Indian ethics code: will industry self-regulation suffice?   
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*The Medical Council of India's (MCI) efforts to regulate the symbiotic relationship between drug companies and physicians have brought to the fore the sticky issue of whether industry itself needs more regulation or whether self-regulation would suffice.* Scrip *'s India Editor Anju Ghan* *g* *urde* *t* *akes a look at some of the issue* *s* *.*

Last December, the MCI amended the Professional Conduct, Etiquette and Ethics Regulations 2002, stating that medical practitioners should not accept gifts, travel facilities, hospitality and so on from industry. Recently, MCI's president, Dr Ketan Desai, is said to have written to the Indian government seeking similar regulations for the pharmaceutical industry, so that the MCI's amended regulations could be implemented effectively.

Industry experts are somewhat divided on whether self-regulation has and will work in India, even as several global companies have attempted to come clean on specific fees paid to physicians by making voluntary periodical disclosures.

Tapan Ray, director general of the Organisation of Pharmaceutical Producers of India ( OPPI), said that the MCI regulations, along with self-regulation by the industry, "should work well" in India without any further government regulations.

"When, in a much larger and diversified fast-moving consumer goods industry, a robust self-regulation under the Advertising Standards Council of India (ASCI) is working so well, it is difficult to understand why a similar system of self-regulation will not work in the Indian pharmaceutical industry," he told *Scrip*.

Dr R B Smarta, managing director of Interlink Marketing Consultancy, which framed the Indian Drug Manufacturers' Associations' code of ethical practices, said that it isn't regulation but "governance" that is required to enforce high ethical standards.

Dr Smarta suggested the formation of a committee or an apex body (possibly along the lines of ASCI), with representatives from various stakeholders including physicians, pharmacists, industry and maybe a lawyer, which could take up issues concerning such practices and perhaps issue warnings to those flouting the code.

There are, however, other opinions. Dr Ajit Dangi, president and CEO of Danssen Consulting and a former executive director of Johnson & Johnson India, said that, while industry associations in India have written guidelines on ethical marketing practices, these have not always worked.

"Unfortunately, this has not worked satisfactorily and there have been some errant pharma companies flouting these guidelines. At the same time there have been pressures from various medical associations on pharma companies for donations to sponsor their annual conferences. Further regulations are therefore necessary," Dr Dangi, who is also a former director general of OPPI, told *Scrip*.

He added that medical associations, which endorse certain OTC products such as nutritional products, mouthwashes and toothpaste, also needed to be regulated.

**disclosure**

There have been global attempts to raise the bar in terms of greater transparency in disclosing payments made by industry to physicians.

Mr Ray referred to self-regulatory efforts by companies such as Lilly, Merck & Co and GlaxoSmithKline, which have published a list of fees paid to US healthcare professionals for speaking and consulting services, besides reporting payments to these professionals or their affiliated institutions for conducting research.

"Similarly in the UK, the Royal College of Physicians has been reported to have called for a ban on gifts to the physicians and support to medical training, by the pharmaceutical companies," he added.

Last year, the Royal College of Physicians issued a report of a working party entitled "Innovating for health: patients, physicians, the pharmaceutical industry and the NHS". This recommended that in rewriting the relationship between medicine and the pharmaceutical industry, and in the spirit of a more balanced and mutually respectful partnership, all gifts to doctors, including food and travel, "become untenable and should end".

"All these are self-regulatory in nature and the concept is increasingly gaining ground. If a transparent, uniform and robust self-regulation system can be made to work effectively within the pharmaceutical industry, I reckon there may not be any further need of increased transparency for gaining public trust," Mr Ray said.

Industry also wants clarity on MCI's new rules since genuine efforts at continuing medical education (CME) or clinical research could be hit, it claims.

Dr Dangi noted that there are genuine initiatives by pharmaceutical companies to educate the medical profession, and unless there are clear guidelines regarding such practices from MCI, ethical companies will suffer.

Mr Ray added that there were apprehensions that "very important and informative" CME, which in turn could help patients immensely, may be adversely affected with the new regulations, as could areas involving medical/clinical research and trials.

"The OPPI Code of Pharmaceutical Marketing Practices, on the other hand, very clearly specifies a practical and neutral 'Do's and Don'ts' in the areas of CME," he claimed.

An MCI official was recently quoted in *The Hindu Business Line* as saying that the ethics code applies to companies sponsoring only individual doctors and not associations, and that CME courses would not be affected.

The report of the Royal College of Physicians had recommended that the Association of the British Pharmaceutical Industry and its members should establish a pooled fund to invest in medical education. "Such a fund would unlink financing from a single company, diminishing the perception of undue commercial influence and bias," it claimed.

**innovation and secrecy**

But CME and clinical research studies are some of the more obvious areas of industry-physician 'collaboration'. Innovation and significant levels of secrecy, traits associated with the pharmaceutical industry, are at times effectively used by companies in this area too.

Gifts in India may include sponsoring the higher education of children of "important" physicians, development of clinics and even payment of premiums on asset loans as long as sales targets are met (on expiry of the loan period for the asset it is passed on to the physician), said an Indian industry expert, who did not want to be identified.

He also added that at times CME may be used to inform doctors about other potential uses of a drug, which may translate into possible "off-label" uses.

The MCI's amended regulations suggest that a medical practitioner may participate and work in research projects funded by pharmaceutical and allied healthcare industries, provided that he or she: ensures the research proposal has permission from the concerned authorities; the source and amount of funding is publicly disclosed at the beginning; and that, while accepting such an assignment, the medical practitioner shall have the freedom to publish the results of the research in the greater interest of society by inserting such a clause in the memorandum of understanding or any other document for the assignment