

Ethical marketing of Pharmaceutical products appliances by Medical practitioners

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Doctors and the pharmaceutical industry have significant common interests. To start, both are concerned with encouraging the use of existing drugs effectively and responsibly in the treatment and care, monitoring of their use, and innovative research.

However, both have different emphases and are answerable to various stakeholders. Doctors are concerned primarily in patient care and scientific advance, while the industry is mainly interested in commercial outcomes. The primary stakeholder for the Doctors is in patient care - the patient, whereas the principal stakeholder in the industry is - the shareholder. In spite of these shared interests and benefits of cooperation, concerns of an ethical nature arise between both the medical profession and the community. There are three main concerns:

1. The possibility that associations between doctors and drug companies may serve commercial objectives of industry and personal interests of clinicians rather than legitimate care, educational or research goals compromising the primary ethical objectives of doctors to patients, undermining the necessary foundation of trust on which clinical relationships depend;
2. The risk that drug promotion will unjustifiably influence doctors' decisions;
3. The danger that industry involvement in research will lead to distortions, now

proven in many cases worldwide, in scientific evidence & independent assessment of data.

An "interest" is a commitment, goal or value that arises out of a particular social relationship or practice. The possibility that dealings with drug companies might lead "conflict of interest", has been of concern, but identifying such conflicts is not easy.

Sources of concern

It is common for relationships to be associated with several interests. Interests of medical practitioners include both altruistic as well as personal:

- Patient welfare
- Community welfare
- Research grants
- Advancement of career by participation in research
- Hospitality & pecuniary interests (eg, consultancy fees, shareholdings, paid sessions)

When a doctor is engaged in a relationship with a pharmaceutical company, a duality of interests exists. It can't be assumed that such a duality will constitute a "conflict" in each case; this depends on the particular circumstances. Dualities of interest are common; conflicts relatively rare. Further, whereas the distinction between the two is sometimes clear-cut, at other times, it may be subtle and depend on values of the community within which it occurs.

Dualities of interest constitute "conflicts" only when they are associated with competing obligations that are likely to lead directly to a compromise of primary responsibilities. To establish whether a conflict of interest exists, it is necessary for the factual details to

be declared and for the community to have the opportunity to scrutinise the issues publicly.

Main areas are:

Drug promotion

Promotion and marketing (including advertising, gift-giving and support for medically-related activities such as travel to meetings), a considerable part of the activities of drug companies (consuming a quarter to a third of their entire budgets). It is estimated that, of this, a third is spent on advertising and a third on sales representatives, while the rest third is spent on physicians.

Advertising

Doctors generally perceive the way they practise to be determined by knowledge and evidence, but they often fail to recognise and underestimate the subtle and pervasive effects of pharmaceutical promotion. Some practitioners rely on pharmaceutical company representatives for much of their drug prosthesis and appliance information. There is considerable evidence that advertising affects clinical decision-making behaviour. As it does in every aspect of day to day life. Contact with drug company representatives leads to prescribing of their drugs and products; physicians exposed to advertising are more likely to accept commercial rather than well established scientific views, and is associated with an inability of some physicians to identify wrong claims and a propensity to engage in non-rational prescribing behaviour.

Gift giving

Gift-giving is another widespread drug-promotion strategy. A study showed that, over a period of one year, psychiatry residents and interns attended up to 35

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meetings and 70 drug lunches and received up to 75 promotional items gifts. Although physicians deny that gifts influence their behaviour, there is clear evidence to the contrary. Those who met with pharmaceutical representatives were more likely to ensure inclusion of the company's products in their prescriptions; those who accepted money to speak at symposia were more likely to do so, and those who accepted money to perform research were also more likely to do so.

Support for travel

There is evidence that drug company support for travel expenses changes the prescribing behaviour of practitioners, it has been shown that a physician who accepts money to travel to a symposium is more likely to prescribe a company-sponsored drug and product after such sponsorship than before.

Meeting sponsorship and continuing medical education activities

Support for meetings is an important issue. There are clearly common interests between professional societies, which are usually responsible for organising conferences, and the pharmaceutical industry: one stands to gain funding for their meetings and other activities, while, for the other, opportunities are provided to showcase their wares. However, the impressions that people go away with may be significantly altered by the choices of speakers and topics at meetings, which may have important implications for pharmaceutical companies. Indeed, sponsorship of conferences has been shown to lead to bias in favour of the sponsoring companies' drugs, with increases in prescriptions for sponsors' drugs in the six months after an event. Similarly, pharmaceutical support for continuing medical education (CME) activities leads to increased prescribing of sponsoring companies' products. This occurs even when the course content is controlled by the society or institution and the drugs are referred to by their generic names only.

Control of publication and research outcomes

The effect of drug company sponsorship

on research and publications is a significant issue. Briefly, there are many ways in which research findings can be directed towards producing the desired result, ranging from careful design of a trial and selection of drug doses to selective reporting of results or actual suppression of unfavorable outcomes, those with unfavorable results are never sent for publications. The prominence of a publication can be enhanced by paying authors to participate or publishing non-peer-reviewed material as a supplement in a respected journal.

Guidelines for action (the new MCI code)

Professional bodies have considered these issues and other organisations, which have from time to time developed guidelines and codes of conduct for their members. Although opinions differ, no professional bodies or institutions have proposed a ban on interactions between doctors and the pharmaceutical industry. Indeed, it is accepted that such a policy would not serve the interests of any party. The most preferred approach is to develop a relationship that allows transparency and is based on clear, but non-coercive guidelines.

The MCI is a quasi-judicial body and its code, though not law, is ethically binding on all practitioners of modern medicine in India. 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

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. The MCI claims that this is the first time in the world that quantum of punishment has been specified. 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 activism of the pharmaceutical industry, attempts at wooing physicians have been taking unique forms. Frequent foreign trips to exotic locations allegedly to attend conferences is well known. Holiday junkets for family, sponsorship of personal celebrations including birthday parties have also appeared on the scene. Things have reached a point where medical practitioners can perhaps no longer envisage continuing medical education (CME) without pharmaceutical presence. The new 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 any biased 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.' Doctors, in general, are opposed to incentives but are also convinced that accepting gifts would not influence their professional behaviour. 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.

Most doctors claim that incentives never obscure their own judgement about drugs and brands, but that other colleagues have 'given in' to the pressure of incentives. 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.

Pharmaceutical companies stated that funding medical conferences had become less cost-effective; they claim that doctors as a group had begun to pressurize pharmaceutical companies into financing their associations' programmes and boycott drug companies that did not do so

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, even if negative, in the greater interest of society by inserting such a clause in the document for the assignment.

Potential Conflicts of Interest

The arrangements between physicians and pharmaceutical companies should be open and transparent. Conflicts ought to be clarified and clearly declared in the relevant context - to the patients, research participants, hospital committees. Whether they constitute conflicts should not be left to the individuals concerned to decide, but to a process of informed public debate within the setting in which the conflict arises. Where conflicts appear likely, special procedures should be devised to avoid unacceptable outcomes.

Drug promotion, including acceptance of gifts and travel support

Ideally, drug promotion should be restricted to the dissemination of well-founded data

about specific products. Various levels of advice have been advanced to medical practitioners about accepting gifts. from blanket rejection to a gradient of moral acceptability based on cost, to the principles that gifts should not be excessive and should not influence decision-making, to the test of whether the recipient would be willing to have the arrangements publicly known.

The safe way for practitioners to adopt is that they should go to the rejection of gifts. Support for travel to meetings (including conferences organised by professional societies and CME courses) should be restricted to those making formal contributions, like speakers and faculty.

Sponsorship of meetings

Full disclosure of commercial sponsorship of meetings should be made. Sponsorship should always be provided through independently organised scientific committees; speakers should indicate dualities of interest at the time of presentation; and sources of commercial funding should not influence scientific, educational decisions. There needs to be lesser expectation of entertainment, grand dinners, receptions and free food in association with conferences and symposia.

Research

In cases where research projects are being funded by the pharmaceutical industry, the overriding principle is that of bias in research and publication. This is an issue of major public importance that needs to be actively addressed by the medical profession in consultation with consumer organisations, government and the pharmaceutical industry.

Conclusions

Medical practitioners and the pharmaceutical industry serve interests that sometimes overlap and sometimes conflict.

· There is strong evidence that associations between industry and doctors influence the behaviour of the doctor in relation to both clinical decision making and the conduct of research. In view of this risk of

compromising relationships with patients and the integrity of the research process, doctors must exercise care in their dealings with industry.

· The basic principles underlying the conduct of doctors with respect to pharmaceutical companies should be open and transparent.

· Clear guidelines should be developed to deal with specific issues such as travel subsidies, receipt of gifts, sponsorship of conferences and continuing education activities, and dualities of interest arising in clinical and research settings. There should be penalties laid down for transgressions.

In the end, the clinician should exercise his fundamental ethical values in all such interactions.

The current pattern of relationships between doctors and the pharmaceutical industry is the outcome of a long-established culture in which gratuities, gifts and the like are both expected and provided. As a result, the change will require a substantial shift in attitudes and values and thus is likely to be slow. Research into the expectations of stakeholders and the impact of the various practices discussed may contribute fruitfully to community debate.

In reviewing a number of the issues concerning the relationships between medical practitioners and the pharmaceutical industry, we have tried to emphasise that benefits received from pharmaceutical companies must leave the independent judgement of physicians unimpaired and that arrangements between physicians and pharmaceutical companies ought to be open and transparent. The overriding principle should be a firm belief that the values of science and clinical medicine must prevail over commercial imperatives. If these simple guidelines are followed, we feel that much progress will be made towards alleviating the concerns of both the community and the medical profession.

Conflict of Interest: NIL
Source of Support: NIL

How to Cite this Article

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