorships increased sales (Ramakumar, 2009).

d) In Gadre and Shukla (2016) several doctors talk of the influence of the pharmaceutical companies on doctors how the malpractices are taking place in the promotion of drugs by pharmaceutical companies. It also describes how doctors lobby and demand for sponsorships, incentives, etc.

A questionnaire based survey among doctors in a tertiary teaching hospital in Tamil Nadu on interactions of doctors with MR showed that of the sample, 69.1 percent of doctors thought that the MR exaggerates the benefits of medicines and downplays their risks and contraindications; 61.7 percent of doctors thought that the MR had an impact on their prescribing; 70.4 percent of doctors had not read the guidelines about interacting with the pharmaceutical industry or its representative (Gupta, Nayak and Sivaranjani, 2016). By and large studies have focused on the impact of promotional practices on doctors and their perceptions about promotion of drugs and responses to it. Since the study in 2007 by Roy, Madhiwalla and Pai, there has been no systematic documentation of the promotional and marketing practices at the ground level, of the nuances of the MR-doctor interaction, especially in the context of various codes of conducts/guidelines that have emerged in the last ten years from various quarters.

In addition, there has been no study to gauge the impact of these promotional pressures on MR.

This study addresses some of these gaps, through a nationwide qualitative study to document and understand current promotional and marketing practices of the pharma industry in India and the status of regulatory mechanisms at the field level.

The Specific Objectives of the Study were:

1. To study the promotional and marketing

practices and processes of pharma manufacturers at the field level

2. To understand the status of the regulatory mechanisms and codes in the Indian context at the field level.

Methodology

The study is primarily qualitative in nature and uses both primary and secondary sources of data. In-depth qualitative interviews were conducted with the various key informants for information on both the objectives. In addition, for Objective-2 a literature review was undertaken on the codes, laws and regulations (national and international), pertaining to interactions/ communications between pharma manufacturers and healthcare providers, and promotional and marketing practices of the pharma industry.

Sampling

The study used purposive and snowball sampling methods. Most of the key informants were from different regions and from six different cities across India.

General Description of Design

Research Question	Sources of Data	Methods	Tools
What are the current drug promotional practices and processes adopted by the pharmaceutical companies?	**Primary sources-** In-depth interviews conducted with various key informants **Secondary Source-** Published Reports, Articles, Government Reports, Newspaper articles reviewed extensively	1. literature review 2. Qualitative in-depth interviews with selected respondents	Prepared In-depth Interview Guide
What are the regulatory codes in relation to drug promotion and what is the status of it at the actual field?	**Primary Source** In-depth interviews conducted with various key informants **Secondary sources** existing codes, laws and regulations analysed extensively	1. Qualitative in-depth interviews 2. literature review	Prepared In-depth Interview Guide

Categories of respondents: Emphasis was on medical representatives as the major focus was to understand the promotional practices of pharma industry at the field level. We also included area sales manager from pharma company, who is in charge of the MRs, Regional Sales Manager - having control over a state or maybe two-three states, Executive director of a pharma company, a former pharma marketing designer, a Professor of pharma marketing, and few doctors (Allopathy and AYUSH).

To capture the regional variation if any in the promotional practices the study was conducted in six selected cities across the country. The cities included Pune and Mumbai from the west region, Hyderabad from the south, Kolkata from the east and Lucknow from the north. Along with this to capture the variations within the region, we selected another city from the western part of Maharashtra state - Nashik. The cities were selected purposively because the respondents who were tapped through the resource persons were available in these selected cities.

For the selection of respondents/key informants, gate-keepers/resource persons familiar with this topic were contacted, such as from the organizations of medical representatives in India, Federation of Medical Representative Association of India (FMRAI), Jan Swasthya Abhiyan, and Alliance of Doctors for Ethical Healthcare. From these resources, MRs, doctors and persons from the pharma industry were contacted through email or by phone. Interviews were conducted with those who were willing to share information.

A total of 50 in-depth Interviews were conducted with medical representatives, area Sales Manager, medical doctors, AYUSH doctors, Pharma executive director, and Ex-Pharma marketing designer. Most respondents (36) belong to the medical representative category.

Out of 36 MRs, five were women. We tried to reach out to more women MRs but faced several constraints. One of the constraints was time availability of the female MR. Secondly, most of them were not ready to participate in the study given the nature of the study which was highly sensitive and could increase the risk to their job. In Pune, we have tried to reach out to the female MR through a resource person but there was reluctance by the female MR. Similar experience was evident in other cities.

Educational background of the MRs ranged from 12th Pass to B.Sc., M. Sc., D. Pharmacy, B.Pharmacy, MBA, LLB, B.Com. The educational background of a majority of the MRs was that of graduation in Science stream (B.Sc.). Out 36 MR, 19 worked in an Indian company, 6 worked in multinational company and 10 had worked in Indian and multinational company, one respondent did not mention the name of the company. **Working experience** ranged from three and half years to 38 years.

Brief Profile of the Respondents

Cities	MR (Male/Female)	Doctor - allopath	Doctor – AYUSH	Key Informants
Pune	8 (7/1)	1	2	
Mumbai	3			1 (Executive Director) 1 (Marketing Designer) 1 (Professor)
Hyderabad	6 (5/1)	2		1 (Regional Sales Manager)
Lucknow	6	1		1(Area Sales Manager)
Kolkata	8 (5/3)	2		
Nashik	5	1		
Total	**36 (31/5)**	**7**	**2**	**5**

Tools for Data Collection

In-depth interview guidelines were used for data collection. The guidelines were modified according to the respondents' background.

Data Collection

Data collection in the selected six cities was carried out from February 2018 to July 2018. All the interviews were conducted either in Marathi, Hindi or English according to the preference of the respondent, after obtaining informed consent from the respondents, and lasted for approximately one hour. With the written permission of the interviewer, the interviews were recorded.

Data Analysis

In order to maintain the anonymity of the respondents, all the respondents were assigned numerical codes before being transcribed. Recorded interviews were transcribed; coded and thematic analysis was done. The coding of the data and analysis was done using RQDA[1] library of 'R' software for qualitative data analysis. The findings are analyzed in a health systems framework.

Ethical Clearance

Ethics approval was obtained from the Institutional Ethics Committee of Anusandhan Trust.

[1] Used RQDA version of 'R i386 3.5.1'

Section II

Promotional Practices and Status of Codes

Section –II

Promotional Practices and Status of Codes

This Chapter presents the findings that have emerged from the interviews regarding promotional practices of pharma manufacturers that are implemented through the MRs and marketing departments and the status of the codes for these practices. They shed light on the trends in the promotional practices over a period of 25-30 years, and also illustrate how the power relations arising from asymmetry of information between the doctor and patient is used by pharma industry and medical profession to derive greater profit or financial gain at the expense of patient's best interest.

A notable observation that needs mention is that nearly every respondent began by saying that they were willing to talk about the current promotional practices of their competitive companies, with an emphasis that their own company did not engage in unethical practices. But often as the interview progressed and the interviewees were at ease, many respondents revealed that the promotional practices in their own company were also as tainted as that of their competitors. Finally, they agreed that the practices they were sharing were of ubiquitous nature and in reality, no company could afford to be ethical. We call this the X minus 1 pattern of response: namely all others are unethical, but we are an exception.

The trends that have set in over the past two decades in the promotional practices among doctors are as follows.

Contacting doctors less for scientific information, more for business negotiation on revenues, gifts and bribes

Respondents who had worked as MR for 25-35 years have witnessed tremendous changes over the years in the promotional strategies of pharmaceutical companies. With advances in technology, the tool for product detailing has shifted from visual aids to using iPads. But most crucial has been a change in priority of pharma companies and even of the doctors. Earlier the MRs used their skill and knowledge to explain the scientific information about the product that the company was promoting. The purpose and nature of interaction between the pharma company and the

doctor has now changed, and hence role of MR also seems to have changed. Now 'pharma companies have converted MRs into postmen and use them to deliver an envelope to the doctor who gives them business', as described by an MR with almost two decades of experience. Now the focus is more on getting business through offering gifts and incentives to the doctors; in other words, bribing the doctors. A senior union leader of an organisation of MRs explained that while earlier they used to give samples and some gifts, after 1990s increasingly corrupt practices began. Along with the changed focus of getting business by any means, over the years the nature of the gifts offered has changed and their monetary value has also increased.

The change in the role of the MR in the pharma industry is reflected in the changes in the people recruited as MRs and in their working conditions, which are discussed later.

'Pampering' of doctors and monitoring of business generated by them

A senior marketing designer used the term 'pampering' to describe these negotiations with the doctors, a term which matches the accounts of nearly all other MRs. Pharma manufacturers make conscious efforts backed by marketing strategies to get doctors hooked on to gifts and bribes in various forms, which are described later on in this chapter, in return for the business that they provide. The justification for this strategy was that if a doctor can provide business of Rs one crore a month through their prescription, then why not invest in this doctor. Marketing departments work on a 'hit-list of potential prescribers' - doctors on this list are bombarded with many gifts; once the doctor bit the hook then they were pampered with gifts, sponsorship for international conferences, and so on. Frequency of visits has increased selectively for a potential doctor who gives good business, which makes business sense. Why spend time on someone who does not give business? Doctor respondents corroborated the prevalence of such practices and admitted that pharmaceutical companies do 'pamper the doctors'

There is also constant threat of withdrawal of these offers of gifts if the doctor cannot generate business as decided. According to one MR, the deal was pitched in the following manner, 'Sir, you purchase the car, we will bear the EMI. The day we start paying EMI for your car you will start prescribing our products and generate prescribed business. The day prescription stops or the business drops, company stops the EMI'. So, the doctor has to keep generating revenue for the company.

Monitoring of the doctors in the list of target doctors was stringent and questions were posed by the marketing manager to the MRs about lack of returns despite spending say Rs. 3 lakhs on a particular doctor. Non-performers were removed from the list and

spared visits: in a list of 25 doctors if it was found after three to six months that five were not prescribing a product then they were removed from the list of prescribing doctors and visits to these doctors were stopped.

So, business sense and pragmatism, not merely sharing of scientific information, are now the objectives of promotional practices. The arguments and justifications are repeated so often that the MRs rationalize and internalize them.

Disregard for medical ethics and ethical promotion

One respondent who had retired after working for forty years as MR pointed out that earlier accepting gifts or bribes would evoke some feelings of guilt or shame, but now for doctors as well as for MRs accepting and giving bribes for getting business has become a routine affair; - ethical issues or feelings of guilt no longer bother MRs as well as doctors.

Ethics has got dumped by the wayside over the last twenty years. Gradually the percentage of doctors taking/ demanding bribes has increased: According to estimates of some MRs nearly 80 % of the doctors do so; according to one MR working for nearly two decades, he had come across only two doctors who never accepted or demanded anything.

In fact the present scenario is one where the doctors also negotiate the terms with the pharma company.

Active Negotiation by Doctors with pharma company

The number of doctors unhesitatingly making demands for the activities (the term – activities was used by many MRs for describing bribes/ offers/ gifts) has grossly increased over the years. Some doctors negotiate and make demands as a matter of right for doing favor to pharma companies by giving them good business. According to one MR, 'now the business is purely on one-to-one basis: what can you give me and what I can give in return; doctors' demands are quite aggressive'.

However, it was also mentioned that not all doctors make demands, few are content with whatever the company offers.

Negotiation and bargaining between the pharma industry and the medical doctors/ hospitals have become sophisticated, and in keeping with corporate business tactics and corporate ways of functioning. Reportedly doctors ask for monthly cash against the prescription generated and then the bargaining starts. Deals with pharma companies are even talked about when doctors meet; and that becomes a friction point for MRs to deal with in subsequent visit to that doctor who is being given lesser offers than his colleague.

There are changes also in the gifts and incentives actually given to the doctors.

Incentives in kind and in cash

Earlier studies have shown that gifts ranging from small value items to high value ones were being given to the doctors for promoting a particular brand/ product, such as: pen, pen stand, prescription pad, notebook, diary to electronic items, jewelry, automobiles, etc. (Roy, Madhiwalla and Pai, 2007). Such gifts continue to be given, at the same time other items and higher value items are also given, such as Apple phones costing Rs 80,000, or microwave ovens, or tablets, or silver items, gold jewelry, or X-ray equipment for the clinic. With advances in technology and increased availability of a wide range of consumption articles, gifts are being offered in several innovative ways. For example, in place of cash gift cards, petro-cards, credit cards, E-vouchers for online purchasing on Amazon / Flipkart etc are given. The advantage of such gifts is that it is very difficult to trace the transaction to the doctors and companies. Such cards are given in name of a person other than that of the doctor to whom it is given for use. Others have also reported that incentives in kind are common in nature and somewhat accepted phenomenon. For instance: Reuters in 2011 reviewed a copy of the Abbott sales strategy where they mentioned the incentives in kind will be given to those doctors who prescribe Abbott's branded drugs or who have already prescribed certain amounts (Joelving, 2012). Cash incentives are also a common phenomenon. Many participants were hesitant to speak about it openly, but some provided details such as that cash transactions are in direct proportion to prescriptions generated. Cash transactions differ from company to company and the magnitude of business. In smaller companies since the magnitude of business is small, the cash offered is small too. With advent of some regulations the focus now is not to be caught red handed, and to ensure that the route and destination of the money spent should not leave any trace. These findings corroborate previous reports that doctors often refuse to write prescriptions unless they are offered at least Rs 50,000 in cash, every time a new drug is launched (D'Souza, 2012).

Sponsoring pleasure trips in the name of CMEs and academic conferences

Various types of sponsorships are given to doctors for attending conferences and seminars– national and international depending upon the business generated. Continuous medical education (CME) has come in handy in a big way to pamper the doctors. The number of conferences has gone up and they are used unabashedly to promote business. Company chooses to use senior doctors as Opinion Leaders and present them in conferences and CMEs, as in medicine senior doctors set patterns of prescription which is followed by many

junior doctors.

Sponsorship covers travel, meals, stay for product launch meetings, round table meetings etc. The list is updated to match with demands for pleasure trips and personal entertainment to doctors and their families. The destinations range from Asian locations to European countries and places like Baku in Azerbaijan: in 2003 trips to Bangkok and Shanghai were financed; now Switzerland and other European cities too are covered. In another case the doctor categorically said that if he and wife were not sent to Europe then the concerned MR need not visit him any more to seek business. Everything is paid for, without any restrictions. In fact one MR said that the honeymoon trip of one doctor was financed by the company.

Several senior MRs described, with a lot of anguish, that some companies even arrange for women to accompany doctors as per their demands. Such arrangements are done by a senior level management and MRs are not directly involved, and is reserved only for the doctors who give enormous business. According to one senior MR with nineteen years of working in a MNC,

> "From Bombay three neurologists were sponsored for a foreign tour and to entertain them the company also sponsored two south Indian heroines. This company ranks number one in that segment. It is really pathetic to see that pharma industry has stooped to this worst level of marketing".

However, it was repeatedly emphasized that not every doctor or every company indulged in such practices; there were good doctors and some companies that followed ethical practices.

Strategies for targeting doctors individually and through associations

Differential strategies are adapted for different categories of doctors. The offers for the specialty doctors, consultants, doctors dealing with chronic segment are different. Every single prescription matters for MR to achieve target. So, doctors placed in government sector are targets as well. Many times, there is an obstacle though. MR has to acquire No Objection Certificate (NOC) from the head of the Government Hospital for visiting the doctors in government service. So very few MRs visit them as there is less possibility of getting business. Additionally, due to heavy patient load doctors have no time to give attention to MR's narrative. Still, efforts are reserved for those doctors in Government hospitals who have their own separate private practice. The main targets for pharma companies are the doctors practicing in the private sector. The company hands over to its MRs the core list/ primary doctors' list, comprising those potential doctors who would give big business. One more list, the secondary doctors' list, contains names of the doctors who have no sufficient potential to generate big business. It is the doctors in

the core or primary list who are targeted for differential and forceful treatment.

As the drug segments dealing with chronic diseases like hypertension, diabetes, are ever-green segments and sustain company's profit for ever, targeting doctors who give business in these segments forms a crucial part of the marketing strategy of pharma companies. There are lucrative schemes for these doctors.

However, the qualification of the doctor does not seem to matter too much for the pharma company, only the volume of doctor's prescription matters. Hence doctors from non-allopathic streams as well as unqualified people providing medical care (popularly known as quacks in India) are also targeted in promotional practices. According to one MR who had worked in Indian and multinational pharma companies, they visited even RMPs[2] for promotion of drugs as they gave business. He lamented that "The RMPs have been sent to Singapore. This is really a very sad state of affairs but the RMPs sell our drugs in volumes unmatched. Why should the qualification of doctors' matter? Qualification of the doctor is non entity."

Contacts with doctors are also established through their associations and conferences. Previously doctors' associations would take donations from pharma companies for their conferences and meetings. Since the regulations of the Medical Council of India (MCI) have come into force, the association asks pharma companies to rent a stall in their conference, for which they charge rent ranges from 50,000 Rs. to Rs 1 lakh. Thus the association provides space to pharma companies, which use these stalls to showcase and market their products and reach wider section of doctors at one time. As a senior family physician described, "At any large conference once you enter the gate you come across many stalls. Stalls are rented out by the organizers so no one can have any proof of companies sponsoring conference directly".

Strategies of pharma companies other than providing direct incentives to doctors:

Direct sale of medicines by doctors

Many pharma companies keep medicines in the premises of the doctor for sale. The business model is skewed to doctors earning from the vast trade margin. The cost to the doctors/ hospitals is much lesser than the Maximum Retail Price printed on the strip or vial at which doctors/ hospitals sell the medicines. Thus they make large profits

2 RMP - Rural Medical Practitioner - is an unqualified healthcare practitioner who is practicing allopathic medicine without any formal registration, often in rural areas and urban slums, and cater largely to the poorer sections.

from such sale of medicines. Sometimes doctors who don't want to be seen as merchants ask patients to get the vial directly from a particular MR, who collects the money and passes it to the doctors. One MR explained it thus: "The MRP of a vial of medicine is 2600/-Rs. The distributor gets it at just 500/-Rs and sells it to the doctor for 600/-Rs, who then sells it to the patient at the MRP. So, doctor earns Rs 2000 per vial when he sells it directly to his patients. This particular doctor earned 42,000/- Rs in one such deal".

Collusion with in-house pharmacy hospitals

Pharmacies located in the premises of the hospitals are very common in India. Often patients are compelled to purchase medicines from the shops within hospital premises.

In case of single-doctor owned small hospitals, the doctor leases out space in the hospital for a pharmacy. In exchange huge advance is collected as lease rent or a slice in commission from the pharmacy owner.

In the last twenty years corporate hospitals have arrived in big way. Pharmacies in their hospital premises and the brands or medicines to be kept in the pharmacies in corporate hospitals are decided by the hospital management and purchase manager. Pharma companies have evolved different strategies and they deal with corporate hospitals quite innovatively. The corporate hospitals generally tie up with the selected pharma company, which give high profit margins. A senior family physician pointed out that the medicine brand prescribed in the corporate hospital may not be available in a pharmacy outside the hospital, compelling the patient to purchase it from the pharmacy within that hospital. There are instances of corporate hospitals having their own pharma industry too. One MR described this case: "Some corporate hospitals have their own pharma industry too. Here, the big group is 'X' hospital. 'K' is the pharmaceutical company owned by them. They don't say it, but it is fully owned by them. No surprise that in that corporate hospital pharmacy 90% of the products sold are of 'K' company. There is no place for medicines of other pharma companies".

There is substantial evidence pointing to effectiveness of the interaction of the MR in shaping the prescription habits of doctors (Bhatt, 1993).Although this study did not use methods such as prescription audits to gauge the impact of these promotional practices, still findings corroborate these findings of an association between promotional practices and increased prescription of concerned drugs by doctors. According to a Regional Sales Manager working in an Indian company for more than thirty years, "If the company gives Rs 2 lakhs to a particular doctor, the same doctor will start giving 6 times more business and hence would start writing prescriptions even when not indicated".

One marketing executive who had worked for seventeen years in an Indian company said, “I have pushed antibiotics down the throat of a doctor. He happily prescribes antibiotics even in viral fever where actually the antibiotic has no place; to create business of a couple of lakhs to couple of crores so that he could get the gift in return, maybe a car or whatever”. According to an MR allopathic doctors (those with an MBBS degree) do not give steroid randomly without indication. However, doctors from other streams, such as BAMS or BHMS prescribed steroid to make the patients feel better, they did not prescribe the full course of antibiotics to appease expectations from patients for minimum medicines. Such findings indicate that the promotional practices actually promote prescription of irrational use of antibiotics and steroids. In addition, it points to the effectiveness of promotion among non-allopathic doctors, who prescribe irrational medications, wrong dosage of antibiotics.

In addition, pharma companies themselves created irrational combinations to circumvent regulatory steps and continued to have sales and profits. If the government introduces price control measures for certain drugs, the company introduces a new 'me too' variant with addition of some other irrelevant molecule and pushes it among doctors. This was done in case of a drug Evion - when Evion which was a very big brand came under Drugs Price Control Order regulations and profit margins came down, one affected company stopped marketing Evion and marketed 'Evion Omega'. On the strip 'Evion' was highlighted while 'Omega' was put below and kept inconspicuous. The cost of Evion increased from one rupee to five rupees. Within 6 months, company made huge money. In a way the so-called price control helped the company to mint money. A Marketing Designer described a similar strategy of promoting irrational combinations that pharma manufacturers adopt, “In India when I realize that the same molecule is available in 500 brands, I will adopt a different marketing strategy. So, I add one more molecule to the original one to establish my own identity. For example, to one pain killer I will add another potent pain killer, to hell with side effects on patient's kidney or liver. I have to be different in the crowd. This is how so many irrational combinations are born in India. 50% of the sale comes from irrational combinations or combinations”.

Whole salers too do not stay behind

Various schemes are offered by the pharma industry to the distributer, stockist and chemist for the purpose to get more business. The percentage of margin given to retailer, wholesaler and stockist differs from company to company and product to product. Generally, retailer chemists get 10-20 percent margin. The modalities of margin differ. Two strips given free for the purchase of 10 strips and that comes to 20% margin. Similarly, stockiest also needs to be

managed by company to keep the company's stock available at his end to supply it to chemist when the order gets generated. **Many times, the distributer demands extra money or discount on the product from MR. If the MR does not oblige the stockiest just does not send the supply to the chemist through whom the MR has generated demand.**MR is compelled to adjust or give extra from his pocket to the distributer in order to achieve their targets.

> "Suppose, a particular *MR is getting 10,000 rupees as an incentive (additional to his salary) after achieving the target. The stockist demands 5,000 Rs. from the MR. If that MR does not accept, the distributor just sits on the orders and spoils that MR's incentive!"*
>
> ***MR (33 years in Indian Company)***

Differences in promotional strategies of Indian and Multinational Companies

While both Indian and multinational pharma manufacturers resort to such promotional practices as described above, Indian companies were perceived to be more ruthless and aggressive, and put lot of pressure on MRs to achieve business by any means. However, it was also told that actually multinationals are giving much larger activities and corruption than their Indian counterpart; the difference is that they do it in a more sophisticated manner and with legal paper work.

Status of Regulatory Codes

Promotion of drugs by pharma industry is meant to provide technical information and knowledge of new drugs to the medical profession. As mentioned in Section 1, codes and guidelines have been laid down for such promotional activities by several agencies. Without exception all of these codes prohibit financial offers and other incentives to medical profession as part of drug promotion.

Our findings discussed so far indicate that in the last two decades the scale and nature of promotional practices of pharma companies have changed for worse. The focus has changed from giving scientific information to negotiating to get more business by offering bribes, offering a range of financial and other incentives, including providing entertainment for doctors and their families. The single point agenda seems to be to pamper the doctors and incentivize them to prescribe a large amount of medicines to simply increase their business. Clearly, the actual needs of patients appear to be of low priority to both, the doctor and the company.

The next Section presents findings on how regulatory codes and advisories are given a toss in the promotional strategies.

> *"Many doctors are not even aware about the MCI codes or medical ethics"*
>
> ***MR (36 years in Indian & MNC)***

This single quote summarizes the grim situation on ground regarding status of the regulatory codes on promotional practices of pharma industry. General awareness about the regulatory codes/ advisories is at superficial level. MRs too are not aware of the regulatory codes/ advisories. Their training barely addresses this issue and the company does not provide information about regulatory codes through any other avenue.

The findings clearly indicate that these Codes are observed more in violation rather than in adherence.

As mentioned earlier, the Code of Conduct of MCI also carries some punitive measures if any doctor is found guilty of violating the Code of Conduct. The quantum of punishment will be in proportion to the value or freebies accepted by the particular doctor from pharma company, and will range from censure to removal from Indian or State Medical Register for more than one year. (MCI, 2009:9; Bhatt, 2010).

The problem with the MCI codes is that they are only applicable to individual doctors and not to associations of doctors. The Executive Committee of MCI exempts medical associations from the purview of its ethics committee (Jesani, 2014). This is fulfilment of promise given by past president of MCI Dr Ketan Desai (Nagarajan, 2016). Dr G. S. Grewal, President of the Punjab Medical Council described this exclusion as a national shame. In his view it is like allowing a gang to do the corruption but not one person. This gives legal sanction to pharma companies to bribe doctors' associations. There is no clear definition of association of doctors as well (ibid)

> Regarding punishing doctors found violating these codes, Dr Ankur Sachan, a general physician based in Kanpur, told India Medical Times, "I don't think quantifying punishment will change the scenario. First of all, how will the MCI prove that a doctor is taking bribe and of what amount? Bribing doctors is not a new practice, yet how many cases actually get noticed? This is merely propaganda by the MCI so that no one can point finger on its functioning. These measures will not discourage doctors from accepting bribes; if the MCI really wants to do something in this regard then it should end the association of doctors and pharma companies altogether (Rathee, 2014).

A senior obstetrician-gynecologists response points to the indifference among sections of doctors towards the MCI code of conduct: "There are MCI guidelines for doctors specifying that they should not take any schemes or benefits the pharmaceuticals offer. But if I do accept them, what would MCI do?

Am I going to be jailed? Does my license get revoked? Does the hospital get shut down?"

One MR pointed out, that MCI guidelines have no impact in the field. Companies continue providing costly gifts like cars to the doctors. According to a BAMS doctor, "No CME takes place without sponsorship. Most of these CMEs take place at the five-star hotels with lavish dinner, liquor. It seems that there are different ways to circumvent regulations".

MCI Code clearly prohibits medical practitioner from accepting any travel facility inside the country or outside country (MCI, 2009:10-11). Some companies now do not pay for international travel but continue paying for national travels. As discussed in the previous section, sponsorships cover travel, stay, food, paid vacations and even in some extent liquor too. The sponsorships do not show on the company's record.

MCI guideline clearly mentions that funding for medical research, study etc. can only be received through approved institutions by modalities laid down by law / rules / guidelines adopted by such approved institutions, in a transparent manner. A medical practitioner is obliged to know the clauses[3] which are imperative for undertaking any research assignment/project funded by industry. These codes are also not adhered to by some doctors. A gynecologist mentioned that, the company offered him Rs. 50000/-, and he needed to just sign few papers showing him as the principal investigator. In practice no research takes place, but everything is legal. According to another doctor, a psychiatrist, "Doctors are taken on advisory board of pharma company and things continue undeterred with no respect for regulatory codes. The transactions between the company and the doctors are in cash and are nowhere reflected officially in company's record."

Cash incentives are also channelized to doctors through the charitable foundations set up by the pharma company. Cheques are issued through this foundation to doctors or the education of their children is paid for through these trusts. Almost every company has got some foundation, and cheques are issued through the foundation, about which people are

3 MCI guidelines have given in detail seven sub-clauses under which medical practitioner have to carry out any medical research.

generally not aware.

Propaganda Cum Distribution Companies (PCDs)

New entities have emerged to circumvent regulatory codes - like PCDs, which are a franchisee of the pharma manufacturing company that buy drugs in bulk from the manufacturers, give their own brand name and directly sell them to the retailers and doctors, at huge discounts and incentives (gifts/cash/hospitality/travel facilities etc.). PCD companies have mostly been established by those who have worked in marketing, who know market trends and doctors who could be targeted. These companies mostly deal with the doctors or with the retailers on percentage based on total sale. The trade margin sometimes goes up to 40 to 50 percent. PCD companies do not appoint MR, they themselves do the dealings. They also deal in cash. As one MR explained, "PCD means small local companies who directly offer 30 % to 40% commission to the doctor. So, if doctor provides business of Rs 10,000, then cash of Rs 3000 is offered to the doctor"

Section III

Medical Representatives: Working Conditions and Impact of Work Life on Personal Life

Section - III

Medical Representatives: Working Conditions and Impact of Work Life on Personal Life

As mentioned in Section I the MR is an important link through whom the business transaction between the pharma company and the doctor is executed. This Section looks at the impact on MRs of the emphasis of drug promotional practices on generating and increasing business by increasing doctors' prescriptions.

No specific educational requirement to be MR, inadequate training

Twenty years back one had to be a science graduate to get employed as MR, and rightly so because the MR was supposed to have some knowledge of physiology and of the structure and functioning of the products to be able to explain to and convince doctors about their efficacy, side-effects, and so on.. It was a tough task given that doctors study pharmacology in their training. This requirement for education in science for MRs has been done away with now, and non-science graduates are also appointed as MR. Business management graduates (MBAs) are preferred over science graduates as the task now of the MR is not so much to impart scientific information as to conduct business negotiations and clinch a deal with the doctor to prescribe their product, as explained by one MR: "In today's scenario having science graduate is not important. Pharma companies are recruiting BA, B.Com., MA, MBA etc., sometimes even persons who have studied only up to higher secondary school level (12^{th} class pass), who have some experience in this getting business".

The nature of training of MRs had also changed, and is focused less on technical knowledge and more on salesmanship, how to speak to the doctor, how to hold oneself, and so on. An MR with more than thirty years of experience in Indian and multinational companies explained that when they joined as MRs the training was very thorough and took place over 45 days, whereas now it gets over in just 4/5 days. All this had given rise to lack of knowledge among MRs about the product.

Some doctors pointed out that the present generation of MRs lacked knowledge and did not have even capacity to acquire the relevant knowledge. There was a tendency to hide the inconvenient information like contra indications, side effects etc. One

doctor pointed this out: "Tetracycline is strictly prohibited for pregnant woman but MR never mention this information"

Some MRs rued the fact that the image of MRs in eyes of doctors has taken a beating due to the ignorant MRs visiting doctors who were more interested in getting scientific information than offers.

Working conditions, designation and income of MRs

The use of iPads has given a stick to MR's supervisors to track their daily movements. Every movement of MR is monitored real time, and become a source of constant stress. They have to report daily on emails about the doctors they visited, and the business brought in. With advent of internet daily reporting by 11 PM has become mandatory; if not done their job is at stake.

MRs do not have a regular 8 hours work routine, but work for extended hours, till 9-9.30 pm. Sometimes it could stretch beyond that till late night, when conferences or a round table meeting have to be organised

Designations and pay of a MR

The designations of MRs have been changed to - Territory Business Executive, Area Business Manager, Business Development Manager, Senior Business Officer, Senior Business Executive, Sales Officer, Clinical Business Associate, Professional Service Representative etc. Such designations place them in the category of an executive or an officer. One MR said "Over a period, the number of Medical Representatives came down from 375 to 25. It means that remaining 325 accepted the change in designation. Those who refused were sent to some other places or were removed." Such strategies have been devised so that the MR cannot join the union.

However, the basic salaries of MRs are very low and do not commensurate with those of actual executives or officers in the company. Their income is linked to the performance and targets achieved. In numerous companies the MRs are paid a paltry amount of Rs 10000/- per month for years, against business generated of say Rs 4-6 lakhs. The organization representing MRs is still fighting for minimum wages, which has not been revised since 1992.

MRs are unhappy about the salary they receive. In Punjab and Chandigarh, MRs went on strike to demand for minimum wages of work i.e. 25,000/- fixed salary and clearly defined timings of eight hours of work each day (Nasim, 2019), indicating that they do not even have a regular monthly income. MRs often travel 50/60 kms on motorcycles with 40/50 kg load to meet doctors.

Pressure of achieving targets

There is constant pressure from the

supervisors and managers of MRs to achieve targets, which increases every month. In the past company set targets yearly, but gradually they were set six monthly, then monthly and have now come down to weekly and even daily. If such targets are not met the management starts creating pressures by giving warnings, by using harsh language in front of colleagues, by withholding the salaries, by giving transfers to remote areas and ultimately giving termination letters. The job insecurity is such that many MRs then go to any extent to meet these targets. When a MR conveys some demand from a doctor to management, the management takes in writing from the MR that he/ she would bring certain amount of business from that doctor. In case that doctor fails to provide business, the MR is answerable to the company. Some pharma companies take in writing from a non-performer MR that he or she would achieve target coming month. Sometimes the management may also take a post-dated resignation letter.

The pressures start mounting at the end of the month where targets are not being achieved. Hence MRs have to keep visiting doctors, hospitals, wholesalers, chemists, distributer, stockists in order to achieve the target. They have to bribe stockist and distributer to get supply to the chemists.

Their visits to the performing doctors have increased in frequency. Meeting doctors carries its own troubles and stresses. They have to struggle and beg to get time from busy doctors. Many times, even after long waiting period the doctor or the receptionist refuses the call. Humiliation at hands of doctors is not uncommon and is stressful. One MR who has been working for more than 25 years said, “To pamper the doctor MR has to wish good morning, say good-night, send messages. This is all quite irritating, but it's ultimately my job”. Rational and ethical doctors have lost their respect for MRs. Doctors said that often MRs use tricks like invoking sympathy, and even try to bribe the doctors without any hesitation. One ENT specialist said, “MR pleads and begs for our mercy. He tells us – *Sir I am going to lose my job if you don't write my drug”.*

This rat race to get business from doctors by any means takes its toll on the personal life of MRs. Respondents revealed that such work and sales pressures cause tremendous psychological trauma and stress for MRs. Because of the pressure tactics adopted by the management of the pharmaceutical company, and the stress it causes, accidents among MRs are on the rise. Some MRs told that new generation is not willing to opt for this profession and there is attrition. Some leave the sector for insurance or bank sectors. The saddest part is that some MRs take the extreme step of committing suicide (Datta, 2016).

Such findings of MRs experiencing high level of stress due to various factors such as

high workload, tight deadlines, high targets, type of work, lack of job satisfaction, long working hours, pressure to perform, etc. have been reported by others too (Kalyanasundaram, 2017; Paliwal, 2017).

What emerges is that not only do pharma companies adopt unethical promotional practices without any regard for their own Codes, as described in Section II; they also place much of the burden of the promotion on the MRs in the field. By employing MRs at low wages, making them work for long hours, linking their salaries to their performance in terms of getting business from the doctors, constantly monitoring them and creating job insecurity, the companies also violate labour laws.

Section IV

Discussion

Section –IV

Discussion

The two main objectives of this study were:

1 To study the promotional and marketing practices of pharma manufacturers in different parts in India.

2 To understand the status of regulatory mechanisms and codes for promotional practices in the Indian context at the field level.

What emerges from our study is that the pharma industry employs promotional practices of extremely unethical nature and even ones not allowed by law. The findings contribute to the existing knowledge of the different kinds of aggressive promotional activities that the industry undertakes. The intensity of such practices has risen over the years, and the value and type of gifts have also changed with the times. The study makes an important contribution to understanding and exploring certain new kinds of promotional practices in the contemporary time period, which did not exist in the last two or three decades.

What emerges sharply is that 25 to 30 years back the focus of the promotional strategies was mostly on detailing the product through visual aids to the doctors and giving scientific information, abiding by ethics and values. This corroborates the description by Mujumdar and Das (1986) that earlier the company's primary focus was on MR's effective communication and detailing of the product with the doctor. Gifts and samples are only cues and considered as secondary stimuli.

However, now the focus is more on getting business through offering various incentives in cash and kind, sponsorships, paid entertainment trips, etc. with little concern for patients, for ethics. New forms have come up with providing gift cards, petro-cards, credit-cards, e-vouchers, expensive cars and other consumer goods, and financing entertainment for the doctors and their families. In fact the current practices in giving gifts and incentives have hit rock bottom, have reached their nadir in terms of ethical codes of conduct.

Different strategies are implemented, such as targeting reputed doctors or specialists to prescribe their products and using them as opinion leaders. These findings are corroborated by Fugh-Berman & Ahari,

2007; Fugh-Berman & Homedes, 2018), who point out that cardiologists and other specialists write relatively few prescriptions, but are targeted because specialist prescriptions are perpetuated for years by primary care physicians, thus affecting market share. The MRs have to prioritise these core doctors in their list, visit them frequently as well take special care to 'pamper' such doctors. Renowned doctors are given special attention by the pharma company (MR), so that they maintain the brand loyalty and prescribe the company's products (Mohiuddin, et al. 2015).

Cash incentives are also provided in indirect ways, such as by supplying the company's products at a much lower cost than the MRP, which the doctor sells to patient at the printed MRP. This has been noted also in case of vaccine supply to doctors by vaccine manufacturers (Lodha and Bhargava, 2010).

The educational background of the doctor doesn't matter, and MRs are compelled to promote allopathic medicines among BAMS, BHMS and even unqualified people (quacks), although these persons cannot prescribe allopathic drugs by law[4].

The regulatory codes for medical professionals are mandatory, but those for pharma industry are voluntary and not mandatory. The study revealed that the regulatory codes are not being adhered to by medical professionals as well as by pharma industry. Many of the MRs are not even aware about the regulatory codes. The MRs and few doctors pointed out that no strict action is taken by the concerned authorities which will help in curbing the unethical practices. In fact it emerged that even doctors are not aware of the MCI Code of Conduct, which corroborates findings of another study conducted in tertiary care teaching hospitals that 70.4 percent doctors have not read the guidelines about interacting with the pharmaceutical industry or its representative (Gupta, Nayak & Sivaranjani, 2016).The regulatory codes are being circumvented by the pharma industry in several ways, such as by keeping doctors on advisory board for name sake, providing funds through their foundation. Clearly there is total disregard by both the pharma industry and sections of doctors for the voluntary codes laid down by their respective associations. The government too has not taken any steps to curb these

[4] BAMS and BHMS doctors quite often use modern medicines for various reasons but status regarding valid legal permission is ambiguous (Dabhade, et al. 2013). However, the Indian Medical Council Act, 1956 (Section-15) prohibits allopathy practice by any person who doesn't possess necessary medical qualification as notified in Schedule 2 and is not registered under any State Medical Register. A Supreme Court judgment in the case of Poonam Verma versus Ashwin Patel, (1996) stated that "A person who does not have knowledge of a particular system of medicine but practices in that system is a quack and a mere pretender to medical knowledge or skill, or to put it differently, a charlatan" (Supreme Court of India, 1996; Central Information Commission, 2018).

practices; almost five years have lapsed since it laid down the UCPMP in 2014 with the stipulation that they will be made into law if not voluntarily adhered to. But there are no moves by the government to take any firm steps in that direction.

This study corroborates findings from other studies that the promotional practices of the pharma industry have an impact on the generation of doctor's prescription (Phadke, et al. 1995; Narendran & Narendranathan, 2013, Wazana, 2000; Salmasi, Ming & Khan, 2016; Gupta, Nayak, and Sivaranjani, 2016; Goyal & Pareek, 2013; Moynihan, 2003).

Implications of Promotional Practices

Even though the study's objective was not to explore the impact of the promotional practices, however from the interviews it emerged that promotional practices led to prescribing of excessive, irrational drugs and push for high-cost brands. Drugs are being promoted to non –allopath doctors (BAMS, BHMS and RMPs) which is not allowed in practice and has led to prescribing non indicated doses of antibiotics as well as less adherence of the BAMS, BHMS doctors and RMPs to prescribing full dose of antibiotics. A study conducted in Pune, comparing prescriptions of MBBS and BAMS doctors using WHO prescribing indicators shows that the percentage of prescriptions with antibiotics and with injections was significantly more in BAMS doctors. Percentage of irrational FDC's prescribed by BAMS doctors was more (57.2 percent) as compared to MBBS doctors (28.6 percent). It emerged that although the prescribing patterns of both MBBS and BAMS doctors are not satisfactory, the BAMS doctors seem to prescribe more irrationally as compared to MBBS doctors. The reason given for such irrational use of medicines was that the majority of the practitioners rely on medical representatives for updating their knowledge. Hence incomplete knowledge, skills or information, unrestricted availability of medicines, overwork of health personnel, inappropriate promotion of medicines and profit motives from selling medicines impact the prescription writing adversely (Dabhade, et al. 2013: 414). Irrational FDCs of antibiotics are among the major causes of antibiotic resistance in India (Srinivasan, Shiva & Aisola, 2016). Pharmaceutical companies influence medical practitioners who have no professional qualification and no license to practice any system of medicine for the purpose of their products (Jadeja, 2012).

Intense competition and the emergence of PCD companies were one of the reasons highlighted by the respondents for prevalence of such promotional practices.

Deconstructing the MR-Doctor interaction and promotional practices of pharma industry

The promotional practices of the pharma industry cannot be viewed simply as a

matter of MRs meeting doctors to give scientific information about new products and hold individual MRs and doctors as responsible for unethical behaviors. What emerges clearly is that the MR-doctor interaction actually involves less of information on new products and more of giving all kinds of gifts to influence, even induce or bribe the doctor to prescribe only the company's products irrespective of its merits, and not that of any other company. MRs are at the lowest rung in the marketing hierarchy of the pharma industry and are just the medium to implement the strategies formulated and designed by the company. So the promotional practices have to be placed in the larger context of the goals of the pharma industry. Given that the major activity of the pharma industry is production of medicines for treatment and cure and to keep people healthy, the implications of such promotional practices of the pharma industry and of the industry-physician relationship for the availability and affordability of medicines need to be understood from a larger health systems perspective. Health is a social good and basic right of populations, the means to remain healthy are also social goods and cannot be treated as commodities. Pharma products help cure and save human lives and in keeping them healthy, hence they should be considered as public goods.

Both, the pharma industry and the medical profession on whom it relies for sales, revenues and profits, associate themselves with high standards of the healing arts and with science. Both have fostered the impression that through scientific research and development, production and prescription of life-saving medicines, they are serving society's needs to cure and prevent disease, to keep society healthy; there is a perception that because they are part of this arrangement for healing and keeping people healthy, by such association itself they are ethical. On this basis, the industry enjoys a range of rights, privileges, and protections -and increasingly partnerships are granted not only by host governments but also by health practitioners and professional associations (People's Health Movement, et al. 2011: 278). However, we find that the pharma industry actually engages in various kinds of unethical and unlawful practices. Our findings on the activities and behavior of the pharmaceutical industry and sections of medical profession in India cast a shadow on the perception that they are ethical and are concerned with health and welfare of the people, and give rise to several concerns about their role in the health system.

I - Role of the medical profession

Although offers of incentives are initiated and pushed by pharma companies, however now there is active negotiation and participation by the doctors regarding what gifts the company should give to the doctor in return for the business generated. What is shocking is that often doctors do not think there is anything wrong or that they are

against medical ethics (Brett, Burr, & Moloo, 2003) and feel that the relationship does not affect their prescription patterns (Wazana, 2000; Goyal & Pareek, 2013, Salmasi, Ming & Khan, 2016). Studies have shown that gifts are used to enhance guilt and social pressure. Gifts create a subconscious obligation to reciprocate (Fugh-Berman & Ahari, 2007; Fugh-Bermana & Homedes, 2018). The issue is not whether it is a small or high-value gift, but it does affect the prescription behavior of the doctor (Katz, 2003). As pointed out by Moynihan (2003) 'the free lunches and the sponsored education are part of a much bigger process of companies buying influence and building problematic relationships, creating conflicts of interest for prescribers, which in turn can affect their judgments about the care of patients and inadvertently drive up healthcare costs'.

Whether gifts or cash amounts are small or big, doctors should be aware that the costs of these promotional efforts are passed on to patients in the form of higher prices for medicines, hence, there is a strong case for physicians to refrain from co-operating in promotional practices of the industry, even when the gifts actually received are of negligible value (Chiong, 2003). In view of these costs, accepting any gift from the pharmaceutical industry that primarily benefit the individual physician violates the standards of distributive justice and of professional obligation to the patient. 'Such gifts involve a surreptitious transfer of wealth from patients to doctors. Hence, a strong objection to physicians' acceptance of gifts from the pharmaceutical industry can be made based upon the extremely high hidden costs of industry-to-physician marketing, which raise problems of distributive justice and physicians' fidelity to patients (Chiong, 2003: W28).

Secondly, by prescribing irrational or inappropriate medicines in return for gifts, doctors themselves contribute to problems of antibiotic resistance, treatment failure from wrong usage and use of wrong drugs, and ultimately wastage of patient's money and time. There could be other more serious consequences too for the patient due to such inappropriate or wrong prescriptions.

As pointed out by Lodha and Bhargava (2010), patients' knowledge of these marketing practices and the acquiescence by doctors to the pharma industry influence, will seriously undermine patients' and the public's reliance on the trustworthiness and professional judgment of Indian doctors. In fact, ignoring medical-clinical factors and allowing considerations of cash and gifts to prescribe only certain medicines, irrational drugs, expensive vaccines, over-medicate, etc., amounts to serious breach of the trust that individual patients and society in general place upon doctors to make decisions in the best interests of patients, to safeguard the interests of the patients.

Doctors who believe that they act in the best interests of patients need to be bear in mind

that their actions are not restricted to merely what medical intervention they advise or adopt; their interaction with the medical supplies industry also matters. By going along with the unethical promotional practices of these industries, not only are they contributing to the vast profits of these industries, such profits are actually made from the high cost of medicine paid for by patients and sick people, whom the doctors claim to cure, whose interests the doctors claim to safeguard.

The medical profession claims to be a noble profession, different from other professions and demands special privileges, and medical practitioners are often respected and trusted a lot. Given this special stature conferred on doctors, the collusion of sections of this profession with the pharma industry or their inaction or even silence on such practices amounts to a huge breach of the trust that society places in them. Such participation of sections of doctors and their collusion with the pharma industry for financial gains has serious consequences for rational use of medicines and cost of medicines, for medical practice itself. The current doctor-pharma industry relationship should therefore be a matter of serious concern for the medical profession in its own interest.

Even though it is known that the self-regulation has failed to curb the unethical practices, still there is a need for the medical profession to introspect on the current state of their professional ethics and their obligation to the patient's wellbeing. Hence, it is strongly recommended that they should restrict themselves from succumbing to unethical promotional practices of the pharma industry.

II - Role of the pharma industry

In the larger health care system, the pharma industries play a major role in producing and supplying medicines to the health care agencies. In the Indian context the pharma manufacturers are largely in the private sector, are part of the national economies, and the main objective of the pharma industry is to increase its market presence and generate profits. As doctors are its target customers, the industry resorts to all means, fair and foul, in the guise of promotional strategies, to increase its business. In this it is the MRs – the field force – who bear the brunt of increasing the business through unethical marketing practices, while the industry as a whole remains aloof from the 'dirty' work. This pressure of unethical promotion on MRs is exacerbated by the fact that they are poorly paid and do not have job security and decent working conditions. Thus the pharma industry violates laws and its own code of ethics, through exploitation of the MRs and indulging in unethical promotion of its products.

Such behavior of the pharma industry is not totally surprising. It begins to make sense when the production of pharmaceuticals is seen as a system comprising a dynamic

network of relationships, with the individual (as patient/consumer), the doctor, the state, the media and the industry all being parts of this system (Davis, 1997).However, from a policy perspective the fundamental dynamics are provided not by considerations of the health system, but by the economic actors, namely the industry, the state, third-party payers, professional organizations, and even consumer and user organizations. Even within this network of economic relationships it is the industry that plays the central, formative and most strategic role. The pharmaceutical market place is highly competitive and the manufacturers strive for long-term survival through scientific innovation, advances in production technology, marketing programmes and organizational restructuring. Driven by the constant search for profit and survival, a pharma company enters into a dynamic set of relationships with other actors, to promote their products, such as with medical professionals and their organizations. A fifth to a quarter of industry costs are devoted to such marketing and promotion. They also work through the media and lobby with the government; industry associations have strategic negotiating relationships with the state and state agencies over prices, subsidies, cost control, essential drug lists, etc that impinge upon the profitability of the industry. As pointed out by Davis, the major fallout of this preoccupation with profitability is that the growth of the industry has not been in consonance with the health needs of the people, of society. For instance: the market is flooded with non-essential, irrational and at times even hazardous drugs. Not only this, its activities actually have adverse and hazardous consequences for health of people, by affecting availability and accessibility to medicines, by pushing up cost of medicines, by coming up with irrational, expensive drugs and vaccines, by tilting medical practice itself towards financial considerations at the cost of clinical factors.

The perception created among the general public and patients is that the high cost of medicines is due to large expenses incurred in research, development, and manufacturing. However, annual reports of pharmaceutical companies found that ten of the largest global pharmaceutical companies spent a total of US$739 billion on 'marketing and administration' between 1996 and 2005, compared to US$288 billion on R&D for the same period (Brax, et al. 2017). Chiong (2003) pointed out that in the US context the industry spends a significant proportion of its sales revenues on advertising and promotions directed at professionals, with much of these expenses going for not only the gifts and advertising in journals but also for the employment of a large number of sales representatives to reach out to physicians. The number of such representatives employed was much more than those employed by the pharmaceutical industry for drug production, research and

development, administration, or distribution.

The trend of reduced investment by pharma companies in basic research and less profitable drug development emerged in the late 1970s when the WHO launched its policy on essential drugs. There was a growing realization of 'the crises of productivity in drug innovation', and pharma companies increased investments in drug marketing and in the intensive promotion of inessential drugs in major markets which had the ability to generate mass demands. This trend especially emerged in the USA following the 1997 legislation of direct-to-consumer advertising of prescription drugs (ibid: 276-277).

The need for regulatory codes on advertising drugs was recognized by WHO in 1975. In the 28th World Health Assembly the WHO Director-General noted that the drugs not authorized for sale in the country of origin –or withdrawn from the market for reasons of safety or lack of efficacy are sometimes exported and marketed in developing countries, and this was unethical and detrimental to health. It noted that most developed countries stringent regulations apply to the advertisement of drugs. In contrast, controls are lacking in the majority of the developing countries. Hence, the proposal was made at the health assembly on drug regulations specifically concerning advertisement and labeling in developing countries. This proposal was opposed by a powerful lobby of IFPMA and the US administration due to which the issue did not appear in the World Health Assembly in 1984 (Mujumdar & Das, 1986: 177-178).

A study was conducted in India around mid-1980s to see how far the MNCs in India implement the voluntary code of marketing practices of IFPMA and it emerged that the MNCs do not follow their own voluntary code of marketing practices in India. Their practices are not only unfair but at times border on illegal activities (Mujumdar & Das, 1986: 178). It is the nature of double standards in sales promotion activities adopted by the MNCs between their countries of origin and the Third World countries with particular reference to India (ibid).

The physician-pharma industry relationship has been a problematic one for a long time now, and its appropriateness has been examined, discussed and debated universally, in developed and developing countries since the 1960s (Lotfi, et al. 2016; Chren, Landefeld & Murray, 1989; Chren, 1999). Liebnau (1987) had pointed out thirty years ago, in his account of the formation of the American pharmaceutical industry, that the pharma industry is no different from other industries operating in similar markets. 'The industry has also had to withstand repeated attacks from critics within and outside the medical world. It has been under almost relentless attack since the late 1950s for a variety of sins, including

market manipulation, price fixing, dumping and all manner of unethical medical and business practices' (Liebnau, 1987: vii). This is the sort of behaviour of large and powerful industries, especially those which operate internationally and wield professional, economic and political power. We should not be shocked by this, or be so naïve as to believe that it differs from other industries' (ibid: vii).

So, the organization of medicine production by private industry, which is motivated by goals of profits, expansion and competition, itself gives rise to such unethical practices; different companies compete to come out with innovative medicines and to then maximize their sales, for which they have to get doctors to prescribe those medicines, and hence justify their promotional practices, such as those above. Further, the dominant influence of big pharmas has affected not only doctors' prescribing habits and patterns of consumption, but also the policies of national governments and health organizations, standards of drug approval, regulation and enforcement and the thrust of international legislation on patent law and access to drugs (People's Health Movement, et al. 2011: 278). The Supreme Court had observed that "Profiteering, by itself, is evil. Profiteering in the scarce resources of the community, much needed life-sustaining foodstuffs and life-saving drugs are diabolic. It is a menace which has to be fettered and curbed". It is pertinent to mention here that our first Prime Minister Jawahar Lal Nehru while laying the foundation stone of the Indian Drugs and Pharmaceuticals Limited (IDPL), had warned against the manufacture of drugs left to the private sector as their only motive is profit making (Mitra, 2018).

Given this highly pernicious influence and power of the pharma industry over medicines, which are a social good because of their significance for individual lives, for society in general, the production, availability and cost of medicines become important public policy issues. The government has a critical role in ensuring access to medicines, in ensuring that people are not deprived of essential medicines because of considerations of profit and unethical practices.

III. Role of government

Given the profit and competitive motivations of private industry, the organization of a country's pharmaceutical sector can have implications for medicine availability, price, and affordability. In the Indian context, the pharma producers are largely in the private sector. Private production of public goods gives rise to tension between the two goals. Profit logic of pharma industry can erode access to essential medicines. Unless the government steps in to formulate and enforce regulations and ensure availability and affordability, such unregulated private production has serious implications for access to medicines, especially for poor

sections of the society. Moreover drug regulation is a public policy that restricts private-sector activities in order to attain social goals set by the State. Drug regulation is the totality of all measures legal, administrative and technical which governments take to ensure the safety, efficacy and quality of drugs, as well as the relevance and accuracy of product information. Public health and safety concerns have obliged governments to intervene in the activities of the pharmaceutical sector (Ratanawijitrasin & Wondemagegnehu, 2002: 7-8).

With respect to promotional practices per se we find that the government has put the responsibility of being ethical on to the doctors and the pharma industry despite knowing that voluntary self-regulation has not worked, that they are brazenly violated. It has still not made the UCPMP compulsory, as stated in 2015. MCI does not have jurisdiction over the industry and it is the responsibility of the government to take strict measures to curb the unethical practices of the industry. The role of the government becomes critical in formulating mandatory regulatory codes, as well in their strict monitoring and their implementation at the ground level. The government also has a role to play in ensuring that the pharma industry observes labor laws and does not exploit the MRs, that it pays proper wages, follows decent terms of work and working conditions for MRs.

Standalone regulation for the industry would not be adequate though in curbing field level malpractices, but will require convergence of regulations on several fronts of the health system. Overall regulation of the healthcare sector is also required - regulation of medical practice by respective professional associations, regulation of the private healthcare sector, that also addresses problem areas such as use of allopath drugs by AYUSH, national policy for eradicating production of "me too" drugs, irrational combinations and formulations, standard treatment guidelines enforcement on medical professionals and capping trade margin of pharmaceutical drugs. Hence, strong legislation needs to be formulated for the pharma industry as well as for the medical profession in order to curb the unethical promotional practices. The medical associations which are out of the purview of the ethics committee should be brought under the MCI's now NMC's ethics committee.

Limitations of the Study:

- The study primarily focused on interviewing MR and a few key informants (doctor, and Pharma industry key informants) hence, the perspectives of the MR have been captured on promotional practices. One main limitation of the study is that it has not included the perspectives from other key informants such as chemists, Stuckists, distributors and

top pharma industry management key persons.

- The study might have given more insights on factors responsible for the ineffectiveness of regulatory codes if it would have included interviewing the government officials.
- Would have got more insights about interviewing category wise specialist doctors as well as AYUSH doctors and to see how doctors think of regulatory codes and the mechanisms to implement it at ground level.
- The study has focused only on promotional practices of pharma industry that too allopath medicines, other aspects of pharma industry promotions such as medical devices, ayurvedic medicines, cosmetics, etc. could also be explored.
- Areas which need to cover, are there any differences in promotional practices for Generic medicines and branded medicines

Areas for further study:

i) Magnitude of the unethical marketing practices unearthed as well as their impact on the cost of medicines and quality of the care.

ii) The genesis of the voluntary codes of the industry, such as UCPMP, their usefulness and effectiveness, and implementation.

iii) The factors responsible for ineffectiveness of MCI's regulatory codes.

iv) The working conditions and stress on MRs and the toll it takes on their health and wellbeing.

v) Role of civil society/patients' groups in curbing unethical practices and ensuring rational use of medicines.

vi) The extent and impact of promotional inputs on influencing the prescribing practice of the doctor (the association of promotional inputs and its effect on prescribing patterns of the doctor).

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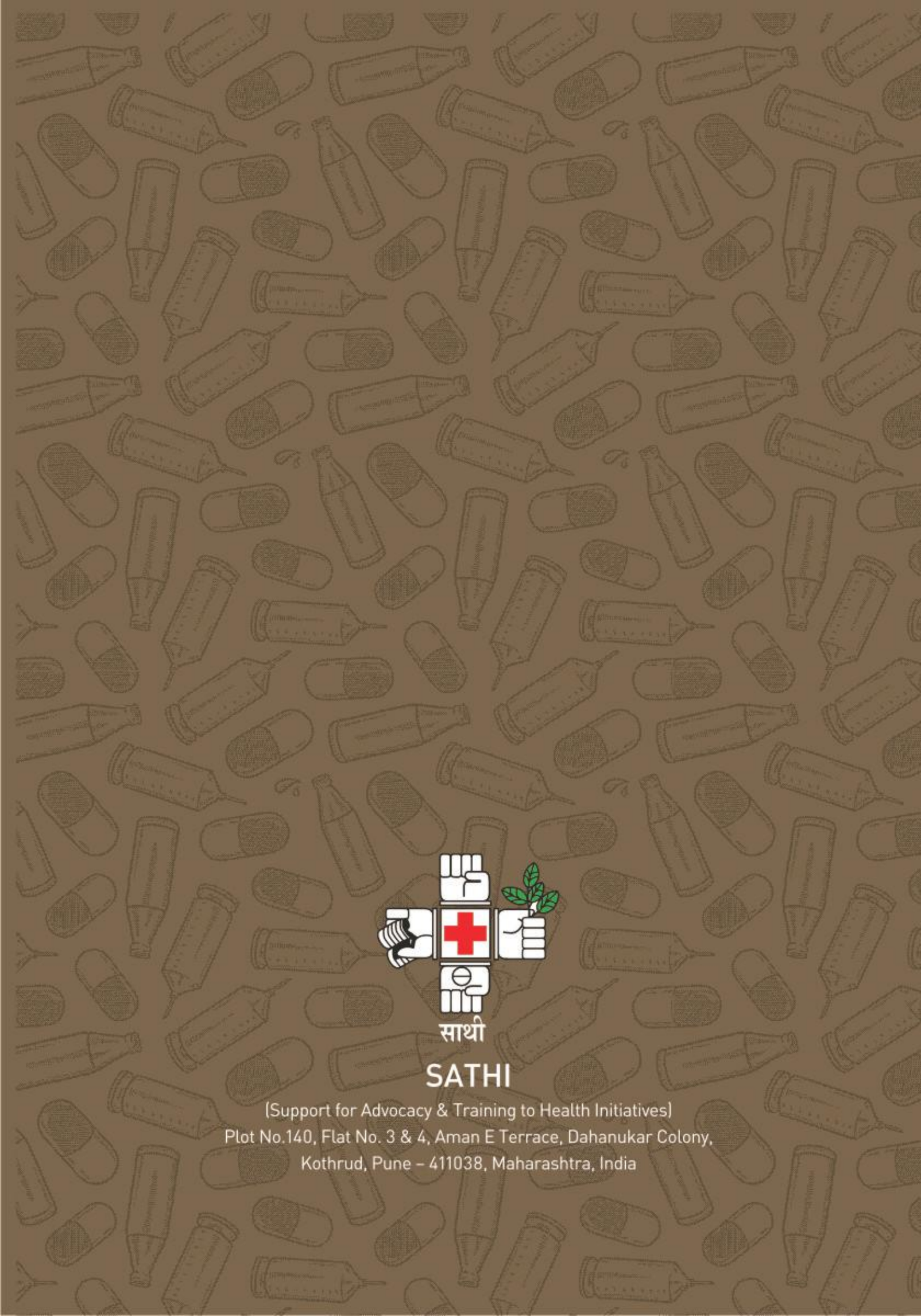

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