The Medical Council of India guidelines on industry–physician relationship: Breaking the conspiracy of silence

The Medical Council of India (MCI) in an amendment to its existing code of conduct, the Indian Medical Council (professional conduct, etiquette and ethics) regulations 2002, has proposed sweeping guidelines on the relationship between the pharmaceutical industry and the medical profession in India.[1] This is an attempt at a code of ethical conduct for doctors and professional associations in their relationship with the pharmaceutical and allied health sector industry. The MCI is a qausi-judicial body and its code, though not law, is ethically binding on all practitioners of modern medicine in India. It is interesting that a council which is not exactly known for its proactive stance on ethics has chosen to issue one of the most explicit and comprehensive set of rules on this subject. The impact of these guidelines on ground reality remains to be seen but, if recent news items are to be believed, by doing so the MCI has at the least succeeded in breaking the conspiracy of silence that surrounded this area in India. In a sense, the guidelines read like a confessional list of a large number of debatable practices in industry marketing that have become commonplace over the years. The guidelines also cover clinical trials sponsored by the industry, an area of current relevance. Following the initial guidelines, the MCI has now gone a step further by announcing a list of punishments which are graded based on the financial quantum of the gift received. For example, those who have received more than Rs 1 lakh (Rs 100 000) will be deregistered for more than a year.[2] The MCI claims that this is the first time in the world that quantums of punishment have been specified.

Throughout the world, the relationship between the pharmaceutical industry and the medical profession has been a contentious one. Both in the context of marketing tactics as well as sponsored research, there have been numerous examples of inappropriate attempts at influencing physician behaviour.[3] Attempts by the industry at affecting physician prescribing habits by influencing content in conferences, journals and medical association guidelines are well known.[3] However, it is the cruder attempts at direct bribing by sponsorship of activities such as all-expense-paid holidays that have raised hackles and exploded onto the public domain. In a well publicised case in 2001, a leading multinational was fined a hefty amount by a Dutch court for entertaining doctors excessively by sponsoring a skiing holiday, contrary to the Dutch marketing code for prescription-only drugs.[4]

The response of the medical profession to such controversy has been variable, but in some countries national medical organizations have come out with codes of conduct for their members. The American Medical Association in its code of ethics has a separate section dealing with gifts to physicians from the industry, which explicitly details what is acceptable and what is not.[5] In the UK both the General Medical Council in its 'good medical practice' document as well as the British Medical Association have laid down guidelines on the issue. From the industry side, the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) has a detailed code in place which was modified in 2007.[6] The Organization of Pharmaceutical Producers of India (OPPI) has also adopted a modified version of this code. The medical profession and its associations in India have however been largely silent on the subject.

The MCI amendments look at two broad areas. First, they address the issue of gifting and sponsorship. In the current Indian scenario, with the increasing expanse and aggression of the pharmaceutical industry and the permissive atmosphere of the new economy, industry attempts at wooing physicians have been taking unique forms. Frequent foreign trips to exotic locations allegedly to attend conferences is the most well known. Holiday junkets for family, sponsorship of personal celebrations including birthday parties have also appeared on the scene. Medical conferences have long ago degenerated into lavish celebrations largely because of liberal industry sponsorship.[7] Things have reached a point where medical practitioners can perhaps no longer

envisage continuing medical education (CME) without pharmaceutical presence. The MCI code now specifically prohibits practitioners from accepting gifts, travel facilities, hospitality and monetary grants from the healthcare industry either in their name or in the names of their family members. It also bars doctors and their family members from accepting rail or air travel facilities, cruise tickets, hospitality and paid vacations from the industry. The guidelines are much more specific on these issues than on many others because they actually do not leave room for interpretation of what is often termed 'reasonable hospitality'. For example, the guidelines explicitly state that: 'A medical practitioner shall not accept individually any hospitality like hotel accommodation for self and family members under any pretext.'[1]

It is paradoxical that doctors, in general, are opposed to incentives, but are also convinced that accepting gifts would not influence their professional behaviour and believe that promotion is ineffective. This is perhaps one of the reasons that there has not been much organized action by the profession to root out the practice of receiving gifts. Gifts are often justified as a token of appreciation for the time the medical representatives took away, which could be more profitably utilized attending to patients. Most doctors claim that their own judgement about drugs and brands is never obscured by incentives, but that other colleagues have 'given in' to the pressure of incentives. This has been labelled by experts as the 'theory of unique invulnerability'. However, there is good evidence to suggest that gifting does influence prescription habits. A large review of published articles from 1994 onwards concluded that meetings with pharmaceutical representatives were associated with requests by physicians for adding the drugs to the hospital formulary and changes in prescribing practice.[8] Drug company-sponsored CME preferentially highlighted the sponsor's drug compared with other CME programmes. Attending sponsored CME events and accepting funding for travel or lodging for educational symposia were associated with increased prescription rates of the sponsor's medication. Attending presentations given by pharmaceutical representative speakers was also associated with non-rational prescribing.[8]

In a study done in 2003, by one of us, very few doctors admitted to having accepted gifts; those who did stated that accepting the gift would not influence their decision about which brand to prescribe.[9] Ironically, almost all of them knew of another professional who had accepted gifts and believed that their prescribing had been influenced by this incentive. Whereas pharmaceutical companies were concerned about the declining cost-efficiency of this strategy, doctors complained that the medical representatives' repeated visits hindered the practice. Drug companies stated that funding medical conferences had become less cost-effective; they suggested that doctors as a group had begun to pressurise pharmaceutical companies into financing their associations' programmes and would even boycott drug companies that did not give in to their demands.

The other area addressed by this amendment is industry-sponsored research which has acquired tremendous importance in view of the explosion of the clinical trial industry in India. It recommends that researchers ensure that the particular research proposal has due permission from the competent concerned authorities including clearance of national, state or institutional ethics committees. It also recommends that the researcher ensure that the source and amount of funding is publicly disclosed at the beginning of the project and that proper care and facilities are provided to human volunteers, if they are necessary for the research. Finally, the guidelines state that while accepting such an assignment a 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 document for the assignment. Although all these areas (and their violations) have been highlighted by health activists, these guidelines coming from the MCI will have added weight.

The MCI can of course go beyond just pontification and be proactive on the issue by increasing access to non-commercial drug information (such as the British National Formulary), encourage CMEs in medical colleges and lead by example. It can engage specialty associations on the issue and for starters offer official CME credits to only

those meetings which honour these guidelines. Unfortunately, the MCI itself lacks credibility among the profession, has been surrounded by controversy and has spent a large part of its recent existence trying to shake off charges of corruption.[10] Therefore, the implementation of such a code in the Indian scenario will be difficult, slow and perhaps subject to constant attempts at subterfuge. For example, the industry has started offering indirect sponsorship for attendance of conference by routing it through medical associations or non-governmental organizations (NGOs) which act as fronts. A distinction is sought to be made between a 'delegate' and 'faculty' as the MCI guidelines use the word delegate for those attending conferences. A recent news report gives details of a sponsored trip to Istanbul for a group of physicians for a meeting on diabetes, and quotes the company chief saying that they need time to implement the MCI amendment.[11]

Sponsorship and gifting is not just an issue of ethics and morality. In the Indian context, one of the dangers posed by industry incentives is the rising cost of sales and promotion which in turn may affect the pricing of drugs. This is why this issue is also relevant to the public health debate. It also has implications for the practice of evidence-based medicine, a movement which is in its infancy in India. There are many key actors in the game of pharmaceutical marketing, which include manufacturers, chemists and medical representatives, besides physicians. Each of these groups has their own voluntary code of ethics. This amendment and its adoption by medical associations could be seen as the medical profession's contribution to a larger process of transparency, accountability and professionalism which is manifesting in some sectors of Indian industry.

The MCI amendment may have provided the spark for a process of reflection among medical professionals and industry in India on their relationship with each other. Among many others this is one good reason to welcome it.

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