

**GUIDELINE OF
THE MALAYSIAN MEDICAL COUNCIL**

MMC GUIDELINE 007/2006

**RELATIONSHIP
BETWEEN DOCTORS
AND THE
PHARMACEUTICAL INDUSTRY**



Malaysian Medical Council

PRELUDE

This Guideline complements, and should be read in conjunction with the Code of Professional Conduct of the Malaysian Medical Council (MMC).

In this Guideline, the words “doctor”, “physician”, “medical practitioner” and “practitioner” are used interchangeably, and refer to any person registered as a medical practitioner under the Medical Act 1971. The words “hospital” and “healthcare facility and service” are used interchangeably and refer to any premises in which members of the public receive healthcare services. Words denoting one gender shall include the other gender. Words denoting a singular number shall include the plural and vice versa.

Adopted by the Malaysian Medical Council on 14 November 2006

FOREWORD

The Malaysian Medical Council, with the objective of ensuring that registered medical practitioners are fully aware of the codes of professional medical practice, issues directives and guidelines from time to time. The purpose of these codes, guidelines and directives is to safeguard the patient and members of the public, to ensure propriety in professional practice and to prevent abuse of professional privileges.

The Guidelines are designed to complement, and should be read in conjunction with, the Medical Act and Regulations, Code Of Professional Conduct of the Malaysian Medical Council and other Guidelines issued by the Council or any related organisation, as well as any statute or statutory provisions in force and all related statutory instruments or orders made pursuant thereto.

This Guideline on **Relationship between Doctors and the Pharmaceutical Industry** has been prepared with careful attention to details, cognisant of the current international stand on the subject. The draft has been reviewed numerous times by the Malaysian Medical Council includes valuable from individuals, organisations and professional bodies in the country, before formal adoption by the Council.

The Guideline is available in the printed form as well as in the MMC website. Registered medical practitioners are advised to familiarise themselves with the contents, as they will serve as documents to refer to or to seek clarifications from, when they need guidance on matters of professional ethics, codes of professional conduct and medical practice in general.

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RELATIONSHIP BETWEEN DOCTORS AND THE PHARMACEUTICAL INDUSTRY

SUMMARY

The relationship of medical practitioners with the pharmaceutical industry is expected to be strictly on a professional level. The practitioner is expected to prescribe a particular pharmaceutical agent to his patient based on his own clinical judgment without any influence from the industry.

However, this ideal situation is believed not to be in play most often and the community at large has often questioned the propriety of the relationship between the practitioner and the pharmaceutical industry, given the lavish marketing strategies employed by the industry.

It is also a belief that the lavish marketing expenditure is inevitably passed on to the consumer.

This Guideline on the Relationship between Doctors and the Pharmaceutical Industry, explores all the areas where this relationship can be conducted with due propriety without compromising the treatment of patients, and sets the standards of behaviour for practitioners towards the industry.

The Guideline draws the line on sponsored talks, travels and gifts.

While the Guideline refers to pharmaceutical companies, the matter discussed is equally applicable in all its context and relevance to firms which design, manufacture and market medical equipment, implants, prostheses and orthoses, and to the association of doctors with such companies.

1. BACKGROUND

1.1 Promotional activities

Both doctors and the pharmaceutical industry are engaged in the treatment of disease and the conduct of research directed towards improvements in treatment. In spite of this common purpose many doctors feel uncomfortable in their relationship with the pharmaceutical industry. In addition, uneasiness has been expressed in the community about the propriety of this relationship.

Possible reasons for these concerns arise out of the fact that both groups are paid for what they do, and conflicting interests can arise in this context. The number of drugs available has increased greatly in recent years, and this has made the industry more competitive, with the need to intensive marketing and promotional activities. The recruitment of patients in industry sponsored clinical trials is also increasing and doctors are commonly called upon to assist with recruitment to these trials.

The promotional activities of the pharmaceutical industry can take many forms, including overt advertising and the provision of gifts and perquisites to individual doctors or to their employing institutions. It is important to recognise that although doctors are the targets for advertising and promotional activities of pharmaceutical companies, they are not the consumers of the products. Indeed, doctors act as the agents of consumers, who are their patients, and their relationships with the latter are guided by ethical considerations as well as awareness of the laws governing, amongst other things, the prescribing of drugs.

Some doctors assume that they are somehow immune to skilled advertising techniques. While doctors are trained to make rational

decisions, they may be no more resistant than other members of the community to expertly designed promotions which are created to appeal to emotions and to tap into personal values and bias.

1.2 Doctors and the Pharmaceutical Industry

The responsibilities of doctors to their patients in relation to pharmaceutical products include:

- to use existing, approved drugs in the most effective and appropriate way (evidence-based) as part of treatment and care;
- to monitor their use and report adverse reactions;
- to participate in post-marketing surveillance of new drugs;
- to keep up to date with scientific developments in their field, including information about new drugs and amended information about established ones;
- to consider the implications of new technologies and pharmaceutical agents for the community as a whole and contribute to discussion about the most appropriate use of resources; and
- where appropriate, to engage directly in research into new drugs or into new applications of existing ones, or contribute to or support such research.

In the context of these activities doctors will be exposed to, and may develop relationship with, pharmaceutical companies. From time to time, this exposure will require doctors to make decisions about the nature and extent of such relationships. On occasions, this may raise the possibility of conflicts of interest, such as those between their responsibilities to their patients and personal gain, and their clinical responsibilities and the responsibilities of researchers.

It is necessary to stress the importance of consultation with industry. These discussions take place within the context of the respective self-regulatory codes of conduct of doctors and members of the pharmaceutical industry. Both doctors and pharmaceutical companies are also subject to laws and regulations governing the prescription of drugs and in the conduct of research.

It is also important to stress the need for openness and transparency in dealings between doctors and pharmaceutical companies. In many cases this will require disclosure of financial or other arrangements to institutions, ethics committee, patients, potential research subjects and others. Such disclosures do not in themselves imply the existence of conflicts of interest, but merely allow public scrutiny of possible dualities of interest to ensure that such conflicts do not develop and do not cloud the primary clinical objectives.

2. GUIDELINE

The Malaysian Medical Council acknowledges that the pharmaceutical industry is a major contributor to patient care and education, medical research, and postgraduate and continuing professional development programmes. The Council believes that the important relationship between the medical fraternity and the industry must be maintained at the highest professional standard. In view of the potential for competing influences, the Council has developed this Guideline.

This guideline will assist doctors in achieving and preserving the highest quality of individual and community health care, to the benefit of both medicine and the pharmaceutical industry. It is recognized that guidelines assume the commonsense and integrity of doctors, while at the same time articulating general community standards. This guideline will be available for public scrutiny and subject to revision from time to time in response to changes in ethical issues and attitudes.

It should be noted that although this Guideline refers specifically to the pharmaceutical industry, it applies equally to other organizations supplying therapeutic or diagnostic materials and devices, or other health products and services.

This guideline is adapted from the Royal Australasian College of Physician's Guideline with appropriate adjustment to the local scenario.

3. CLINICAL TRIALS, INCLUDING COMMISSIONED RESEARCH PROJECT¹

3.1 Responsibilities of the doctor-investigator

Each investigator should consider:

- i. whether the proposed study is to address scientific questions, or whether it is a promotion to familiarise doctors with the drugs, or a device to encourage a particular brand usage, or a commercial undertaking to permit registration of a drug;
- ii. whether the discomfort and inconvenience, or risks, to which patients are to be exposed are reasonable, taking into account the nature of the project, the patient population to be studied, and the likely benefits;
- iii. whether the patients will be able to consent freely to participation, and whether consent issues are satisfactorily addresses in other ways;

1. Guideline on Clinical Trials and Biomedical Research, MMC 2006

- iv. whether the information to be provided to patients includes and adequate description of the nature of the project and any potential risks or discomfort associated with participation in or withdrawal from the project;
- v. whether patients' privacy and confidentiality can be assured;
- vi. resource issues, including the financial implications of the study to the institution (investigation, bed usage and staff time) and expected demands imposed on researchers.
- vii. proposed methods for monitoring the conduct of the trial and obligations imposed on researchers to ensure that the trial remains in accordance with various guidelines published by the Ministry of Health on Good Clinical Practice and other relevant guidelines.

3.2 Payments to investigators, departments or institutions

As investigators, doctors should not derive direct personal or financial benefit from the conduct of a pharmaceutical company sponsored clinical trial, other than adequate compensation for personal expenses arising from the trial, including reimbursement of practice expenses. Consultancy fees are allowed as defined by the institution to which the doctor is affiliated.

The quantum of compensation must reasonably relate to income or practice time lost and should be administrated under a formal contractual arrangement, endorsed by the relevant committees in the institution. All remuneration should be paid into a fund subject to appropriate institutional guidelines. The remuneration should be used to finance the execution of the study. Any other use of this fund must satisfy institutional approval.

Payments on per capita basis pose an additional problem because they directly raise the possibility of a conflict between the clinical responsibilities of a doctor and financial gain, either personal or to the institution. It is therefore especially important that the arrangements are specifically approved by an institutional ethics committee. If such payments are approved, care should be taken that subjects are included in the trial only according to the approved protocol and not influenced by the payment system.

Since payments to investigators, departments and institutions have ethical implications, the Research Ethics Committee must be aware of financial arrangements for clinical trials, including proposed payments to researchers and research participants and the provision of other resources required to carry out the study.

Payments to research participants should not be so large as to constitute an inducement to participate in the project.

Financial grants or equipments by pharmaceutical companies to hospitals, healthcare centers and universities specifically for the purpose of research are generally acceptable but should always be made to and administered by the institutions and not by individuals, and should be appropriately acknowledged in research and other publications. If the donation is linked to, or contingent upon, a clinical trial or specific research project, a formal contractual arrangement which is open to scrutiny should be in place.

3.3 Collaboration

When research facilities in a private facility are inadequate, research projects conducted by private practitioners may include an investigator with an institutional or organizational affiliation and be assessed by an ethics committee associated with that body if such a committee is not available in the private facility.

3.4 Notification to appropriate Institutional Review Boards/ Research Ethics Committees

All research projects involving human subjects must be assessed by an Institutional Review Boards or Research Ethics Committees (REC/IEC) that is constituted according to recommendations laid down in the Good Clinical Practice Guideline and in Clinical Trials and Biomedical Reserch.

3.5 Publication of Results

Before a study commences, the sponsor and principal investigator should agree upon access to any data from the study and how these are to be used and/or published. This should be clearly stated in the study document.

The investigator and the ethics committee should ensure that decisions concerning publications of the results of the proposed studies are the responsibility of the investigators and not solely of the sponsoring company.

The results should preferably be made public in the form of a published report in refereed journal.

It is inappropriate for a publication of the report to be subjected to approval by the sponsoring company, although the latter may be given an opportunity to comment before publication provided such comments are not aimed at influencing the findings and conclusions of the study.

With multi-centre trials, a committee of the investigators, independent of the sponsoring company, should be responsible for the analysis of the results for publication.

It is important that the results, whether negative or positive, are allowed to be published. At the very minimum, negative results should be made known to the IRB/IEC once the study is completed.

Financial and other support should be acknowledged in publications, as should any other association with the sponsoring company.

3.6 Responsibilities of doctors as members of Institutional Review Boards/Research Ethics Committees

Doctors may be called upon to become members of Institutional Review Board (IRB) or Research Ethics Committee (REC), or any Research or Drug Committees, and should be ready to make their particular expertise available when asked to do so.

The IRB/IEC may be asked to consider a variety of applications that have been developed jointly by the investigator and a pharmaceutical company as a local project, or part of a multi-centre trial. Doctors should excuse themselves from discussions concerning research projects in which they are personally involved. Where an IRB/REC is to discuss a project involving a company with which a doctor has a current or previous relationship that could raise the possibility of conflict of interest this should be openly declared.

IRB and REC have a responsibility to ensure that trials are conducted in accordance with national standards, as set out in the Malaysian Good Clinical Practice Guideline. The main principle to be followed is that the likely benefits of the proposed experimentation are reasonable in terms of any risks or potential discomfort to participants, and that consent for participation is freely given. The questions that should be addressed by ethics committee naturally overlap those mentioned above for doctors.

4. PHARMACEUTICAL INDUSTRY SPONSORED TRAVEL AND ATTENDANCE AT MEETINGS

4.1 Sponsorship for professional development

The pharmaceutical industry provides sponsorship both for organising meetings and to doctors for attending them. While this sponsorship is provided with the expressed aim of contributing to continuing professional development (CPD) programme, the manner in which it is provided may leave the reasons for its provision open to the perception that the doctor is being unduly influenced by the pharmaceutical industry.

The ideal manner for the industry to provide sponsorship is through an independently organised scientific meeting for which the costs of bringing in invited speakers are defrayed by the funds provided by industry; the cost of travel and attending such a meeting is met by doctors because of its value to their continuing professional development.

In accepting sponsorship outside these arrangements, the main issues with ethical implications that need to be considered by a doctor are that:

- the sponsorship must be clearly linked to education;
- there should be no loss of professional independence through accepting the sponsorship offered;
- the doctor should have no reservations regarding the sponsorship being publicly scrutinized;
- the criteria to select invited speakers and delegates can be made available to organisations invited to contribute to the event; and
- leisure activities must be kept to the minimum and must not interfere or coincide with the main educational activities

4.2 Attendance at a meeting in which the doctor is making a formal contribution

Sponsorship may be offered to an individual doctor to travel to a meeting in which he/she is already involved as speaker, chairperson or in some other significant capacity (e.g. organizing a future or subsequent meeting). Where this is for the scientific meeting of a Specialty Society, for example, and where the arrangement has been made by the organisers of the meeting, this form of sponsorship recognizes the standing of the individual and the Council would have no objection. With such sponsorship, actual payment to the individual should be made by the organisers of the meeting, and not by the sponsor. The sponsorship should be acknowledged, and should be at a reasonable level as judged by the organisers of the meeting and by the institution to which the doctor is affiliated.

Sponsorship may be offered to an individual who is already involved as a speaker or chairman independently of the organizing committee of the meeting. This is less appropriate and the sponsor should be encouraged to make the support available through the organizing committee of the meeting.

Particular care must be taken for meetings which are not regular meetings of Specialty Societies, especially if there is no independent organizing committee and the meeting is organized by a pharmaceutical company. It must be recognised that the invitation almost certainly arises from the fact that the company considers that the doctor's contribution will be to the company's benefit. In addition, the lack of an independent organizing committee may call into question the independence of the speaker. If undertaken, support for such travel should always be declared to relevant hospital, university or other bodies.

Speakers should refrain from using lecture materials directly prepared by the company. Speakers must remember that their reputation is at stake if they are seen to endorse the company's product particularly in the absence of credible scientific evidence.

4.3 Attendance at a meeting at which the physician is not making a formal contribution

Accepting sponsorship from a company to attend a meeting at which the doctor is not making a formal contribution, will inevitably raise the possibility that the individual could be compromised by a conflict of interest in subsequent decisions about products of the sponsoring company. If circumstances are such that acceptance of such sponsorship seems reasonable using the criteria outlined above, prospective agreement from appropriate institutional committees is strongly recommended. This reduces the risk of the propriety of the sponsorship being subsequently questioned.

The principles for attendance at meetings of a group of doctors are the same as those for individuals. In particular, it must be remembered that group participation does not in any way absolve individual doctors from their own ethical obligations.

Accepting sponsorship from a pharmaceutical company for a spouse or partner to attend a meeting, even if its educational value is unquestionable, and cannot be justified under any circumstances. Such demands by the doctor from the pharmaceutical company are also questionable.

4.4 Types of meetings for which pharmaceutical company support is provided

In addition to support for clinical and scientific meeting organised nationally or internationally by independent organizing committees, pharmaceutical companies provide sponsorship to physicians to participate in a variety of meetings. This includes:

- launching of pharmaceutical products;
- local meetings of specialist group which usually have an independent organizer or organizing committee;
- hospital grand rounds and departmental scientific meeting.

While these meetings usually have a clearly defined primary educational aim, they again may be potentially open to unethical interaction between physicians and the pharmaceutical industry. Doctors involved in organizing or attending such meeting need to have a high level of awareness of this risk.

Doctors should ensure they could meet any allegations of unethical behaviour, through avoiding any secrecy regarding the source and extent of sponsorship, and by ensuring that the provision of food or other attractions at these meeting is not so lavish as to cast doubt on the primary educational purpose of the meeting. The cost should not exceed the level which recipients might reasonably be expected to incur for themselves under similar circumstances.

5. SUPPORT FOR MEETING AND OTHER EDUCATIONAL ACTIVITIES

All of the following can be legitimate extensions of a mutually advantageous liaison between doctors and pharmaceutical companies. Where the support of companies is sought for meetings, doctors should maintain an even-handed approach and be careful not to favour one company over another as a matter of policy. Independent institutional and organizational continuing professional development programme providers who accept industry-sponsored activities should develop and enforce explicit policies to maintain complete control of the programme content.

5.1 The supporting pharmaceutical company selects and sponsors both the speakers(s) and the meeting

Under these circumstances it is appropriate that the supporting company issues invitations in its own name, that it supplies the venue for the meeting, that it supports the speaker and meets other costs. It should not be or purport to be under the auspices of the doctor. If the topic is likely to be of interest to a significant number of members of a Specialty Society, then it is appropriate to provide information through the Specialty Society or other sources from the company.

5.2 The company provides a speaker and support for a meeting primarily organized by the doctor

A pharmaceutical company may offer to provide a speaker for a meeting organized by the doctor. The overriding principle for acceptance of such offers should be that the programme is arranged by the doctor responsible.

Use can be made of visiting speakers, but care should always be exercised in acceptance of such offers to ensure that an unbiased (not promotional) presentation is to be made.

Companies may be disinclined to sponsor speakers unless it is known that they are likely to support the objectives of the company. If there are areas known to be contentious, care must be taken to ensure that there is an appropriate balance of speakers canvassing alternative views.

It may be appropriate for the company to further support the meeting by payment for the venue, satchels, refreshments etc., but such support must be made clear on all invitations and publicity for the meeting, and the guidelines for travel of individuals doctors to such a meeting should apply as defined in section 2 on Guideline, above.

5.3 The doctor approaches a supporting body to supply speaker

The doctor may approach a pharmaceutical company to support a meeting by supplying a speaker.

If the company chooses the speaker, the principles of support are the same as if the company had offered the speaker. If the speaker is not chosen by the company, appropriate acknowledgement should be made of the support given by the company.

A contractual arrangement should be entered into with the agreement of both bodies. The terms of the arrangement should be fully understood by all parties, including the use of the names of the speakers for publicity purposes.

5.4 Seeking funds from pharmaceutical companies

Companies may be approached to support scientific meetings in such ways as supplying dinners, programmes or satchels as well as taking part in an exhibition of pharmacological or other products. Such support is appropriate provided it is never contingent upon alterations in the programme, speakers or other aspects of the format of the meeting.

In these circumstances, appropriate acknowledgement generally should be given, but this should be by general reference to the company without reference or endorsement of a single product.

The doctor should not accept or acknowledge sponsorship that could in any way damage the public standing or reputation for independence of the profession in the eyes of:

- peers, colleagues and co-workers;
- the media;
- patients and their relatives; and
- the general public

The question should always be asked, and responded with a comfortable answer: “Can this presentation stand on its own without the financial support and influence of an outside body?”

6. GIFTS AND ENTERTAINMENT PROVIDED TO DOCTORS

This includes not only gift items, but also payment for dinners, entertainment or expenses associated with daily living.

Benefits or subsidies received from pharmaceutical companies must leave doctors independence of judgment unimpaired. As a general rule, arrangements between doctors and pharmaceutical companies should be open and transparent. Where the possibility of a conflict of interest could be raised, either in clinical practice or in research, they should be declared openly to patients and employers.

Doctors must judge for themselves what is and is not acceptable, but should err on the side of rejection of gifts. Service oriented items may on occasions be acceptable, e.g. patient's counseling or teaching aids, or nomograms (charts) for surface area calculations.

Non-service oriented items should in general not be accepted. However, there is an obvious gradient of acceptability from, on the one hand, items of trivial value, to, on the other hand, more substantial items, acceptance of which anyone would find objectionable.

The possibility of impropriety should be considered before accepting lavish dinners and entertainment, even if accompanied by a scientific presentation. For such educational and scientific meetings organised or sponsored by pharmaceutical, and instrument and equipment companies, even in collaboration with a local professional body, all hospitality must be simple and modest and interactions with doctors should successfully withstand public and professional scrutiny.

It is recognized that judgment on these matters may sometimes be difficult. In specific cases it may be helpful to discuss issues that arise with colleagues, institutional representatives, or an ethics committee, or the Malaysian Medical Council.

7. DRUG SAMPLES

Drug samples are packages containing pharmaceutical products distributed by manufacturers or their agents to doctors. These samples commonly are starter packs that may be provided to patients who need to commence treatment immediately. The provision of samples which may appear to be for service is in many instances a marketing exercise intended to accustom the clinician to prescribing a particular product, or to establish a cohort of patients on long-term treatment with a particular drug.

On occasions there may be a good reason for accepting a sample, e.g. to evaluate the clinical performance of medication outside the context of post-marketing surveillance studies. However, drug only in sufficient quantity to enable the particular need to be met should be accepted.

Asking for drug samples is not recommended. The acceptance of free samples that may influence the choice of prescribing is not recommended. Requesting samples for personal use is also not acceptable.

Distribution of drug samples to patients should not involve material gain to the doctor or to the institution in which he is working.

8. REMUNERATION FOR SERVICES

Doctors are entitled to remuneration for services provided to the pharmaceutical industry. In such cases the relationship should be public knowledge. Doctors should not request or accept a fee equivalent consideration from pharmaceutical companies in exchange for seeing them in a promotional or similar capacity.

8.1 Consultancy

An individual doctor may act as a consultant for a pharmaceutical company. This may be in general terms or in relationship to a particular product. The arrangement should be like that of any business undertaking. If a doctor acts as a consultant to the industry, this information should be public knowledge, and be appropriately reported to and recognized by all relevant committees, and also so recognised when involved in promotional activity.

8.2 Research and development

New discoveries by doctors and the development of new drugs or other agents should be encouraged, and those involved in these activities should be eligible for reward for this work.

8.3 Employment

Doctors are not precluded by any of these guidelines from full-time direct employment in the pharmaceutical industry and are not expected to continue practising or treating patients.

9. DUALITY OF INTEREST

9.1 Conflict of Interest

Doctors should take care in having interest in pharmaceutical companies that may conflict with their professional responsibilities.

It is impossible to lay down precise guidelines for such interests, but one guide could be that an objective outsider should not consider that a doctor's judgment about the role of a particular pharmaceutical agent in therapy might be significantly influenced, for example, by financial interest in the company involved.

Interest most likely to influence a doctor may be called Pecuniary Interest and include:

- share holding, board membership;
- paid employment, including consultancy, commissioned fee-paid work, paid speaker, paid expert adviser;
- fellowship, research grant, education grant; and
- travel grant, conference expenses or significant hospitality expenses

Other interests that may influence a doctor are:

- clinical trials sponsored by a pharmaceutical company;
- other research, safety testing; and
- expert advice (non-paid)

In all cases, if a doctor or close family member has such a duality of interest in a pharmaceutical company, it should be declared to appropriate committees.

9.2 Advisory Boards

It is appropriate for a doctor to be appointed as a member of or to chair an Advisory Board established by a pharmaceutical company. Such a board may be set up to give advice to the company about a particular drug or technique or a group of products, and opinion leaders will usually be sought. Board activity may involve all aspects of products development, from preclinical studies to marketing.

It is possible that membership of such a board will encourage a feeling of commitment to a product as well as a feeling of reciprocity and friendship towards the drug company and its representatives. While such feelings are common following any such collaboration,

doctors should realize that there is no obligation to prescribe such a product or recommend its use to other clinicians. Product use and recommendations should always be based on sound scientific and clinical principles regardless of personal feeling and friendships.

In view of the fact that membership of an Advisory Board could pose a question of duality of interest, Board members should declare involvement of this sort in appropriate circumstances, for example to ethics committees considering clinical trials of products of that particular company or a competitor.

Payment for participation in Advisory Boards should meet the principles given Section 6.

9.3 “Advertorials”²

Doctors, particularly those who are seen as opinion leaders by members of the pharmaceutical industry, may be asked public comments supporting a particular product. While such comments may be appropriate in some cases, promoting commercial interests in the guise of editorial comment is unacceptable.

10. GENERAL GUIDING PRINCIPLE

A useful criterion in determining acceptable activities and relationship is “Would you be willing to have these arrangements made publicly and generally known?”

2. MMC Guideline on Dissemination of Information by the Medical Profession, 2006

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