

IMO Feedback on the Medical Council's Ethical Guide in relation to doctors' interactions with pharmaceutical and medical device companies

The Irish Medical Organisation would like to thank the Medical Council for the opportunity to comment on the proposed explanatory memorandum clarifying the existing provisions given within the Guide to Professional Conduct and Ethics.

The Irish Medical Organisation also congratulates the Medical Council for undertaking this body of work, particularly as this is an environment that is constantly changing, in light of economic and resourcing changes that exist. Such environmental challenges, including the introduction of compulsory Competence Assurance Schemes may alter interactions and balances that previously existed between commercial entities and the medical profession. Additional guidance on the matter will further assist in informing doctors of their responsibilities and in raising awareness regarding their interaction with commercial entities.

General Comments

Consistency

The Guide should be regarded as a reference document for their professional behaviour on this topic. Consistency between the *2007 Regulations*, *The Code* and *The Guide* should be sought to avoid confusion for doctors in their dealings with commercial entities.

Terminology

From experience at an international level, a glossary of terms is often useful to ensure that there is no opportunity for misinterpretation. What is identified as sponsorship or hospitality by one body or individual, may not be considered as such by another.

Competence Assurance Schemes

Given the introduction of compulsory Competence Assurance Schemes, the growth of CPD sessions offering credits has intensified. While the training bodies provide accreditation for these events and have criteria in place for the declaration of sponsorship and conflict of interest, how strictly this is adhered to or if there is a random auditing process to ensure such criteria is maintained is unclear.

International Experience

The IMO is the representative body for Irish doctors, and represents their interests at a European and International level.

As you are aware, UEMS (European Union of Medical Specialists) provide accreditation through the European Accreditation Council for Continuing Medical Education

(EACCME) and have developed strong criteria for the accreditation of live education events.

Additionally, the European Commission and stakeholders in CME/CPD are discussing plans towards stricter regulations regarding the support of medical meetings. UEMS are contributing to the discussion directly with the European Commission, and more information on these developments should become apparent in the coming months.

Once published, this should be reviewed and evaluated for use in Ireland to reinforce transparency, accountability and to promote trust between industry and the medical profession.

Question 1: Is it appropriate to accept drug samples from medical representatives?

The Guide is silent on the topic of receiving drug samples from medical representatives. Most GPs report that they only accept drug samples with the sole intention of using this medication for emergency medication during night-calls. If confined to this use, it is unlikely that the receipt of drug samples from medical representatives would be considered inappropriate.

IMO Comments:

The *Code of Marketing Practice for the Pharmaceutical Industry (Section 13: Samples)* and the *2007 Regulations (Section 22: Free Samples)* have largely consistent information on this topic. Both indicate instruction around the provision of free samples, therefore the inclusion of a summary of each into the text of the memorandum may be useful for doctors to increase their awareness around the conditions of the provision of free samples.

Question 2: Is it appropriate to accept gifts and hospitality from pharmaceutical, medical devices or other commercial enterprises?

At paragraph 59.9 of *the Guide*, it is stated that doctors are advised not to accept gifts (including hospitality) from pharmaceutical, medical devices or other commercial enterprises.

It should be noted that this does not preclude the payment of reasonable fees for work done by a doctor as part of a contractual arrangement with such a commercial enterprise.

It also states that doctors should be aware that even low value promotional materials are offered by commercial enterprises with the intention of influencing prescribing and

treatment decisions.

The *2007 Regulations* state that if the hospitality offered by pharmaceutical, medical devices or other commercial enterprises is *reasonable*, then it may be appropriate to accept such hospitality and consequent gifts. Not only should the level of hospitality be *reasonable* at sales promotion events or at other events for purely professional and scientific purposes, but the level of hospitality must be strictly limited to the main purpose or scientific objective of the event.

On the issue of gifts and hospitality, the council's advice to doctors is therefore somewhat more prescriptive than the *Regulations*. This is due to the potential risk that the doctor's professional judgement might be affected by the receipt of such gifts or hospitality and so should be avoided.

IMO Comments:

The Guide advises not to accept gifts, however the *2007 Regulations* state that if it is reasonable then it may be appropriate to accept 'such hospitality and consequent gifts' and that if the hospitality offered is 'reasonable' it may be appropriate to accept such hospitality and consequent gifts. However, what is considered 'reasonable' is open for interpretation. Consistency between *the Guide*, *the Code* and the *2007 Regulations* should be concordant to avoid confusion among doctors. Doctors should also be made aware of the multifaceted and often creative approaches taken by some pharmaceutical/medical device/commercial enterprises to influence. Possibly the addition of case examples may help to clarify this particular question.

Question 3: Is it acceptable for doctors to charge a fee for medical representatives' visit?

Although not specifically mentioned in the *Guide*, the *Code* stipulates at paragraph 12.6 that Medical representatives must not employ any inducement or subterfuge to gain an interview. They must not pay, under any guise, for access to a healthcare professional.

It may be interpreted from the *Guide's* advice in relation to non-acceptance of gifts other than reasonable fees for professional services, that the Council might view the charging of fees for visits of medical representatives as inappropriate.

Question 4: Are you and your staff aware of the guidelines and regulations which deal specifically with doctors' interactions with pharmaceutical and medical device companies?

The Medical Council's *Guide*, the *2007 Regulations* and the *Code of Marketing Practice* all set out the recommended codes of conduct relating to a doctor's interactions with

pharmaceutical and medical device companies. As a doctor, it is your duty and responsibility to familiarise yourself and educate your staff regarding the latest guidelines and regulations in this area.

The Guide states that you must always be guided by your primary responsibility to act in the best interests of your patient, without being influenced by any personal consideration.

IMO Comments:

It should be noted in this section that while yes, doctors and their staff should be aware of interactions with pharmaceutical and medical device companies, doctors are not necessarily always the employers of staff – particularly when they are employed themselves in the practice or hospital setting. Frontline staff in practices and medical offices are often the first interface with pharmaceutical or medical representatives and they should be aware of the guidelines and legislation that surround their interaction with the medical profession – the responsibility of who ensures this must be clarified. Clarification on whose responsibility it is to ‘educate’ staff in these circumstances, and possibly a guidance document aimed at staff would benefit as well.

Question 5: Are you currently sponsored by a pharmaceutical, medical devices or other commercial company? If so, are you aware of your responsibilities?

If you have such sponsorship, you have a responsibility to ensure that your work is not influenced in any form by virtue of sponsorship.

If you are paid directly or indirectly by a pharmaceutical, medical devices or other commercial company to conduct medical research, *the Guide* advises that you must make sure that such payment does not sway your study, design or interpretation of any research data or impact your research or education in any way.

Question 6: Is educational sponsorship/funding advisable?

The Medical Council has stipulated at paragraph 59.10 of its *Guide* that, in general, educational sponsorship/funding from commercial enterprises should be channelled through unrestricted Education and Development Funds and should be managed without influence from the commercial enterprise in question.

If these criteria are met, then there is no reason why educational sponsorship cannot be continued to be used to ‘fill the gap’ between the costs of Professional Competence Schemes (PCS) costs and any State funding available.

IMO Comments:

The IMO agrees that funding of this nature should be processed transparently through the Education and Development Funds. We would propose to replace the word 'advisable' in the question with 'appropriate'.

Question 7: Are you doing enough to keep up-to-date with development in medication safety?

The Guide states that you must keep up to date with developments in medication safety. You should not rely solely on promotional literature distributed by pharmaceutical companies for information about particular drugs. You should seek independent evidence based sources of information on the benefits and risks of all medication before prescribing.

IMO Comments:

The IMO agrees with the guidance for this question.

Question 8: What is a 'Promotional' meeting?

A Promotional meeting is a meeting held by pharmaceutical, medical devices or other commercial companies which characteristically focus on one specific drug from the sponsor company. The purpose of this type of meeting is to teach the attendees about a particular new drug or device.

The Guide advises doctors not to rely solely on promotional literature distributed by pharmaceutical companies for information about particular drugs and to seek independent evidence based sources of information on the benefits and risks before prescribing.

IMO Comments:

The IMO agrees with the guidance provided on this question.

Question 9: What is a 'Sponsored Educational' meeting?

A Sponsored Educational meeting is the most widely attended type of meeting. Pharmaceutical, medical devices and other commercial companies have altered their former sponsorship-type meetings where the emphasis is now on medical education instead.

The Guide advises doctors not to accept hospitality from such companies to ensure that their professional judgement is not affected by such hospitality. It is likely that the

Council would interpret any such receipt in light of the 2007 regulations extracted at page 4 above.

IMO Comments:

Clarification of how hospitality interacts with the sponsored educational meeting would be beneficial to doctors as it is unclear how these two aspects intertwine. Further detail on this topic should note that should these meetings be accredited for CPD credits, the organisers should declare the sponsorship of the meeting.

Detail in this section should also advise that if sponsors provide either material or non-material support for an event, such as speakers or material for speakers that declarations are necessary and should be considered essential in providing transparency in such meetings.

Furthermore, the use of participants' details who have attended sponsored events to send further advertising or to make other unsolicited contact, as well as passing on participant details to partner or third party companies to utilise is inappropriate unless consent has been given to the sponsor.

Please also see the comments in the Competence Assurance Schemes in the General Comments section as well.