Special Communication

National Bioethics Committee Guidelines For Healthcare Professionals* interaction with Pharma trade and industry**

Shaukat Ali Jawaid¹, Maqbool H. Jafary², Farid Khan³, Sohail Karim Hashmi⁴

1. INTRODUCTION

Healthcare professionals and pharma industry are an integral part of health care delivery system the world over.¹ The prime beneficiary of the relationship of the two is the patient as long as this relationship is based on strong ethical principles. Increasingly, however, ethical considerations in the recent years have been observed to be violated due to financial and economic interests. Thus this relationship has come under intense scrutiny and a lot of criticism during the last several years within Pakistan as well as globally.¹-⁴ Pharma industry and the companies making medical devices and products which help practicing modern medicine and healthcare professionals have to interact with the industry for developing new treatment, conduct studies besides implementing clinical trials.⁵,⁶ However, their impact on patient care, medical research, medical education, besides physicians professional relationship with the industry are concerns constantly being expressed by the general public as well as the medical press. At the same time one also hears voices which challenge these concerns and emphasize the positive value of these interactions which is also getting place in the media.⁷,⁸

Physician’s interaction with the pharmaceutical industry starts early in the medical schools and it continues into the practice.⁹ The frequency with which healthcare professionals benefit from industry sponsored meals and samples decrease as they enter practice.¹⁰ However the frequency of receiving honoraria, conference travel and research funding increases as they become more busy in their practice.¹⁰,¹¹ Studies have shown that receipt of money, gifts even of minor value can have an impact on physicians prescribing decisions.¹²,¹³ Concerns have been expressed that all this eventually increases the cost of medical treatment.¹⁴ It has also been pointed out that if the research is funded and sponsored by the companies, it is more likely that the physicians conducting clinical trials will report favourable results.¹⁵ In view of these concerns, various countries have been addressing this issue, and there is a strong feeling that it is time to reassess the nature and extent of this relationship between healthcare professionals and the pharmaceutical trade and industry in Pakistan.

In order to address this issue many professional bodies both in the medical community and in the industry have established Codes of Ethical Practices which serve to guide, monitor and censure its members. These guidelines also extend to students and resident staff. Where these codes have been ineffectual Governments of some countries have introduced legislation with punitive penalties to curb unethical practices.

2. General Principles

Physicians and health related professionals including those in training are expected to act in the best interest of the patient as failure to do so undermines the trust of public in healthcare professionals and its willingness to seek medical care. In order to avoid negative consequences there is a need for a funda-
mental change in the culture to limit the nature and extent of unethical relationships particularly related to marketing. These steps are considered essential to safeguard public trust and protect the integrity of the healthcare professions besides promoting the well being of the patients.

Several professional societies have developed their own guidelines to monitor the interaction of physicians with the pharmaceutical trade and industry. These guidelines also recommend that students and resident staff should also be informed about these but most of them are not aware of any such documents or guidelines. Recent efforts to develop such guidelines for Pakistan include the “Ethical Guidelines for Physician Pharmaceutical Industry interaction” formulated by Karachi Bioethics Group.21

Health related professionals should maintain professional autonomy and independence in the interest of the patients while avoiding any self-interest in prescribing and their referral practices. Inspite of the temptations patient interest must be supreme and at the forefront of one’s mind. It should be a common and transparent practice to declare any involvement, specially the financial interests, through ties with pharma industry.

The following guidelines cannot anticipate every eventuality; hence there may be exceptions in exceptional and unusual circumstances. But great care must be taken to ensure that while making any exceptions, the possible negative consequences must be kept in mind. All efforts must be made to ensure that well being of the patients and integrity of the medical profession is not compromised.

3. Medical Research

When healthcare professionals participate in research which may involve the financial interest of a company irrespective of the source of funding, any financial relationship with the company raise serious concerns about the objectivity of the research findings. This relationship can include equity ownership in the company, receipt of royalty payments from the company, membership of the company advisory board, funding for participation in conferences and seminars, funding to professional associations and societies, consultation to the company besides participation in speaking engagements on behalf of the company. American Medical Colleges and the American Association of universities recommend that in case their own, spouse or children have financial interests, they should not participate in such research. The only exception can be initial clinical use of a device invented by a researcher which is unlikely to be pursued by other investigators and only when an acceptable plan for managing the conflict of interest created by such a relationship has been developed and implemented. These recommendations have also been endorsed by the American Psychiatric Association.

3.1 Industry sponsored research: Funding from the pharmaceutical trade and industry including those marketing medical devices should cover the actual costs of performing research including salaries of researchers and research staff, costs of various tests and investigations, procedures, medication, data analysis costs besides appropriate overheads. However, payments unrelated to actual cost and appropriate compensation for time utilized may influence the physician’s decisions as regards enrollment of study subjects leading to inappropriate pressure on study subjects to participate. Physicians should not participate in any research study which involves payments not related to actual costs and appropriate compensation for the time spent. Suppression of unfavourable findings of clinical trials funded by companies threatens the integrity of medical research and validity of data on which clinicians base their decisions which affect the patient care and researchers design of future investigations.22,23

Publication of negative findings is also important. As such it is critical that a mechanism be created within the study protocol to ensure publication of clinical significant findings including negative ones if any. Health related professions should refuse to participate as authors if they do not have full access to relevant data and ability to report results including adverse events.

The Association of British Pharmaceutical Industry (ABPI) in its guidelines on relationship with the medical profession recommends that physicians conducting clinical trials should expect realistic payment. All details regarding payment should be specified as part of the formal agreement including the purpose for which staff or equipment have been funded. Furthermore details relating to such clinical trials must be submitted to the local Research Ethics Committee or the institution along with the trial protocol. Meetings organized for groups of healthcare professionals, health officials, administrative staff of hospitals which are wholly or mainly of social nature should not be sponsored by the industry.

Before being enrolled in any research the study subjects have the right to know if the researchers have any financial relationship with the pharmaceutical company sponsoring the study. Hence it is mandatory that the study subjects are told in clear terms
about such a relationship before asking for their consent to participate in the study. In all such cases the researchers are expected to comply with the necessary applicable disclosure requirements of their respective institutions or funding agencies.  

3.2 Industry sponsored Surveillance Studies: These studies must not be marketing oriented; instead these should be meant for advancement of science related to a recently marketed drug in which the drug is used in a large number of patients in a real life situation. Observations about the efficacy of the drug are desirable but more importantly the primary objective is to document the adverse event profile, especially the uncommon ones which may not show up in relatively smaller number of patients studies in the phase 2 and 3 clinical trials. These studies should also go through appropriate Ethics Review Committee approval.  

3.3 Authorship of Research Findings: Sometimes it is the employees of the pharmaceutical companies who draft and revise these research reports and findings and their role is not mentioned in the acknowledgements. It makes it extremely difficult for the Editors, reviewers as well as readers to ascertain the reliability and validity of the data and their interpretations which are being presented. Ghost writing also involves listing authors who have not played any meaningful, intellectual role in writing or revising the paper but their names do appear on the paper as authors. It is recommended that all authors must be acknowledged and their role in research as well as preparation of the manuscript must be accurately described. They should strictly abide by the authorship criteria laid down by the International Committee of Medical Journal Editors (ICMJE). This authorship credit should be based on:  
1. Substantial contributions to conception and design, acquisition of data or analysis and interpretation of data.  
2. Drafting the article or revising it critically for important intellectual content.  
3. Final approval of the version to be published.  
4. Continuing Medical Education and Professional Development:  
Most of the medical institutions in Pakistan except a few in the private sector have no faculty development programme. As a result, healthcare related professionals and faculty have to rely on the pharmaceutical industry’s assistance to attend international conferences, seminars and workshops in other countries. It is not possible for many to even participate in such academic activities within the country in the present circumstances. Hence, Pharma industry support for such CME and CPD programmes is inevitable but steps need to be taken to ensure that such facilities are not misused and abused. However, studies have shown that accepting funding to attend such academic activities is often associated with increased requests for addition of their drugs in the hospital’s formulary. It also influences the physicians prescribing practices.  

4.1 Travelling and lodging to attend academic activities: It is unethical on the part of healthcare professionals who are being sponsored by the industry to attend academic activities to request for the sponsorship of their spouses as well. The sponsorship should not include pleasure trips and sight seeing which involves additional expenditures. Some of the new entrants to the field of pharmaceuticals in Pakistan have lately resorted to sponsoring huge delegations to such meetings supplemented with pleasure trips to a few other cities and countries. Some of these companies even have started sponsoring pleasure trips overseas with no academic activity at all. On return those sponsored oblige their sponsors through irrational and unethical prescribing to reciprocate these favours. Such practices must be eliminated as it is bringing bad name and destroying integrity of medical community. All the pharmaceutical companies and those involved in marketing medical devices must furnish details of the healthcare professionals sponsored by them for visits within the country and abroad every month to the National Bioethics Committee secretariat or the Ministry of Health. This information will be posted on the NBC website as public information. Such regular reporting and its accessibility to all will serve to discourage those healthcare professionals who make such practices their norm. Pharmaceutical industry is increasingly required to make such disclosures in several countries.  

4.2 Sponsored CME programmes: Pharmaceutical sponsorship of CME programmes affects presentation contents wherein the sponsor’s drug is always preferentially highlighted. Some of the speakers even repeatedly name their products by brand names while comparing with competitors whose names are mentioned by generic names. Changes in prescribing practices in favour of sponsor’s drug have also been reported.  

4.3 Pharma Company employed speakers: There is an increasing trend in the Pharma industry to employ some medical graduates or medical advisors who are then used as speakers at company sponsored
meetings. This has an inbuilt mechanism whereby they promote the company’s drugs under the disguise of scientific meetings termed as CME programmes. Studies have reported that resident’s exposure to Pharma representative speakers at lunch meetings was associated with dissemination and learning of inaccurate information about the sponsor’s and competitor’s drugs. This resulted in inappropriate treatment decisions by attending residents. Most healthcare professionals now agree that Pharma industry employed speakers should be completely banned.

4.4 Satellite Symposia: Pharma industry sponsored satellite symposia organized at breakfast, lunch or dinner time during conferences should be discouraged.

4.5 Medical Conferences: In a country where almost 40% of its population lives below the poverty line, billions of rupees are spent each year by the pharmaceutical trade and industry on hosting medical conferences in Five Star Hotels. The industry passes on this burden to the public in the shape of high cost of drugs and medicines which are beyond the reach of many. In order to reduce the cost of these conferences, it is imperative that the medical profession must make every effort to return to the lecture halls and auditoriums of medical institutions from the Banquet Halls of Five Star hotels except in exceptional situations. With the passage of time these facilities should be created in all institutions.

Recommendations: In case when sponsorship by the Pharma industry is unavoidable:

* Modest, working lunch should be offered at these conferences.
* Conference participant name badges should not contain any company or product logo.
* No product, company, banner should be displayed inside the meeting hall nor should any lucky draws be permitted during the meeting. All these activities should be restricted to the Exhibition area.
* All the speakers must declare their financial relationships if any with the industry before making their presentations. In case their participation has been sponsored by any company, it should also be declared in the beginning particularly if they are going to make a presentation which involves the sponsor’s drug.
* Purely Drug promotional presentations should not be allowed as a part of the main scientific programme.
* Back drop at the conference venue should not contain the name of any company or product.
* Conference organizers should not force the Pharma industry to sponsor participants to these conferences by making payment of Registration Fee just to generate funds. In many cases those registered seldom turn up and their name badges are seen lying with the sponsors in the exhibition area.
* All direct payment to the conference organizers from the Pharma trade and industry should be discouraged. Instead, they should be asked to make direct payment for all the services provided (i.e. catering firms, audiovisual service providers) to those who arrange these services. Organizing a conference has become a money making business for some and such a practice will discourage this unethical practice.
* At the end of the conference, the conference accounts and expenditures should be prepared and it must be made available to the general membership and displayed on the website of the organization concerned.
* Continuous Professional Development committee of PMDC or any other agency should undertake the task of issuance of CME credit for all such academic activities from seminars, symposia to workshops based on their scientific programme. This will prevent many conferences that are just social get togethers and the quality of their scientific programme is not good. Such a system will encourage organizers to strengthen & improve the scientific contents of these meetings.
* Once these conferences are approved for CME credit, the Ministry of Health and Higher Education Commission must provide them some funding for organizing these conferences so that the organizers are not totally dependent on the support of the Pharmaceutical trade and industry. However, no grants should be provided to those organizations that do not provide detailed financial account of their conferences to its members or display it on their websites.
* Information provided by Pharma industry regarding sponsorship, financial assistance to the medical institutions will be posted on the NBC website.

5. Drug Samples:

Pharmaceutical industry distributes free drug samples to physicians worth billions of dollars all over the world each year. The quantity of these samples in Pakistan is 2-3% of pharma market which is worth twenty to thirty million rupees. The purpose of these samples is to familiarize doctors about...
a drug but numerous studies have shown that dis-
tribution of these free samples significantly influences
the decisions by the physicians as well as patients as
to which medication to prescribe and hence these are
considered very useful and effective marketing tech-
nique.\textsuperscript{33-35} Distribution of these free drug samples
encourages physicians to start patients on these fre-
cently much more expensive medications. In some
cases physicians feel obliged and become dependent
on the medical representatives for continued free
supply of these drug samples for some of their pa-
tients. Some healthcare facilities in various countries
and even in Pakistan have established some mecha-
nism where in these free samples are deposited at a
central place from where they are distributed to the
deserving patients.

**Recommendations**

Physicians must limit the use of free samples
provided by the Pharma industry to only those in
the interest of patient care. All healthcare facilities
should work out a system of central collection of
samples e.g., hospital pharmacy for further distribu-
tion to deserving patients.

6. Medical Representatives

**visit to healthcare facilities:**

Medical representatives from various pharmaceu-
tical companies are seen visiting the healthcare
facilities in large number during the working hours.
This seriously affects the teaching, training and
patient care as well. Recently hospital administra-
tion in some parts of the country banned the entry
of medical representatives to hospitals in the morn-
ing hours which led to strike and protest demonstra-
tions by the medical representatives. Their presence
does affect patient care and physicians are being per-
suaded by representatives particularly in the OPDs
to prescribe their drugs. These gestures are of course
reciprocated.\textsuperscript{13} Many healthcare facilities all over the
world now limit the activities of these representa-
tives and prohibit the visit to patient care areas.

**Recommendations**

Healthcare facilities should fix some timing on
particular days of a week for the visit of these medical
representatives and this must be implemented in
letter and spirit. However healthcare professionals
should not rely on these representatives from the
industry as their primary source for drugs and treat-
ment related information.

6.1 Gifts, Giveaways, Vacations and Support for
Clinic refurbishing: The practice of expensive gifts,
giveaways, financial support for vacations in and
outside the country and setting up the clinics and
even help for children’s weddings has become rampant. This is a highly unethical practice meant to
induce physicians to write prescriptions for a prod-
uct or group of products of a specific pharma com-
pany. A gift should be meant to benefit the patients
(stethoscope, BP apparatus, weight machine, tongue
depressor, hand wash etc.). Educational material like
books, medical journals etc. may be accepted. Cash
payments of any kind should be prohibited.

7. Role of Professional Specialty Organizations

Professional specialty organizations are playing a
vital role in keeping the healthcare professionals
 abreast of latest developments in medicine by vari-
ous ways, i.e. publication of journals, holding annual
conferences, organizing hands on workshops, semi-
nars and symposia. Some of these specialty organi-
izations have also formulated Practice Guidelines or
standard treatment protocols. Most of these activi-
ties are funded or sponsored by the pharmaceutical
trade and industry. This can influence clinical deci-
sion making and seriously undermine the reputation
of the medical profession and erode integrity and
credibility of these professional specialty organi-
zations. It is important that the organizers or office bear-
ers of these organizations distinguish education from
marketing activities. They have a duty to provide
their members the best scientific evidence as regards
efficacy and suitability of drugs and equipment, in-
struments used in clinical practice. Great care must
be taken to separate it from the industry’s promo-
tional activities.

**Recommendations**

These organizations must independently prepare
the scientific programmes for their meetings, select
the speakers and their topic. Industry funding should
not in any way influence the scientific programme.
Relevant committees of specialty organizations
should provide a transparent account of all expenditure
following all sponsored activities to its members.

8. Product Endorsement:

It is highly unethical on the part of professional
specialty organizations to endorse commercial prod-
ucts. In Pakistan certain organizations and individu-
als have provided their seal of endorsement on tooth
pastes, certain foods and soaps, health insurance,
nutritional products etc. in the print and electronic
media. With or without donation or payment
healthcare professionals must not allow their name
or logo to be attached to a commercial product or
service in order to safeguard professional integrity. (Some other specific guidelines are covered in the section on Medical Conferences.)

8.1 Peer-selling: Physicians should not be involved in the unethical practice of peer-selling the product. This involves an expert on the subject giving talks (and endorsement of the product) to a small group of doctors focussing on a product or a device. Generally, a series of such meetings are held throughout the country, especially for the newly introduced products designed to increase the sale of such products.

8.2 Advisory Boards: The common practice in Pakistan of healthcare professionals and senior management and CEOs of institutions providing healthcare to patients, serving on the Board of pharmaceutical industry is a source of major conflict of interest. This can be detrimental to professional integrity and such relationships should be avoided at all cost.

9. Creating a balance:

As mentioned in the introduction of this document, the healthcare professionals and pharmaceutical industry are integral part of health delivery system. They have to interact with each other but the objective is to make the focus patient-centric rather than self-centric to maximize individual gain. Therefore, we have to look at ways and means to strike a balance. It is important to balance conflict of interest against overly restrictive policies. In this situation, prohibition of pharmaceutical industry funding for CME/CPD or availability of drug samples for needy patients, could have negative consequences in patient care. The need of the hour is as follows:

* Create awareness of the unethical practices amongst the stakeholders
* Ensure oversight agencies to monitor wrong practices and take punitive actions against defaulters as deterrence.
* Create forums where ethics committees of professional medical associations and pharma associations and MoH representatives from NBC can meet and agree on a plan of action regarding respective defaulting members and their unethical activities.

Voluntary observation of ethics guidelines is the best way for all concerned to avoid potential legislative action by the authorities. These guidelines are intended to be a living document which can be amended from time to time, or updated when new issues are highlighted which require attention.

10. Acknowledgement:

For the preparation of these guidelines the authors have benefited from the following documents that is gratefully acknowledged:

1. Association of British Pharmaceutical Industry (ABPI) guidelines on relationship between the medical profession and the pharmaceutical industry.
3. Report by American Psychiatric Association Working Group on Relationship between psychiatrists and the pharmaceutical and Medical Device industry.
5. Pakistan Hypertension League: Guidelines for scientific meetings and annual conferences concerning scientific, ethical and organizational issues. Revised in March 2009.
7. Dr. Afzal Javed Consultant Psychiatrist, UK.

11. References


