

Guidelines For Healthcare Professionals*interaction with Pharmaceutical trade and industry**

Drafting Committee

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* Healthcare professionals (includes Physicians, Specialists, GPs / Family Physicians, Medical Students, Nurses....)

** Trade and Industry (includes industry and trade engaged in the manufacturing and marketing of diagnostics, equipment/ machines, medical devices and pharmaceuticals)

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Note: National Bioethics Committee in its meeting held at Islamabad on July 30th, 2009 had formed this sub-committee to draft these Guidelines. It was discussed in detail and finalized in NBC meeting held at Karachi on May 22nd 2010.

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1. INTRODUCTION

Healthcare professionals and pharma industry are an integral part of health care delivery system the world over. The prime beneficiary of the relationship of the two is the patient as long as this relationship is based on strong ethical principles. 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 interaction⁹ with the pharmaceutical industry starts in the medical schools and continues till practice. 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 favorable 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 under training are expected to act in the best interest of the patient as failure to do so undermine the trust of public in healthcare professionals and its willingness to seek medical care. 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 as most of them are not aware of any such document

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 referral practices. Patient interest must be safeguarded. 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 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 companies 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.

Recommendations

1. The study should only be conducted by an investigator after due disclosure and approval by the ERB/IRB of the Institution in line with the GCP guidelines and the rules and regulations of that Institution.
2. Every clinical trial must meet the current scientific and ethical requirements and the existing legal regulations and must conform to the internationally recognized principles of Good Clinical Practice.
3. It should be ensured that investigators responsible for or taking part in a trial may not put their credibility in question by taking part in marketing promotions for the product or procedure investigated.
4. 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.
5. Drugs provided by the industry for research purposes should similarly be given to the relevant institutional committee (or pharmacy) designated for such work. Distinction must be made between drugs donated by a company to an institution as a philanthropic

gesture and drugs provided for the purpose of research. Drugs intended for clinical trials must be labeled as such and differentiated from the commercial or physician sample packs.

6. Utilization of research funding should be at the institution's discretion. The funding industry must not influence the research agenda, methodology employed, participant selection, data analysis or publication of findings. All research proposals must be assessed and approved by the Institutions Ethical Review Committee (IERC) prior to initiation.
7. Research involving human subjects and/or human materials, whether healthcare funded or otherwise, should be approved by a properly constituted IERC/ REC of NBC which will be responsible for review of ethical issues including research agenda, informed consent, risks and benefits to participants, and communities etc.
8. In case the institution does not have its own IERC, ethical review must be sought from an Provincial Bioethics Committee or NBC for approval and of the funding by industry.
9. IERC should have multidisciplinary compositions. Besides clinicians ERC should have representation from non medical sectors.
10. Declaration of the funding by industry must be made by researchers in all publications and during presentations that emerge as a result of research.
11. The institution involved or individual researcher should also declare the nature and amount of funding received for research on its website and other appropriate forum.
12. Healthcare Professionals may accept an honorarium against the time of their involvement in a clinical trial/research study ensuring complete disclosure and without any conflict of interest, in the following cases:
 - a) Industry initiated trials / studies.
 - b) Investigator / Doctor initiated trials / studies.
13. The investigators who are involved in a trial should inform the academic institution for which they are working of the financial interests associated with their participation in any clinical trial/study.

3.1 Industry sponsored research: Funding from the pharmaceutical 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 on enrollment of study subjects. Physicians should not participate in any such research study which involves payments not related to actual costs and appropriate compensation for the time spent. Concealment of un favorable findings of clinical trials funded by companies threaten the integrity of medical research and the validity of data on which clinicians base their decisions. These acts may affect the patient care and researchers design for 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 requirements²⁴ of their respective institutions or funding agencies.

3.2 Industry sponsored Surveillance Studies: These studies must not be market 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.²⁵ 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)²⁶

The authorship credit should be based on substantial contributions to conception and design, acquisition of data or analysis and interpretation of data, drafting the article or revising it critically for important intellectual content and final approval of the version to be published.

Financial support for the preparation of the manuscript, if any, should also be disclosed.

4. Continuing Medical Education and Professional Development:

Most medical institutions in Pakistan have no faculty development programme. As a result, healthcare related professionals and faculty rely on the pharmaceutical industry's assistance to attend international conferences, seminars and workshops within and outside the country. 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 programs is inevitable but it must be ensured that such facilities are not misused and abused. 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.²⁷ It also influences the physicians prescribing practices.

4.1 Traveling and lodging to attend academic activities: It is unethical for industry sponsored healthcare professionals who are attending academic activities within country or abroad to simultaneously request for the sponsorship of their spouses/children or family members. The sponsorship should not include pleasure trips and sightseeing. All 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 and the Ministry of Health. This information will be posted on the NBC website as public information. Regular reporting and accessibility to such activities will discourage unethical practices.

4.2 Sponsored CME programs: Pharmaceutical sponsored CME programs affect presentation contents wherein the sponsor's drug is always preferentially highlighted. Some of the speakers even repeatedly use their brand names while comparing it with other generic drugs.²⁸ This practice results in undue favor of sponsor's drug.

4.3 Pharma Company employed speakers: Often Pharma industry employs medical graduates or medical advisors who act as speakers at company sponsored meetings, thus promoting their own drugs under the disguise of scientific meetings/ CME programs.²⁹ This results in biased treatment decisions by the health professionals. It is generally agreed that Pharma industry employed speakers should be banned to give lectures in conferences/CME.^{30,31}

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 Pakistan billions of rupees are spent each year by the pharmaceutical industry on hosting medical conferences in hotels. The industry passes on this burden to the patients in the form of high cost of medicines/devices. In order to reduce the cost of the medicines it is imperative that the medical conferences must return to the lecture halls and auditoriums except in exceptional situations where such facilities are not available. With the passage of time these facilities should be created in all institutions.

Attempts should be made by the Healthcare professionals to generate resources from within their institutions and from personal contributions. Since continuing medical education (CME) or scientific and educational conferences or professional meetings can contribute to the improvement of patient care, therefore, financial support from healthcare companies in its organization of such meetings / CME is permissible. Cash transactions or direct payment to the conference organizers from the Pharma trade and industry should be

discouraged. Direct payment may be made to the catering firms, audiovisual service providers etc. Financial support and donations should always be in the form of certified cheque/draft deposited in the institutional/association/organization accounts. Funds generated must be declared on website and /or published and is able to withstand public and professional scrutiny.

1. The primary purpose of an educational meeting must be the enhancement of medical knowledge and the quality use of medicines. Physician's involvement in these events must have the objective of gaining current, accurate and balanced medical education in an ethical and professional manner. When a Congress / Symposia are organized, a minimum of 70 per cent of time should be spent on core agenda activities of the Congress/Symposia and a maximum of 20 per cent of time may be devoted to recreational personal activities, secondary to the main purpose.
2. Healthcare professionals should not demand or accept invitations to the pleasure trips & outings (not associated with academic activities) or the hospitality from the industry in the form of passes or tickets to attend expensive games or music concerts etc. just for the sake of entertainment.
3. There should be a modest working lunch in the 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. Back drop at the conference venue should not contain the name of any company or product. All these activities should be restricted to the Exhibition area
4. Continuous Professional Development committee of PMDC or some other agency should issue CME credit for all such academic activities based on their scientific programme. Such a system will encourage organizers to strengthen & improve the scientific contents of these meetings
5. All the speakers must declare their financial relationships/ sponsorship if any with the industry in their presentations. Pure drug promotional presentations should not be allowed as a part of the main scientific programme
6. Air travel for healthcare professionals attending a company educational meeting, if needed to be provided by the industry partner, must be by economy class only. Physician may accept hospitality of a trip/journey from companies to another city within country or to a foreign country if there is an academic component/activity during the trip,if he/she is presenting a scientific paper/lecture or participating in a scientific board or meeting.
7. Healthcare professionals should not accept or demand hospitality of a trip/journey for their spouse/children/family members from industry within country or abroad.
8. Healthcare professionals should not accept invitations/coupons to company sponsored meals, Iftar dinners or any other invitations which are not associated with any academic activity.
9. Funding should not be accepted by the Healthcare professionals to compensate for the time spent attending the conference or meeting.
10. Healthcare professionals should not receive any cash or monetary grants from any pharmaceutical and allied healthcare industry for individual purpose, which is not related to any academic activity or patient benefit.
11. Healthcare Industry and the medical societies should declare any sponsorship, grants, financial support etc. provided to any Health Care Physician/Institution on their website and also on NBC website, or if required declared to the Regulatory

Authorities. However, no grants should be provided to organizations that do not provide detailed financial account of their conferences to its members or display it on their websites.

5. Drug Samples:

Pharmaceutical industry distributes free drug samples to physicians worth billions of dollars all over the world each year.³² 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 studies have shown that distribution of these samples significantly influences the decisions of the physicians and hence are considered useful and effective marketing technique.³³⁻³⁵ Distribution of these free samples encourages physicians to start patients on these 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 their patients. Some healthcare facilities abroad and within Pakistan have established mechanisms where these free samples are deposited at a central place for distribution to deserving patients.

Recommendations

Physicians must limit the use of free drug samples in the best interest of patient care. All healthcare facilities should work out a system of central collection of samples e.g., hospital pharmacy for further distribution to deserving patients.

6. Medical Representatives visit to healthcare facilities:

Medical representatives visit healthcare facilities during the morning/peak working hours which affect the teaching, training and patient care. Many healthcare facilities have now limited the activities of these representatives and prohibit their visit to patient care areas.¹³

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 treatment 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 support for children's weddings has been observed. This is highly unethical and induces the physician to prescribe a product or group of products of a specific pharma company.

In dealing with healthcare industry, a healthcare professional shall always ensure that there shall never be any compromise either with his / her own professional autonomy and / or with the autonomy and freedom of the medical institution / association. To avoid conflict of interest, gifts, items or benefits are to be discouraged and should not be accepted by the healthcare professionals, keeping in view the larger interest of the profession and to remain very careful. Nothing should be accepted or demanded by the healthcare

professional in a manner or on conditions that would interfere with the independence of their professional prescribing practice.

1. Healthcare professionals should not accept a gift, benefit in kind or economic advantage as an inducement to prescribe, supply, administer, recommend, buy or sell any medicine / product.
2. Healthcare professionals may accept promotional aid items from the healthcare industry that primarily benefit patients, so long as the items are not of substantial value and are only occasionally offered (such as stethoscope, BP apparatus, weight machine, tongue depressor, hand wash etc.). Personal Items (e.g. Mobile Phone, Laptop, Car, AC etc.) and cash payments are specifically not acceptable.
3. Healthcare professionals may accept text or reference-books/information; medical journals, CDs and other educational material if they serve a genuine educational function and should be subscribed in the name of Hospital / Institute.
4. Healthcare professionals should not enter into a written or verbal deal / agreement of any kind with healthcare industry against any service or support from them for personal gains or for the benefit to the Hospital/Institute (donations in cash or kind) or for the patient against providing support for generating prescriptions
5. Promotional items of insignificant value, provided free of charge, are permissible as long as they are related to the Healthcare professional's work and/or entail a benefit to patients.

Health care professional are responsible for and must ensure that any discount received from the suppliers is passed on to the patients and practitioners do not use it as an inducement to generate financial rewards.

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 through publication in journals, annual conferences, hands on workshops, seminars and symposia. Most of these activities are funded or sponsored by the pharmaceutical trade and industry. This can influence clinical decision making and undermine the reputation of the medical profession, and the integrity and credibility of the professional specialty organizations. It is important that the organizers or office bearers 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, instruments used in clinical practice. Great care must be taken to separate it from the industry's promotional activities.

Recommendations

These organizations must prepare a scientific program and select speakers and their topic independent of the pharma sponsored speakers. Industry funding should not influence the scientific programme. Relevant committees of the organizations should provide a transparent account of all expenditures following all sponsored activities to its members.

8. Product Endorsement:

It is unethical for professional specialty organizations to endorse commercial products. In

Pakistan certain organizations and individuals 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 focusing 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 Affiliations: The 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. Healthcare professional may work for pharmaceutical and allied healthcare industries in advisory capacities, as consultants, researchers, speakers, treating doctors or in any other professional capacity. In doing so, a healthcare professional shall ensure, that his professional integrity and freedom are maintained, patient's interest is not compromised, affiliations are within the law and such affiliations / employments are fully transparent and disclosure is made explicitly in an agreement.

9. Creating a balance:

The healthcare professionals and pharma industry are integral part of health delivery system. It is important to balance conflict of interest against overtly restrictive policies. In this situation prohibition of pharma industry funding for CME/CPD or availability of drug samples for needy patients, could have negative consequences in patient care. These guidelines are being prepared to create awareness of the unethical practices amongst the stake holders, ensure oversight agencies to monitor mal practices and take punitive actions against defaulters. Create forums where ethics committees of professional medical bodies, pharma association's representatives from MoH and NBC can meet and decide about penalty on 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:

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Definitions

Health Care Provider may refer to a health professional or an organization that provides services of a health professional

Health Care Professional includes members of the medical, dental, Healthcare and nursing professions, Pharmacists and any other persons, who in the course of their professional activities and delivery of patient care may prescribe, recommend, purchase supply (or influence the supply) or administer a medicine

Physician is Doctors with basic Medical/ dental qualification or basic Medical/ dental qualification with post graduate degree/ diploma or with equivalent qualification in any medical discipline registered with PMDC

Health Care Industry The Global Industry Classification Standard and the Industry Classification Benchmark divide the industry into two main groups:

(a) **Health care equipment & services** comprise companies that provide medical equipment, medical supplies, and health care, such as hospitals, home health care providers, and nursing homes, ambulatory care specialist and general medical practitioners (GP's)

(b) **Healthcares, biotechnology & related life sciences** comprise sectors companies that produce biotechnology, healthcares, and miscellaneous scientific services.

Substantial Value of Gift / Promotional Aid Item: Any gift / item bearing worth of Pak Rs.2000 only

Medicine means any branded or unbranded medicine intended for use in humans which requires a marketing authorization as defined in Drug Act 1976

Representative means a representative of health care industry calling on members of the health professions and administrative staff in relation to the promotion of medicines