Pharmaceutical marketing: ethical and responsible conduct

A survey on effectiveness of the guidelines

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Recent media articles have brought to the fore the nexus between health care professionals (HCPs) and pharmaceutical companies. HCPs are lured by promises of costly gifts and foreign trips to exotic locales in the guise of seminars and conferences in return for prescribing a company’s products. This tends to impair the judgment of the HCP due to a conflict of interest between patient safety and personal gain. Several other instances of unethical behaviour on the part of HCPs and pharmaceutical companies frequently keep making the news.

Indian regulators have been attempting to effectively regulate and monitor the professional conduct of medical practitioners and pharmaceutical companies for a long time. The Department of Pharmaceuticals (DoP) under the Ministry of Chemicals and Fertilizers, Government of India, has been recently formed to look into the activities of the pharmaceutical industry. In order to check any irregularities the DoP introduced a voluntary draft uniform code of pharmaceutical marketing practices (UCPMP) for the Indian pharmaceutical industry in June 2011. Some of the areas covered in the code include claims and comparisons of medicinal products, advertising and promotional material, the activities and conduct of medical representatives as well as the hospitality extended and gifts given to HCPs. Voluntary implementation of the UCPMP by pharmaceutical associations and companies will be reviewed after six months from its initiation, and if it is discovered that it has not been effectively implemented, the Government may consider making this a statutory code.

On the other hand, the Medical Council of India amended its guidelines in 2009 to regulate the conduct of medical practitioners, to keep pace with the changing medical scenario in the country. It has introduced new regulations with regard to the relationships of HCPs with pharmaceutical and allied health sector companies.

Along with these guidelines and code of marketing, India has adopted a two-tier approach that covers HCPs (doctors) and pharmaceutical companies operating in the country, to create a transparent and ethical environment that will benefit consumers. However, diligent and effective implementation of the regulations and periodically monitoring them is imperative to ensure that the intent of the legislation is interpreted uniformly and a level playing field is maintained for all players.

At Ernst & Young, we have conducted a survey among HCPs and pharmaceutical companies to understand their perspective of the MCI’s guidelines and the DoP’s marketing code. We are pleased to share the findings of our study with you in this report.

We take this opportunity to express our gratitude to the people and organizations who took time to respond to our survey. The report and the findings would not have the same value without the support of these respondents and all those who made the survey successful.

We hope you find this report relevant and insightful.

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The ethical conduct of health care professionals is vital for maintaining professional autonomy, integrity and independence in their interactions with pharmaceutical and allied health care organizations. Implementation of good marketing practices by pharmaceutical companies demonstrates their adoption of ethical practices and transparency in their operations.

This survey is an attempt to provide an insight into how current regulations are affecting health care professionals and the pharmaceutical industry.

The survey is in two parts:

1. Part one of the survey was conducted among marketing professionals in the pharmaceutical sector on the draft uniform code of marketing practices for the Indian pharmaceutical industry (UCPMP) issued by the DoP, Ministry of Chemicals and Fertilizers, Government of India.

Some of the significant findings of the survey

- Around two-third of the respondents felt that the implementation of the UCPMP would change the manner in which pharma products are currently marketed in India.
- According to the survey, more than 50% of the respondents are of the opinion that the UCPMP’s guidelines may lead to manipulation in recording of actual sampling activity.
- More than 50% of the respondents indicated that the effectiveness of the code will be very low in the absence of legislative support provided to the UCPMP committee.
- An overwhelming majority of the respondents (90%) felt that pharma companies in India should focus on building a robust internal controls system for ensuring compliance with the UCPMP.
- Around 72% of the respondents felt that the MCI was not stringently enforcing its medical ethics guidelines.
- And only 36% of the respondents felt that the MCI’s guidelines would have an impact on the overall sales of pharma companies.

2. Part two was conducted among health care professionals on the guidelines issued by the Medical Council of India (MCI) regarding its code of conduct for HCPs in their relationship with pharmaceutical and allied health care companies.

Methodology

- Ernst & Young was assisted by a market research agency in conducting interviews.
- All the interviews were conducted telephonically.
- In all, 100 respondents participated in the survey.
Marketing of pharmaceutical products

According to the survey, three out of every five respondents indicated that the UCPMP issued by the DoP would impact marketing of drugs in India.
India has one of the fastest-growing pharmaceutical markets in the world, and its market size has nearly doubled in the past five years. The country’s pharmaceutical market is expected to reach US$20 billion by 2015 from US$11.5 billion in 2009 at a CAGR of 11.7%, and establish its presence among the world’s leading 10 markets. At present, it is the third-largest market in the world in terms of volume and 14th in terms of value.\(^1\)

In 2002, over 20,000 registered drug manufacturers sold US$9 billion worth of formulations and bulk drugs in India. However, most of the players in the market are small to medium enterprises and 250 of the largest companies control 70% of the Indian market.\(^2\)

Around 72% of the respondents indicated that the code of marketing practice will impact the manner in which pharma products are marketed to consumers.

Statistics clearly indicate the tremendous growth potential of India’s pharmaceutical sector and the degree of competition among players to secure a larger share of the market. In this industry, direct-to-consumer marketing is not popular, since patients rely on doctors’ prescriptions and guidance on any medication. Therefore, pharmaceutical companies focus more on promoting their products among HCPs. In such a scenario, this takes three main forms – such companies giving gifts and free drug samples, and their sponsoring continuing medical education (CME) for doctors.

The DoP released a draft uniform code on voluntary regulation of the marketing practices\(^3\) in the Indian pharma industry on 2 June 2011. The regulator intends to ensure that promotion of pharmaceuticals to health care professionals and interactions between pharma companies and the latter is carried out in a responsible, ethical, professional and legal manner. This will help to assure consumers that their choices in respect to their medication are made on the basis of the efficacy of each product for the individual health care needs of patients.

**Figure 1:** Will implementation of the UCPMP change the manner in which pharma products are currently marketed in India?

**Figure 2:** Will UCPMP guidelines on claims and comparisons, and textual and audio-visual promotional material result in more transparent and ethical marketing of pharma products in India?

According to the code, pharma companies will be required to disclose relevant information on indications for use, known side effects and contra-indications of drugs for patients, to enable them to make informed decisions on their choice of medication. Furthermore, misrepresentation of existing products as new ones by simply changing their packaging will not be possible under the provisions of the code.

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\(^1\) Taking wings, Ernst & Young, 2009; “Indian pharma market valued at over Rs 55K crore in FY10,” The Economic Times, 30 July 2009.


\(^3\) www.pharmaceuticals.gov.in/uniformcode.pdf
Record-keeping of samples and hospitality provided

Drug samples distributed by drug companies to medical practitioners form an essential part of their overall marketing strategy. According to the survey, more than 50% of the respondents felt that enforcement of UCPMP may lead to manipulation in recording actual sampling activity.
The record-keeping requirements defined in the code, relating to distribution of free samples, is expected to bring transparency on the number of units sampled, the names of medical representatives, as well as the place, quantity and date of sampling, and also identify the beneficiaries of the free samples. This will help to curb unethical practices in the guise of sampling. Furthermore, it will also help to identify whether organizations are complying with the other provisions of the code.

Figure 3:
In light of UCPMP regulations relating to distribution of free medicinal samples, would field formations indulge in manipulation of records to conceal non-compliance with the code?

Sample: 50 | Base: All

In the absence of any clear directives or quantification for extending hospitality to HCPs, it appears that the regulator may have left a gap for pharma companies to take undue advantage of the code.

More than 80% of the respondents felt that the words “reasonable” and “appropriate” in the code are open to interpretation by pharma companies.

Figure 4:
What is the possibility that lack of explicit monetary limits set in the UCPMP in respect to guidelines on “reasonable hospitality,” as well as on “appropriate travel expenses, meals, refreshments, accommodation and registrations,” etc., for HCPs will be open to interpretation by pharma companies?

Sample: 50 | Base: All
Impact on pharmaceutical sales

Nearly two-third of the medical practitioners who participated in the survey felt that the MCI’s guidelines will have no impact on the sales of pharmaceutical companies.
Figure 5: Do you think the MCI's guidelines, issued on 10 December 2009 in respect to the interactions of practicing physicians with pharmaceutical companies, will have an impact on the overall sales of pharmaceutical companies?

Sample: 50 | Base: All

- Yes: 36%
- No: 64%

MCI code of medical ethics for HCPs do's and don'ts

- No gifts, travel facilities or hospitality to be accepted from pharmaceutical and allied health care organizations
- No cash or monetary grants accepted in individual capacity
- Ensure that medical research conducted is accurate and ethical
- Maintain professional autonomy
- No public endorsement of drug/ industry products

More than three-fourth of the respondents, out of those who indicated that sales will be affected, felt that the extent of this effect would be more than 6%.

Figure 6: To what extent will the sales of pharmaceutical companies be affected by MCI's guidelines?

Base: 18, All who agreed that MCI guidelines will impact the sales of pharmaceutical companies

- >6% of total sales: 78%
- 4% to 6% of total sales: 17%
- 1% to 3% of total sales: 6%
- <1% of total sales: 0%

Medical Council of India

The MCI was established in 1934 under the Indian Medical Council Act, 1933. Its main function is establishing uniform standards of high qualifications in medicine and recognizing medical qualifications in India and abroad. Faced by the challenges posed by the speedy development and progress of medical education in the country, the old Act was repealed in 1956 and a new one enacted. This was further modified in 1964, 1993 and 2001.

The MCI initiated with a regulation related to the professional conduct, etiquette and ethics of registered medical practitioners in 2002. This is called the Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002.*

In 2009, these regulations were further amended with the aim to achieve the following:

- Build a healthy relationship, based on self-regulation, between doctors and the pharmaceutical and allied health care sector, and prevent the unscrupulous practices of some doctors
- Enhance transparency in sales promotions, ban bribes paid to doctors for drug promotions and control other unethical practices
- Stop medical professionals from accepting gifts or perquisites such as free holidays from drug manufacturers and ensure that they prescribe drugs by their generic rather than their brand names

Effectiveness of the regulations

More than 50% of the respondents felt that the MCI’s guidelines for medical practitioners and the DoP’s code of marketing practices for pharma companies will not suffice to ensure ethical marketing of drugs in India.
Nearly three-fourth of the respondents have highlighted inadequate enforcement of these guidelines. Therefore, it may take some time before the unethical drug promotion practices of some medical practitioners and pharma companies are stopped.

Figure 8:
Has there been significant enforcement of these guidelines by the MCI?

According to 72% of the respondents, there has not been significant enforcement of the MCI’s guidelines.
According to the survey, 90% of the respondents felt that pharma companies need more robust internal controls to ensure their compliance with regulations.
The relationship between medical practitioners and the pharma industry goes a long way back, since they are dependent on each other. What initially began as an information-sharing practice has evolved over a period of time into aggressive marketing strategies targeted at HCPs, to ensure greater coverage and translate into enhanced sales for pharma companies. Consequently, practices such as giving gifts and other incentives to HCPs have crept into the system. This has raised serious concerns relating to the professional autonomy and integrity of HCPs accepting such enticements and their duty and responsibility to their patients.

Specific regulations in the amended MCI guidelines, prohibiting such practices, have therefore been put into practice. However, our survey respondents felt that the MCI has not been effective in implementing these regulations.

The draft UCPMP for the Indian pharma industry aims to specifically regulate practices related to pharma companies marketing their products to HCPs and their relationship with the latter.

The Government will continue to introduce new regulations to monitor the relationship between health care professionals and the pharma industry. **Pharma companies will need to demonstrate their compliance with these regulations and be transparent in their interactions with health care professionals. They can achieve this by putting in place an effective internal compliance review program (CRP).**

Some of the essential characteristics of a CRP:

- Assess existing processes and controls on activities covered by the code
- Design guidelines or frame SOPs and templates to implement practices laid down in the code
- Implement guidelines and establish independent approvers for transactions with respect to the code
- Conduct periodic testing and monitoring of transactions to assess their compliance with the code
- Review and improve practices for effective compliance
- Impart training to target audience for effective implementation of SOPs and guidelines
Annexure

Profile of respondents

Figure A:
Total no. of respondents - 100

Pharma professionals 50%
Health care professionals 50%

Figure B:
Total no. of respondents from pharmaceutical companies - 50

Marketing professional 58%
Product manager 16%
Others 20%
Brand managers 6%

References

• www.pharmaceuticals.gov.in/uniformcode.pdf
• http://www.mciindia.org/RulesandRegulationsCodeofMedicalEthicsRegulations2002.aspx
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