

RELATIONSHIP BETWEEN THE MEDICAL PROFESSION AND THE PHARMA INDUSTRY: Need for greater scrutiny, transparency and accountability

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The relationship between the medical profession and the pharmaceutical industry has come under severe criticism all over the world in the recent years. The industry is being blamed for corrupting the medical profession. This disease is not only prevalent in the developed world but in the developing countries too where prices of most of the drugs remain beyond the reach of the common man. The industry is alleged to indulge in all sort of unethical practices to influence the prescribing habits of the doctors for which they are rewarded through various ways. These include joy rides for the physicians and their families to picnic spots within the country and overseas, provision of costly gifts, entertainment for the families at five star hotels, sponsoring birthday parties, wedding receptions besides furnishing the doctors homes and clinics. Of late even allegations of providing cars on leasing have also been reported. All this has brought a very bad name to the entire community of doctors although vast majority of them are conscientious, ethical and God fearing and mostly refrain from accepting such favors despite lot of temptations. Time has come that this relationship must be looked into carefully to ensure transparency and accountability.

Change in the doctors' attitude

During the past few years, there has been manifold increase in the demand and expecta-

tion of medical profession. The attitude of doctors has changed. For example:-

- They ask for or readily accept the offer for free travel and hotel accommodation.
- Give green cards against donation for building fund and refuse to see the Medical Representatives if donation is not given.
- Group of doctors have formed companies and are prescribing their products.
- They have an increasing liaison with chemists to prescribe a product which provides more discount to chemists.
- They ask money per prescription particularly for prescribing more tonics and vitamins.
- Request for renovation of clinics, hospitals etc.

Discussion on these sensitive issues in the Medical Press

This sensitive issue has been the subject of discussion in editorials and the correspondence section of even prestigious medical journals. Lancet in one of its editorial wrote that "It begins on the first day of medical school and lasts through to retirement and it is the only reliable "cradle to grave" benefit that doctors can truly count on any more. It starts slowly and insidiously, like an addiction and can end up influencing the very nature of medical decision-making and practice. It first appears harmless enough, a textbook here, a penlight there and progresses to stethoscopes and black bags, until eventually come nights on the town at aca-

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demic conventions and all expenses paid educational symposia in lovely locales".¹

Sarmiento A in a letter to the Editor in JAMA wrote that "The corporate world owns many of our political representatives in Washington DC. The medical situation is not very different; industry owns physicians and dictates the course of education, research and ultimately the practice of medicine in degrees previously unimaginable."²

Yet another report alleged that "one pharmaceutical company employs several eminent British cardiologists to lecture to other doctors around the country to promote the company drugs. These cardiologists, known to company employees as the Road Show are each paid three to five thousand Pounds plus traveling expenses for a lecture lasting one hour. Those who agree to speak fortnightly for the company receive more money each year and this payment is more than their annual salary from hospital or university. Some opinion leaders involved in pharmaceutical research now command speaker fees that are so high that their engagements are negotiated by an agent".³

Conflicts of interest involving Pharma companies

The Pharma industry's influence on physicians, medical education and patient treatment is much more than these physicians themselves realize and all this involves greater ethical problems than their accepting gifts of penlights and free lunches, dinners to all expense paid participating in seminars, symposia and medical conferences. Many big pharmaceutical companies are now alleged to keep track record of individual physicians prescribing patterns and then attempts are made to change those. At times they are persuaded to prescribe more expensive drugs although the less expensive drugs are as effective. To achieve these objectives, the industry makes use of the sophisticated computer technology by compiling resume on prescribing patterns of eminent healthcare professionals who are considered as opinion leaders and they influence the pre-

scribing habits of the young doctors. Generous distribution of samples is yet another way to influence the doctor's prescribing habits. According to a report the pharmaceutical industry distributed samples worth 7.2 billion dollars to US doctors in 1999.⁴

And this is not all; the Pharma industry is also alleged to be in "The practice of buying editorials in prestigious medical publications" which reflects its ever-growing influence on medical care. At times information meant for the physicians is carefully prepared by public relations firms. While in the past publication from the drug trials used to be written by principal investigators but now professional medical writers do this job which is known as "*non-writing author non-author writer syndrome*". This has two features; a professional medical writer the ghostwriter is employed by the drug company who is paid to write but is not named as an author and a clinical investigator (guest author) who appears an author but does not analyze the data or write the manuscript. In one study 19% of the articles surveyed had named authors who did not contribute sufficiently to the articles to meet the authorship criteria".⁵

All these actions are carefully planned and executed as recommended by the peers in the industry. For example a 24-page guide published as a supplement in May 2001 edition of Pharmaceutical Marketing "advises the marketers to identify opinion leaders instead of wasting money on those who have no credibility with their peers. It further suggests that marketers should aim at those members of the medical profession who are on the Editorial Boards of important medical publications, those who are on the scientific committees, members of the important professional societies and associations, representative of national and international guidelines committees besides key players in the Formulary Committees". The key aim, this guide says "is to ensure that you are working with a mix of people who can be ultimately used to communicate on your behalf in different situations". As such it is not surprising to note that many national

and international guidelines committees are loaded with researchers and investigators who have strong financial interest in pharmaceutical industry.

The Year 2003 saw a great surge in efforts by the Pharma industry trying to buy doctors and thereby influence their prescribing decisions by developing a close relationship with them. These ethical issues are increasing with the passage of time. Dr. Richard Smith Editor of BMJ addressing an industry audience recently is reported to have concluded that “the relationship between the industry and the Prescriber was in trouble”. He suggested for disentanglement of industry and medicine.⁶

Last year BMJ even devoted one of its issues to this wherein it even questioned the conduct of a part of the healthcare professionals. It went even so far to depict the doctors as pigs and the industry as lizards feasting on a table. But complete disentanglement of industry and the medical profession may not be as easy as according to a report it sponsors about 50% of GPs education in UK.⁶

According to another report the Pharma industry provided 57% of the revenue for CME programmes in UK last year for the 685 Accredited CME providers of the Association of Accreditation Councils for CME (ACCME). The medical establishment and the government agencies in UK are now looking for CME which is fully independent of Pharma industry's influences.⁷ According to another report the pharmaceutical industry in USA spends approximately 12 billion US Dollars annually on gifts and payments to physicians.⁸ Hence it is essential to draw a line between education and promotion and define boundaries of acceptable behaviour. That is why new regulations are being framed in many countries of the world to reshape the way Pharma industry is working with the health care professionals. It is also adding many complexities to the fast growing educational efforts.

Prosecutors in United States have started to apply anti-kickback and false claims laws in cases dealing with healthcare professionals and the Pharma industry.

The Lupron Case: In 1997 they investigated relationship between TAP Pharmaceuticals a joint venture by Takeda Chemicals and Abbot Laboratories. It found that TAP encouraged urologists to bill Medicare at the average wholesale price for Lupron a potent gonadotropin releasing hormone agonist used for the treatment of prostate cancer although they received the drug free or at discounted price.⁹ TAP also encouraged sale of this drug through many other ways particularly employing consultants without requesting any service in return. Eventually TAP entered into an agreement with the government and agreed to pay US\$ 290 million in criminal fine plus US\$585 million in civil penalties while the whistle blowers received about one hundred million dollars of the total damages.¹⁰

Another case pertains to AstraZeneca which in 2003 settled criminal fraud charges of US\$355 million in a case dealing with its drug Zoladex¹¹ Another multinational pharmaceutical concern Schering Plough pleaded guilty on July 14th 2004 and paid a fine of US\$350 million dollars for providing grant to private physicians to conduct educational programmes which the prosecutors charged as kickbacks.¹² Schering Plough is also facing charges which are being investigated regarding its sham consulting arrangements and clinical trials to provide remuneration to physicians for prescribing its hepatitis drug Intron-A.¹³

Investigation by House of Common's Health Committee

In London the House of Commons Health Committee held its first hearing in September 2004 to study the influence of Pharma industry over healthcare systems. This committee is investigating Pharma industry's influence on education of doctors, drug evaluation, health information and medical research. It will particularly study the industry's influence on professional societies, universities, regulatory authorities and media. The Pharma industry is accused of “disease mongering”- inappropriately widening the boundaries of illness that

leads to over consumption of drugs.¹⁴ In the meantime the ABPI has cautioned the Committee against tougher restrictions on industry's communications and marketing.

Guidelines by Medical profession and Pharma industry

Royal College of Physicians Code of Practice

It was in this background that the Royal College of Physicians (RCP) has recently come up with a code of practice for its members when dealing with commercial organizations.⁶ It states that publications or meetings should not carry any promotion of sponsors which is not acceptable to the Association of British Pharmaceutical Industry (ABPI). ABPI is hopeful that RCP will redraft the rules to be compatible with the code drawn by them.⁶

ACP-ASIM Guidelines

The American College of Physicians/American Society of Internal Medicine (ACP/ASIM) has also published its own guidelines¹⁵ which are as follows:-

- * "The acceptance of individual gifts, hospitality, trips, and subsidies of all types from industry by an individual physician is strongly discouraged. Physicians should not accept gifts, hospitality, services, and subsidies from industry if acceptance might diminish, or appear to others to diminish, the objectivity of professional judgment.
- * Physicians who have financial relationships with industry, whether as researchers, speakers, consultants, investors, owners, partners, employees, or otherwise, must not in any way compromise their objective clinical judgment or the best interests of patients or research subjects. Physicians must disclose their financial interest in any medical facilities or office-based research to which they refer or recruit patients.
- * Public and private CME and CME providers that accept industry support for edu-

cational programs should be aware of potential conflicts of interest and should develop and enforce explicit policies that maintain complete control of program planning, content and delivery.

- * Medical professional societies that accept industry support or other external funding should be aware of potential bias and conflicts of interest and should develop and enforce explicit policies that preserve the independent judgment and professionalism of their members and maintain the ethical standards and credibility of the society.
- * Pharma industry should educate their representatives on these new guidelines and instruct them on appropriate compliance;
- * It should evaluate their policies and procedures governing gifts, entertainment, grants, and support for educational programs to ensure that they are consistent with the ethical guidelines of the medical community; and
- * The Pharma industry should periodically review the activities of reps who deal with physicians to ensure compliance."

World Medical Association Guidelines

More recently after two years deliberations, World Medical Association (WMA) in its meeting in Tokyo in October 2004 has also issued guidelines on this very sensitive issue. These guidelines cover medical conferences, gifts, research and affiliation. This is a bid to satisfy the public demand of greater transparency in healthcare professional's relationship with the pharmaceutical industry.

WMA did acknowledge that industry support help doctors attend medical conferences; undertake medical research besides learning about new medical developments. However the conflict of interest WMA council felt occurs when commercial considerations affect a doctor's objectivity. Since the doctors and the Pharma industry have to work closely, WMA felt it is advisable to establish certain guidelines for such a relationship.¹⁶ These guidelines are a set of principles which should be met by the

healthcare professionals before they agree to attend commercially sponsored medical conferences. These principles are:

- * The main purpose of the conference must be to exchange professional or scientific information.
- * Hospitality during the conference should be secondary to the professional exchange of information.
- * The name of a commercial entity providing financial support should be publicly disclosed.
- * Presentation of material by a doctor must be scientifically accurate, give a balanced review of possible treatment options and not be influenced by the sponsoring organization.

The guidelines further state that doctors should not accept gifts from any commercial organization unless they are allowed to do so by law or as approved by their national medical associations. WMA guidelines also emphasize that any gift should not be in cash and be of minimal value. Furthermore it should not be binding on a doctor to prescribe certain medication, use certain instrument or materials or refer patients to a particular healthcare facility. Doctors conducting research which is sponsored by a commercial organization, must disclose the source of funding, sponsorship while publishing the results of research.

They should also be free to publish any unfavourable results. And in case a doctor enter into an affiliation with a commercial concern he or she must ensure that their integrity or conflict with their obligations to their patients and their affiliations are fully disclosed. WMA feels that these guidelines will be in line with the current trend of transparency and the "patient's right to know about possible conflict of interest".

The Swiss Academy of Medical Sciences (SAMS) has also formulated its recommendations on collaboration between the medical profession and the pharmaceutical industry which were approved by the SAMS Executive

Committee on September 9th 2002. It mainly covers the clinical research areas keeping in view principles of Good Clinical Practice as well as undergraduate and postgraduate medical education, training besides Continuing Medical Education.¹⁷

AMA, ACCME and PhRMA Guidelines

American Medical Association(AMA) and Accreditation Council for CME (ACCME) issued new guidelines in 2002 regarding physician's interactions with pharmaceutical industry. In July 2002 the Pharmaceutical Research and Manufacturers of America PhRMA also adopted a broad code of conduct for its members. Although the wording is different but the essence of the message of these codes and guidelines is the same. Its salient features are that meals at conferences should be modest, conference subsidies should be accepted by conference sponsors not by the physician attendees and it should not cover travel and lodging except the faculty while the honorarium to faculty should be modest. Conference organizers should have control over selection of contents, faculty education methods, scholarships to trainees is permitted if their selection is controlled by training institutions. CME providers must be responsible for contents, quality, and scientific integrity of activities. This necessitates elimination of commercial bias. The CME providers should accept support only in the form of educational grants. It must also be ensured that the academic activities are sponsored and organized by professional medical organizations. Grants should be separated from sales and marketing functions. Avoid payments to physicians for listening to product presentations.¹⁸

The Sevagram model in India

There have been some developments in our neighboring country India as well. Taking a serious note of the growing influence of the Pharma industry on medical profession thereby affecting their prescribing practices, the

Governing Council of Mahatma Gandhi Institute of Medical Sciences (MGIMS) has redefined the relationship between drug companies and doctors at the institute. The guidelines which emerged after discussions specify that the Pharmaceutical industry, medical equipment manufactures would no longer sponsor or support any conference, seminar or workshop at Sevagram. These guidelines also oblige the organizers of CME programmes not to accept advertisements or money from drug companies for publishing the proceedings, souvenir and information leaflets. Dr. Dhirubhai Mehta President of the Governing Council of Sevagram feels that "medical profession must safeguard its academic independence and reinforce the integrity of science." The institute is also looking into the possibilities of preventing growing influence of medical representatives on junior doctors. The new rules forbid medical representatives from seeing doctors in the hospital. If the company representatives want doctors to know about their products, they could leave the information brochure with the medical superintendent or at the drug store of the hospital.¹⁹

SCENARIO IN PAKISTAN

When the physicians are willing to be corrupted, the industry alone cannot be blamed. It takes full advantage of the opportunities that are provided to it to exploit the situation to increase its sales. Since most of these conferences, academic activities are sponsored by the Pharma Industry, at times it also has a major say in the finalization of the scientific programme. Hence it was not at all surprising to see that at the 13th national psychiatric conference held at Abbottabad during September 1999, the scientific programme started with nine papers on a particular atypical antipsychotic in the first session. What was most disgusting was the fact that some of the presenters described their experience of the drug on five to six patients.

At the 17th International Gastroenterology conference at Rawalpindi in 2001 there were over a dozen presentations related to a par-

ticular drug and all the speakers were sponsored by one particular pharmaceutical concern. Fed up with this over dose, one of the foreign delegates an eminent surgeon from South Africa stood up during the discussion to say that he had come to attend the gastroenterology conference but here everybody seems to have been sold to a particular drug as if there are no other problems in Gastroenterology. During cardiology conference at Quetta in 2003, the organizers had to cancel a scientific session, as the participants were more interested in cricket match than to listen to the speakers. Extremely poor attendance at the 19th Annual Gastroenterology conference at Lahore during 2003 and the paediatric conference also at Lahore during the same year were witnessed which was a great embarrassment for the organizers.

At the biennial cardiology conference held at Hyderabad in December 2003, the drug related papers were scheduled in the main auditorium while the other scientific papers were slated in a hall which was not easy to locate. From speakers to the participants a large number of delegates to the medical conferences all paid for are sponsored by the pharmaceutical industry. However, the attendance in the scientific sessions is most often highly disappointing.

At the 14th biennial international psychiatric conference held at Peshawar in 2003 while the renowned guest speakers from overseas were waiting for the audience, most of them were still fast asleep in their hotel rooms. It was with great difficulty that chairman of the scientific committee could start the morning session almost an hour late. At the Orthopaedic Conference at Faisalabad one of the guest speakers from Middle East refused to make his presentation when he saw half a dozen people sitting in the audience. The chairpersons struggled to bring in the people from the pharmaceutical exhibition, representing the Pharma industry to fill in the chairs so that the session could start.²⁰ At the recently held conference of Pakistan Society of Hepatology at Karachi during September 2004, the hall was

full and many people were standing in the hall at lunch time. But after the lunch, the hall was almost empty, only about a dozen or so participants still interested to listen to the speakers. All this shows the interest of the healthcare professionals in academics. Since all these medical conferences are mostly sponsored by the pharmaceutical industry, they are successful to prevail upon the organizers to include their speakers most of whom do not mind to act as “glorified sales representatives”. They feel no hesitation to make presentations which at times are prepared by the product managers. They are not at all ashamed to show company prepared slides of their presentations with company logo and brand name of the drug appearing prominently on each slide. A meeting of the chest physicians held at a Hilly Resort near Rawalpindi which was to finalize its guidelines regarding management of asthma was sponsored by a multinational marketing asthma preparations. Another multinational has formed so-called experts groups on TB and chest diseases. Its members frequently tour within the country and on Joyride overseas. It is alleged that they are working to promote anti-TB drugs of the company mixing drug promotion with education. No one bothers about the conflict of interest.

While in the past it was only the multinationals with huge resources which could afford to indulge in all sort of unethical marketing practices, now even some of the national pharmaceutical companies are also successfully competing the multinationals in their bid to capture greater share of the Pakistani pharmaceutical market.

While all this was going on, we did have some “whistle blowers”. Pakistan Medical Journalists Association (PMJA) has been highlighting these issues of ethical medical practice and unethical marketing practices by the pharmaceutical trade and industry at different forums for the last many years. The PMJA even published a book “Medical Ethics in the Contemporary Era” to point out these issues and draw attention of all those concerned.²¹

Pakistan Association of Pharmaceutical Physicians (PAPP) has also published a Code of Pharmaceutical Marketing Practices recently.²² This code incorporates the IFPMA Code of Ethics and the ethical clauses of Pakistan Drug Rules. However, its implementation by the Pharmaceutical trade and industry still leaves much to be desired.

Need for healthy collaboration between doctors and industry

Collaboration between the medical profession and the pharmaceutical industry is an established fact which is in the interest of the good medical care. It also helps to increase knowledge of healthcare professionals and keep them abreast of latest developments. However, this collaboration could lead to conflict of interest and dependence is not at all a healthy sign. Particularly in a country like Pakistan where there is no monitoring and accountability, 44% of the population live below poverty line, it is all the more important to ensure healthy ethical relationship between the medical profession and the pharmaceutical industry, since all these gifts, joyrides to hill stations and sponsorships to conferences eventually add to the cost of the drugs which many cannot afford. Pharma industry and doctors are dependent on each other and they will continue to work together to their mutual benefit. However, both must realize that their primary responsibility is to serve the needs of the patients.

There are about 417 Drug manufacturers and 35,000 formulations available in the market. Hence with the growing competition, it is becoming more and more difficult for the marketing people to promote these drugs. Hence they indulge in all sort of unethical marketing practices to achieve their targets.

Time has come that this relationship must be looked into carefully and certain measures should be taken. Academic activities including organization of medical conferences all over the world are sponsored by the pharmaceutical industry but there has got to be certain checks and balances so that it is not misused

because eventually all this cost is going to be born by the patients. In Pakistan organizing medical conferences is fast becoming a business. Some times conference accounts are not properly maintained and presented for scrutiny to the organizing committee.

SUGGESTIONS

Here are some of the suggestions as regards medical conferences and doctors relationship with the pharmaceutical industry:-

1. Encourage the medical profession to hold medical conferences at lecture halls and auditoriums of medical institutions rather than banquet halls of five star hotels.
2. No drug banners should be displayed inside the meeting hall. They can be displayed outside.
3. No Lucky draws inside the hall during sessions. It should be held in the exhibition area
4. Name badges for conference delegates, participants should not carry the name of any company or any product.
5. Speakers should not show slides with company or product monogram.
6. The speakers should be advised to use scientific generic names of drugs instead of using brand names in their presentations as far as possible.
7. Doctors should be encouraged to practice rational prescribing.
8. No sponsorships of lunches, dinners at five star hotels during these conferences. Working lunch, tea should be permissible
9. No sponsorships of music, cultural or variety programmes by the industry.
10. No sponsorships of joyrides to picnic resorts.
11. A distinction must be drawn between conference attendees and the faculty. It is appropriate for the faculty members, speakers at the conference to accept sponsorship from the Pharmaceutical trade and industry but sponsorships of conference attendees should be discouraged.
12. The speakers who have been sponsored must declare before their presentation the name of their sponsors.
13. The Pharma industry should be encouraged to provide books, journals to libraries by arranging their subscriptions or providing secretarial assistance at medical institutions.
14. Drug companies should be asked to publish on their websites details of offers made to sponsor doctor's travel, accommodation and other promotional benefits
15. Drug companies should be encouraged to donate drugs, equipment to wards, hospitals, build seminar rooms, and provide audiovisual equipment to medical institutions and healthcare facilities.
16. The industry should sponsor research projects and provide scholarships to Post-graduates. These funds should be given to academic institutions and the recipients should be carefully selected by these academic, training institutions. These institutions can also provide financial assistance from these funds to postgraduates, research fellows to attend carefully selected educational conferences.
17. Industry should be asked to provide computers and other equipment helpful in medical writing to these institutions rather than individuals.
18. The industry should sponsor academic activities within the medical institutions.
19. Doctors should refuse to accept gifts if there are strings attached.
20. Fixed timings for the medical representatives to visit healthcare facilities, wards and OPDs.
21. All medical conferences, workshop should have accredited CME hours to ensure their standard and quality. This will also help in initiating re-certification programme for the healthcare professionals.
22. The drug control department in the federal health ministry should be strengthened to ensure its improve functioning keeping an eye on these unethical marketing prac-

tices by the Pharma Industry. Similarly the ethics committee of the PM&DC as well as National Bioethics Committee should closely monitor the unethical medical practices. Doctors ordering and pressurizing pharmaceutical companies for favours should be taken care of.

23. Companies violating these codes of ethics should be punished. Their drug prices should be reduced besides rejecting any further registration or price increase.
24. Professional Association/Societies on one hand and Pharma industry on the other should inculcate the spirit to adhere to their respective codes of ethics eg, PM&DC/ NBC Code and National Code of Pharmaceutical Marketing.

Adherence to the above mentioned Codes framed by various organization and ensuring implementation of the suggestions can eliminate some of the worst practices witnessed these days involving healthcare professionals and the pharmaceutical industry.

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