GUIDELINE OF

THE MALAYSIAN MEDICAL COUNCIL

MMC Guideline 008/2024

RELATIONSHIP BETWEEN DOCTORS AND THE HEALTHCARE INDUSTRY

CONTENTS

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”, “registered medical practitioner (RMP)”, “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.

SUMMARY

The relationship of medical practitioners with the healthcare 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 Healthcare 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 behavior for practitioners towards the industry.

The guideline draws the line on sponsored talks, travels and gifts. RMPs should declare their sponsorships during their presentations, and be ready to clarify when requested to do so by their employers, or regulatory body. In addition, they should comply with any funding and sponsorship rules and/or guidelines imposed by their own respective organizations.

1. BACKGROUND

1.1 Doctors and the Healthcare Industry

Industry physicians are doctors who are employed by the industry primarily for development of new diagnostic or therapeutic options. On the other hand, there are a range of doctors who are not employed but interact with the pharmaceutical industry, among them employees of Contract Research Organization (CRO), academic and non-academic clinician-investigators, or clinician from both public and private sector. All the above are subjected to rules and regulations of MMC.

The healthcare industry involves pharmaceutical, medical devices, diagnostics, residential, health information technologies, and health insurance entities providing goods or services with curative, preventive, rehabilitative or palliative intent.

Pharmaceutical companies and healthcare providers interactions help enhance technological innovation, new medicines, fosters knowledge creation, aids disease control, and reduces polypharmacy issues yet there are concerns that these interactions are primarily geared towards promoting the products of the pharmaceutical company. (Bodenheimer, 2000)

From time to time, these interactions 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.

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

- to use existing, approved drugs, medical devices or diagnostic tests 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 and medical devices;
- to keep up to date with scientific developments in their field, including information about new drugs and devices, as well as 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 and medical devices or into new applications of existing ones, or contribute to or support such research.

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 healthcare industry. Both doctors and healthcare companies are also subject to laws and regulations governing the prescription of drugs, use of medical devices, and diagnostic test and in the conduct of research.

It is also important to stress the need for openness and transparency in dealings between doctors and healthcare 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.

1.2 Promotional activities

The promotional activities of the health care industry can take many forms, including overt advertising and the provision of gifts and perquisites to individual doctors or to their employing institutions.

The following has been recognized as part of healthcare industry promotional activities; (Brett et al, 2003) (Ferrari et al, 2014)

- Stationery items with reminders as gifts.
- Patient education materials
- Textbooks as gifts
- Dinner speaker with product mentioned favourably or not mentioned
- Invitation to lunch or cocktails at local restaurants
- Grand Rounds speaker with product mentioned favourably or not mentioned
- Trip to resort
- Free drug samples for office
- Free lunch for resident conference, with formal or informal presentation by drug representative
- Unrestricted cash gifts to department
- Drug representative present during clinic hours
- “Happy hour,” with drug representative present or not present
- Funding of registration fee, travel arrangements to attend conferences

The number of drugs available has increased greatly in recent years, and this has made the industry more competitive, with the need for intensive marketing and promotional activities.

Doctors have an obligation to offer the best therapeutic options with his patient’s interest the primary concern. As such he should take all precaution to address issues that may cloud his judgment.

Doctors were shown to be willing to meet up with pharmaceutical representatives (PR) and in the process receives gift as PR were viewed as a convenient and efficient resource for information. Most doctors believed that their prescribing will not be influenced by PR. (Salmasi et al, 2016) PR presentations to doctors however are often incomplete, focused on

indications and doses leaving out risk and harmful effects of their products. (Othman N et al, 2010)

It is important to recognize 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.

Contrary to doctor's perception, studies have shown that gifts of any size from pharmaceutical companies were found to affect prescribing behaviour leading to more expensive and branded prescriptions. Larger gifts elicited larger impacts on prescribing behaviour. (Fickweiler et al, 2017). Pharmaceutical industry-sponsored meals which constitute the most frequent promotional gifts tendered, even at an average cost of less than USD 20 was able to significantly influence physician prescribing pattern. (DeJong et al, 2016). In order to preserve professional integrity, physician should decline:

i. cash or in-kind gifts of any value from an entity that has a direct interest in physician's treatment recommendations
ii. any gifts for which reciprocity is expected or implied.

Physician may accept gifts that would directly benefit patients, such as material for patient education. (AMA, 2016)

Malaysian Organisation of Pharmaceutical Industries (MOPI) has produced its own code of ethics related to promotional activities, accessible at their website. It includes voluntary gift restriction policy for its organization members. (The Malaysian Organisation of Pharmaceutical Industries (MOPI), (2013). However, compliance to the policy cannot be ascertained as mechanism for mandatory public disclosure is yet to be in place.

2.0 GUIDELINE

The Malaysian Medical Council acknowledges that the pharmaceutical industry is a major contributor to patient care and education, medical research. The Council believes that 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. 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.

3.0 CLINICAL TRIALS, INCLUDING COMMISSIONED RESEARCH PROJECT

The rapid development of new drugs, therapies, and devices results in a dramatic increase in the number of clinical research studies which leads to greater participation by both physicians and patients into clinical trials.

3.1 Responsibilities of the doctor-investigator

Investigators, both principal and co-investigators must ensure that the clinical research (Biomedical Research or Clinical Trial) has been accurately presented and cleared by the Institutional Review Board (IRB) where the research is to be conducted. This compliance still holds true, for multinational research project that has received IRB clearance elsewhere. Presentation to Research Ethics Committees (REC) may also be required if this function is not performed by IRB according to local situation.

The investigators are responsible at ensuring that all research requirements as outlined in the Malaysian Guideline for Good Clinical Practice, 4th Edition or any later version has been fulfilled.

Conflict of interest is bound to arise in clinical research when a doctor accommodates both roles as a physician providing optimal care with undivided loyalty for his patient and an investigator who is duty bound to adhere to the scientific process as described in the protocol. In the event of

such conflict, the patient's outcome is to be given priority keeping to the fiduciary viewpoint. Each investigator should consider:

i. whether the proposed study is to address scientific questions, or whether it is a promotion to familiarize 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. Is the patient in the control arm of a randomized control trial provided with best medical care, in accordance to the spirit of equipoise? (Resnik, 2009)
iv. Whether patients (or their representatives) have adequate decision-making capacity, receive the information they need to make a decision, understand the information, and are not facing any conditions (such as coercion or duress) that could interfere with their ability to make a free choice.
v. whether the information to be provided to patients includes adequate description of the nature of the project and any potential risks or discomfort associated with participation in or withdrawal from the project. This is especially when the research methods are known to involve ethical debates such as randomized control trial (RCT), placebo-controls, and drug washout period.
vi. whether patients' privacy and confidentiality can be assured;
vii. resource issues, including the financial implications of the study to the institution (investigation, bed usage and staff time) and expected demands imposed on researchers.
viii. proposed adequate monitoring and auditing processes overseeing 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

Investigators are allowed to receive adequate compensation for personal expenses arising from the trial, including reimbursement of practice expenses. The quantum of compensation must reasonably relate to income or practice time lost and should be administered 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.

Direct payments on per capita (subject/patient) basis pose a 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 equipment by pharmaceutical companies to hospitals, healthcare centres 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 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 and published manuscript.

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-center 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.

Ghostwriting and ghost management (Sismondo, S., 2007) involve industry-financed writers generating articles that either promote the sponsor company's products or discredit competing ones, with eventual authorship credited to academic researchers who provide little or no input, concealing industry involvement. Doctors should protect their integrity by refraining involvement. Both guest writer and the credited author are answerable to injury arising from misrepresentation of facts in the court of law. (Bosch, X., 2011) Medical writer employed to prepare manuscript should be declared.

Generating fraudulent publications either positive or negative results is a serious misconduct and will lead to disciplinary action.

If any Artificial Intelligence tool is used, that should be acknowledged in the publications, specifying in what ways it was used.

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

Impartial parties, such as institutional Review Board (IRB) mitigate conflicts in the ethical responsibilities of physician-investigators to research subjects from those of physicians to their patients and, thus, help to protect the rights and welfare of research subjects. (Grady, 2015)

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. IRB and REC have a responsibility to ensure that trials are conducted in accordance with national standards, as set out in the latest Malaysian Guideline for Good Clinical Practice, accessible online at the National Committee for Clinical Research (NCCR) website.

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-center trial. Doctors who are members of IRB board must declare their relationship with investigator and trial sponsors, and eligibility to sit on an assessing board for that particular trial to be determined by consensus.

As members of IRB, doctors may assist to facilitate well acquainted fellow physician-investigators through the review process (Cartwright et al, 2015) but not to an extent that this relationship compromises impartiality.

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.

4.0 HEALTHCARE INDUSTRY SPONSORED TRAVEL AND ATTENDANCE AT MEETINGS

The all-encompassing principle for this section is that, all remunerations, honorariums, grants, reimbursements and sponsorship (of travel, accommodation and food) whether direct or indirect to a doctor by a healthcare industry player must be declared by both parties in a transparent manner.

4.1 Sponsorship for professional development

The healthcare industry provides sponsorship both for organizing 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 healthcare industry.

The ideal manner for the industry to provide sponsorship is through an independently organized 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 organizations 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 organizers 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 organizers of the meeting, and not by the sponsor. The sponsorship should be acknowledged, and should be at a reasonable level as judged by the organizers 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 healthcare company. It must recognize 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.

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 healthcare company for a spouse or partner to attend a meeting, even if it has educational value, is questionable, 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 organized nationally or internationally by independent organizing committees, pharmaceutical companies provide sponsorship to physicians to participate in a variety of meetings. This includes:

- launching of healthcare 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 healthcare 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 behavior, 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.

5.0 SUPPORT FOR THE CONDUCT OF MEETING AND OTHER EDUCATIONAL ACTIVITIES

The purpose of the section is to detail how the healthcare industry should contribute and interact with regards to educational meetings. The Code of Conduct recognizes that the industry plays a vital role in the provision of accurate and reliable information to healthcare professionals by a number of means, including the holding of educational meetings, the sponsorship of such meetings

or the involvement in educational meetings, and this collaboration should not be profit driven.

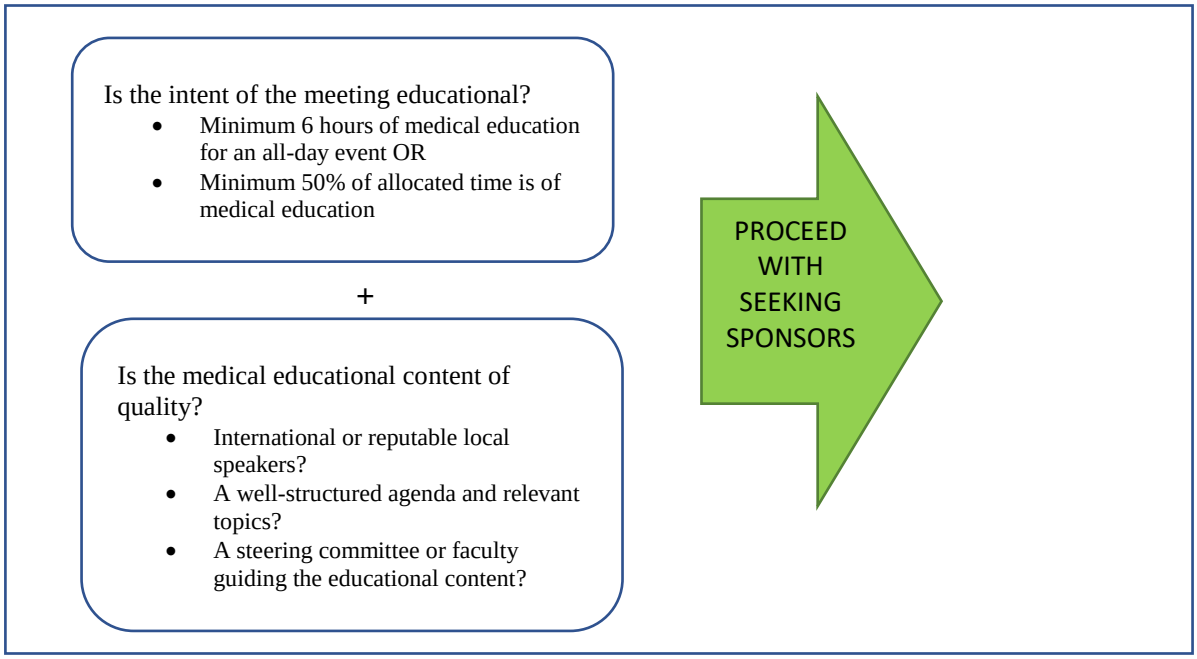
All listed in this section are legitimate extensions of a commonly beneficial association between doctors and healthcare companies. The categories of these beneficial association would include the following activities that are sponsored by financial support; sales calls, educational events, consultancy arrangements, advisory boards, sponsorship of healthcare professionals, and medical practice activities.

When there is requirement of support for meetings, doctors should maintain an even-handed approach and be careful not to favor 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.

The primary purpose of educational meetings, seminars or events are important for the sharing, the distribution and enhancement of medical knowledge and experiences to healthcare professionals for quality use of medicines and services.

The healthcare industry should not offer education to doctors with the objective of financial and commercial gains from the doctors that is similar to quid pro quo situations. However, provision of training that will enhance the interaction of healthcare professionals with their peers or patients may be justifiable.

The following diagram in Figure 1 describes the flow of dealing with sponsorships to avoid any possible quid pro quo situations.



Other factors to consider:
Quality of accommodation – business hotel preferred to luxury resort.
Location of accommodation – city venue preferred to holiday resort.
Level of entertainment at dinners - focus (for example highlighted on the invitation to attract attendance) preferred to incidental.

Figure 1: Diagram showing attributes of educational meetings that should be present before seeking sponsorship from healthcare industry.

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

Under these circumstances, it is appropriate that the supporting companies issue invitations in their own name, which they provide the venue for the meeting, the speaker and cover other costs as well. It should not be at any relevance 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.

Participants are not encouraged to participate in activities that do not conform to MMC guidelines pertaining to sponsorship.

The following general principles should apply to ensure that the participation in sponsored medical events appeared as a legitimate educational activity and does not appear to endorse the sponsored company products or services, or to persuade patients or members of the public to use its products and/or services:

i. The programmes that the doctor is sponsored for are primarily for education and not be focused on extravagant meals, entertainment or any other kind of leisure activity.
ii. The sponsorship needs to be directed towards facilitating the doctor's attendance of the programmes including reasonable logistic support.
iii. The majority of 6 hours and/or 50% and above of education time ought to be spent attending the formal content of the programmes rather than unrelated activities.
iv. When accepting sponsorships for educational events, the doctor must not show or be perceived by reasonable persons to show favouritism to the companies that provide such sponsorships.

v. The doctor has to personally pay for the costs of unrelated activities including any extension of their stay before or after the period of the formal programme or the costs of any accompanying persons that is not part of the programme.
vi. Sponsorship/s by the doctor can only be for their own participation and not for any accompanying person/s who are not participants of the programme, unless there is insignificant or no additional cost (for example, sharing a hotel room at no extra charge, meals, transport, etc).
vii. If there is a pharmaceutical/medical/nutritional company/ies support for the Speaker's participation in educational events, the speaker must disclose them to the audience.
viii. If the doctor is invited to participate in medical events, conferences, talks, publications or educational websites sponsored by medical companies, the doctor must ensure that their participation does not occur in such a way as to appear to endorse the company/ies products and/or services.
ix. If the doctor is funded as a delegate to an educational event, the doctor may only receive support up to the extent that it facilitates its attendance, inclusive of reasonable logistic support.
x. When accepting sponsorships from the healthcare industry, the doctor must ensure that the programme of the event is focused primarily on education or research and not on extravagant meals, stand-alone entertainment or any other kind of leisure activity.
xi. The doctor must not ask for or accept extravagant gifts, hospitality or other inducements from companies that could be seen by reasonable observers as potentially affecting the professional clinical judgment in making decisions about patient care. Accepting educational materials and items of medical utility of modest value are allowed if they improve patient care.

If the doctor accepts sponsorship/s for legitimate educational events, the doctor needs to act ethically and not show, or appear to show favouritism to the companies that provided such sponsorships.

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

A healthcare 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. Any financial reimbursement or honoraria that the speaker receive for the role as an expert participant in educational events must be fair, reasonable and commensurate with the complexity, time and expertise rendered.

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 this guideline.

5.3 The doctor approaches a supporting body to supply speaker

The doctor may approach a healthcare 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.

Both parties should be bonded in a contractual arrangement, where the terms of the arrangement should be fully understood by all parties, including

the use of the names of the speakers for publicity purposes. Similarly, any financial reimbursement or honoraria that the speaker receive for the role as an expert participant in educational events must be mutually agreed by both to be fair, reasonable and commensurate with the complexity, time and expertise rendered. Honorariums are to be documented as an acknowledgement from both parties.

It is compulsory for the speaker to disclose of the relationships and to declare any affiliation between the Doctor and healthcare Industry. This will lay the right platform of expectations and credibility between the speaker and the audience.

Part of the service to the community as doctors may involve giving talks, interviews or writing articles to increase public awareness of health issues to help improve the health of the community. Depending on how the doctor does so, this may be a form of advertising and must be done ethically. This means:

i. When the doctor gives medical talks to colleagues or the public, or place information in the public domain, the information doctor provides must be objective. Any unsolicited information the doctor provides about their practice must abide by the standards required of Medicine Advertisements Board (MAB) which was established under the provisions of The Medicine Advertisements Board Regulations 1976.
ii. If the doctors are featured in the press or media, the doctors must ensure that the statements they make and the information they provide abide by the standards required of Medicine Advertisements Board (MAB). Where the doctors have the opportunity to do so, the doctor must ensure, to the best of their ability, that the output is consistent with these standards.
iii. If the doctor use case studies, images (for example, photographs, videos, graphics, and animations), devices, models or other props to illustrate or explain medical procedures or treatments or their outcomes, the doctor must ensure that it is for educational purposes and not used gratuitously. These must not be used in such a way as to

exaggerate the quality of the services or to mislead the public into thinking that the doctors are making a claimer guarantee of your expected results.

iv. If the doctor has paid for the right of publication or broadcast in any media, or entered into an arrangement where paid advertising is a condition of publication or broadcast, or the doctor have paid for what appears to be impartial information originating from a third party, the doctor must disclose this prominently to the audience at the beginning of the article or broadcast in such a way that it is clear that these are advertisements and to adhere to Medicine Advertisements Board (MAB) guidelines.

5.4 Seeking funds from healthcare companies

Companies may be approached to support scientific meetings in such ways as supplying programmes, brochures, booklets or even by taking part in pharmacological exhibitions. Such support is appropriate provided it is never contingent upon alterations in the programme, speakers or other aspects of the format of the meeting.

Under these circumstances, appropriate acknowledgement or accreditation should be given, as general reference to the company without any endorsement of a single product or brand.

The doctor should not accept or acknowledge sponsorship that could in any way damage their reputation and independence of the profession towards:

- 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 “Is the sponsorship of this activity defensible following public and professional scrutiny?”

6.0 GIFTS AND ENTERTAINMENT PROVIDED TO DOCTORS

Doctors should not receive any door gifts, freebies or entertainment of any form from healthcare industry. Service oriented items may on occasions be acceptable, e.g. patient's counseling or teaching aids, or nomograms (charts) for surface area calculations.

7.0 DRUG NON-DRUG, SERVICE 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 to request 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.

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.

The industry is obligated to provide samples for all medical practitioners and should not deny any medical practitioner a legitimate request. However, the industry should also refrain from using samples to enhance its marketing of a particular pharmaceutical product. The industry is therefore encouraged to make public on an annual basis, an itemized quantum of all samples given out to individual doctors, clinics, or institutions. This data should be forwarded to the MOH and made accessible to all professional medical bodies such as the MMA. This will encourage proper issuance of samples and inappropriate sampling or over-sampling.

Handling and dispensing of samples for doctors in institutions in the public sector should be under the control of the respective pharmacy department. Doctors in public and private health facilities should not receive, store or dispense any samples for the sake of maintaining patient safety and avoid undocumented

dispensing. This practice should also be encouraged in the private sector where the services of pharmacists are present but the patient must not be charged if the doctor prescribes a sample.

Drug samples should also carry with them specific identification numbers or codes so as to discourage the unwarranted appearance of doctors' samples in retail outlets.

8.0 REMUNERATION FOR SERVICES

Doctors may provide services to industry in the capacity as an employee, consultant, director, speaker, advisory board member and participate in industry sponsored research. In such cases the relationship with industry and any conflicts of interest should be declared and made public knowledge. It is appropriate for doctors who provide a service to industry to receive remuneration for that service. This should be openly declared, and the RMP must also comply with all rules and guidelines of their respective organisations regarding this matter.

However, it is inappropriate for doctors to request or accept a fee, loan or equivalent consideration from industry in exchange for seeing industry representatives in a promotional or similar capacity.

8.1 Consultancy

An individual doctor may act as a consultant for a healthcare company. This may be in general terms or in relationship to a particular product.

Both parties should be bonded in a contractual arrangement, where the terms of the arrangement should be fully understood by all parties. This information should be made publicly available on the MMC website.

8.2 Research and development

Doctors may also participate in industry- sponsored research. The research should be of genuine merit, have ethical approval, be socially responsible and have scientific validity.

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 reimbursement for this work.

Doctors may also participate in properly designed and ethically approved post-marketing surveillance studies that enable monitoring of a product under conditions of actual use.

It is ethically acceptable for doctors to receive remuneration for participation in approved surveillance studies when it involves a significant amount of professional time and skill beyond that practiced in standard patient care.

8.3 Employment

Doctors are not precluded from full-time direct employment in the healthcare industry and in certain situations, they may need to decide whether it is still ethical to continue practicing or treating patients.

9.0 DUALITY OF INTEREST

9.1 Conflict of Interest

Doctors should take care in having interest in healthcare 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 healthcare products 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; shareholding, board membership, paid employment, including consultancies, commissioned fee-paid work, speaker fees, fees provided in return for an expert opinion and performance bonuses tied to particular outcomes, fellowship, research grant, education grant, and travel grant, conference expenses or significant hospitality expenses, 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. Effective management of dualities and conflict of interest lies in identifying them, making clear declarations, maintaining openness and

transparency, and developing appropriate processes to deal with specific issues.

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. A doctor cannot be a member of advisory board for healthcare industry and at the National or Hospital drug formulary committee at the same time.

While there is a legitimate role for the doctor to play in these capacities, the following principles should be observed:

a. The exact deliverables of the arrangement should be clearly set out and put in writing in the form of a contractual agreement. The purpose of the arrangement should be exclusively for the physician to impart specialized medical knowledge that could not otherwise be acquired by the hiring company, and should not include any promotional or educational activities on the part of the company itself.

b. Remuneration of the physician should be reasonable and take into account the extent and complexity of the physician's involvement.
c. Whenever possible, meetings should be held in the geographic locale of the physician or as part of a meeting which he/she would normally attend. When these arrangements are not feasible, basic travel and accommodation expenses may be reimbursed to the physician advisor or consultant.

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.

It is necessary to distinguish between scientific comment and support for a particular product. The context in which the comments appear may be very important. A paid advertisement from a company may legitimately quote comments made in a scientific publication. However, comments should not be provided for the express purpose of supporting the advertisement of a product.

Every advertorial must be subjected to MAB (Medicine Advertisement Board) approval with a valid KKLIU serial number, eligibly displayed.

10. GENERAL GUIDING PRINCIPLE

A useful criterion in determining acceptable activities and relationship is, "Is the involved arrangement defensible, when exposed to public and professional scrutiny?"

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12. NOTE

1. The following are the members of the drafting committee for updating this guideline:
    - Prof. Emeritus Dato' Dr. Wan Mohamad Bin Wan Bebakar
    - Dr. Letchuman a/l Ramanathan
    - Dr. Zanariah Binti Hussein
    - Dr. Radhakrishna a/l Sothiratnam
    - Dr. Abu Dzarr Ganesh bin Abdullah
    - Dr. Mohd Azhar bin Ahmad
    - Mr. Alvin Seah
    - Mr. Jason Ng
2. This guideline was approved by the Ethics Committee on 26th November 2024 and endorsed by the Malaysian Medical Council on 18th February 2025.
3. This guideline is scheduled for review two years after endorsement. Any changes to the law before the review is completed may render parts of this guideline obsolete.