



Comhairle na nDochtúirí Leighis
Medical Council

GUIDE TO PROFESSIONAL CONDUCT AND ETHICS FOR REGISTERED MEDICAL PRACTITIONERS

Relationships between doctors and industry

Frequently Asked Questions

Frequently asked questions

About this document

The Medical Council regulates registered medical practitioners in the Republic of Ireland. The Council's purpose is to protect the public by promoting and ensuring high standards of professional conduct and professional education, training and competence among doctors.

This document clarifies the ethical guidance that the Medical Council gives in relation to doctors' interactions with pharmaceutical and medical device companies.

As a doctor, it is your duty and responsibility to be familiar with the latest guidelines and regulations in this area. Your main responsibility is to act in the best interests of your patient. You should not be influenced by any personal consideration.



The questions and answers section of this guide has been edited and approved for NALA's Plain English Mark.

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Relevant professional guides, regulations and codes

- A. Guide to Professional Conduct and Ethics for Registered Medical Practitioners, 7th Edition, 2009 (In this document, we will refer to this as *the Guide*)
- B. Medicinal Products (Control of Advertising) Regulations 2007 (S.I. 541 of 2007) (In this document, we will refer to this as *the 2007 Regulations*)
- C. The Irish Pharmaceutical Association (IPHA) Code of Marketing Practice (In this document, we will refer to this as *the Code*)

You will find the relevant paragraphs from *the Guide*, *the 2007 Regulations* and *the Code* in the second part of this document which starts at page 9.

Questions and Answers

Question 1. Is it right for doctors to accept drug samples from pharmaceutical sales representatives?

The Guide does not deal directly with the issue of doctors receiving drug supplies. Most general practitioners (GPs) say they only accept drug samples to use as emergency medication during night calls. If the samples are used only in this way, it would be acceptable for doctors to receive them as long as they meet section 22 of *the 2007 Regulations* (see page 10). Doctors must store the samples in line with their marketing authorisations and must make sure that all relevant safety and quality measures are in place to maintain the safety, quality and effectiveness of the drugs.

You can get more guidance at: http://www.thepsi.ie/Libraries/Publications/Guidelines_on_the_Sourcing_Storage_and_Disposal_of_Medicinal_Products.sflb.ashx?download=true

Question 2. Is it right for doctors to accept gifts and hospitality from pharmaceutical, medical devices or other commercial companies?

Paragraph 59.9 of *the Guide* says that doctors should not accept gifts (including hospitality) from pharmaceutical, medical devices or other commercial companies.

However, doctors can accept reasonable fees for any work they do as part of a contractual arrangement with a commercial company.

Paragraph 59.9 also says that doctors should be aware that commercial companies may use even low-value promotional items to try and influence prescribing and treatment decisions.

The 2007 Regulations say that doctors may accept reasonable hospitality and gifts from pharmaceutical, medical devices or other commercial companies as long as this happens at sales promotion or other professional or scientific events and as long as the level of hospitality is limited to the main purpose of the event.

The reasoning for the Medical Council's advice to doctors is because of the risk that the doctor's professional judgement might be affected by accepting gifts or hospitality. Doctors have a professional obligation to obey the Medical Council's guidance.

Question 3. Is it acceptable for doctors to attend promotional or sponsored educational meetings?

A 'promotional meeting' is a meeting held by a pharmaceutical, medical devices or other commercial company to teach doctors about a particular new drug or device. In general, promotional meetings do not give objective educational information and doctors should not use them for continuing professional development (CPD) points unless the event has been approved by a professional body.

The Guide also advises doctors not to rely solely on promotional literature from pharmaceutical companies for information about particular drugs and to seek independent, evidence-based sources of information on the benefits and risks before prescribing. Useful resources for independent, evidence-based information are the Irish Medicines Board (www.imb.ie) and the National Medicines Information Centre (www.nmic.ie).

A 'sponsored educational meeting' is a professional educational meeting or conference sponsored in whole or in part by commercial companies. Pharmaceutical, medical devices and other commercial companies have changed the type of sponsored meetings they hold and the emphasis is now on medical education.

The Medical Council advises doctors not to accept direct hospitality from pharmaceutical, medical devices or other commercial companies so that their professional judgement is not affected by the hospitality.

The Medical Council accepts that payment of travel and accommodation expenses for doctors to attend meetings, either as participants or speakers, supports the aim of continuing professional development. However, the Council says that these payments should go through unrestricted Education and Development Funds made available by the sponsoring company to the institution which is hosting the meeting or the conference organiser.

Unrestricted Education and Development Funds are not linked to or controlled by the organisations that contribute to them and healthcare institutions can choose to spend the funds any way they see fit.

Question 4. Is it acceptable for doctors to charge a fee for a visit by a sales representative?

The Guide does not specifically deal with this. However, *the Code* states at paragraph 12.6 that sales representatives must not use any incentive or ploy to gain an interview with a doctor. They must not pay in any form for access to a healthcare professional.

It is likely that the Medical Council would view the charging of fees for visits by sales representatives as wrong.

Question 5. Are you 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 your dealings with pharmaceutical and medical device companies. As a doctor, it is your duty and responsibility to be familiar with the latest guidelines and regulations in this area.

The Guide says that your main responsibility is to act in the best interests of your patient. You should not be influenced by any personal consideration.

Question 6. Is it acceptable for a doctor to accept sponsorship from a pharmaceutical, medical devices or other commercial company?

Doctors have a responsibility to make sure their work is not influenced in any way as a result of sponsorship or any other relationship with a pharmaceutical, medical devices or other commercial company. Doctors should tell patients, employers and other institutions where they see or treat patients about the relationship. If the relationship involves medical research, the doctor must make sure that the relationship does not influence the study, design or interpretation of any research data or affect the research or education in any way. The doctor should also tell the relevant ethics committee about the relationship.

Question 7. Is educational sponsorship or funding a good idea?

Paragraph 59.10 of *the Guide* says that, in general, educational sponsorship or funding from commercial companies should go through unrestricted Education and Development Funds. The funding should be managed without influence from the commercial company.

Question 8. Are you using the right sources to keep up-to-date with developments in medication and device safety?

The Guide says that you should not rely solely on promotional literature distributed by pharmaceutical companies for information about particular drugs or medical devices. Instead, you should seek independent evidence-based sources of information on the benefits and risks of all medication and medical devices before prescribing. The following resources may be useful in this regard:

The Irish Medicines Board www.imb.ie

The National Medicines Information Centre www.nmic.ie

Relevant paragraphs from *the Guide*

Paragraph 53.6 - *If you are paid directly or indirectly by pharmaceutical, medical device or other commercial companies or organisations to conduct medical research, you must make sure that such payment does not influence your study design or interpretation of research data.*

Paragraph 53.7 - *If you are paid directly or indirectly by pharmaceutical, medical device or other commercial companies or organisations to conduct medical research, you must address any potential conflict of interest arising from such payment and make appropriate disclosure in any publication of research results.*

Paragraph 59.8 - *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 before prescribing.*

Paragraph 59.9 - *You are advised not to accept gifts (including hospitality) from pharmaceutical, medical devices or other commercial enterprises. This does not preclude the payment of reasonable fees. You should be aware that even low value promotional materials are offered by commercial enterprises with the intention of influencing prescribing and treatment decisions.*

Paragraph 59.10 - *In general, educational funding from commercial enterprises to the healthcare sector should be channelled through unrestricted Education and Development Funds and be managed without influence from the commercial enterprise in question.*

Paragraph 59.11 - *If you receive financial support or other resources from pharmaceutical companies and/or related enterprises in connection with professional activities, including lectures, presentations and publications, development of clinical services or conducting research, you should address any potential conflicts of interest that arise. In these circumstances, your patients and any other relevant party should be informed about any potential professional relationship you have with these companies.*

Relevant sections from *the 2007 Regulations*

Section 21 **(1)** says that:

“A person shall not, in the course of promoting medicinal products to persons qualified to prescribe or supply such products, supply, offer or promise to such persons any gift, pecuniary advantage or benefit in kind, unless it is inexpensive and relevant to the practice of medicine or pharmacy.

(2) *Notwithstanding the provisions of paragraph (1), a person may offer hospitality at sales promotion events or at other events for purely professional and scientific purposes, provided such hospitality—*

- a. is reasonable in level,*
- b. is strictly limited to the main purpose or scientific objective of the event,*
- c. is not extended to persons other than health professionals.*

(3) *A person qualified to prescribe or supply medicinal products shall not solicit or accept any gift, pecuniary advantage, benefit in kind, hospitality, sponsorship, or any other inducement, where the provision of such is prohibited by paragraphs (1) and (2) of this Regulation.”*

Section 22 says that:

(1) *A person shall not supply a free sample of a medicinal product to any person unless that person is qualified to prescribe such product, and in such case only where the following conditions are satisfied—*

- a. such sample is provided on an exceptional basis only and for the purpose of acquiring experience in dealing with such a product;*
- b. the number of such samples of each product that may be supplied to any one recipient in any one year shall be limited and in any case shall not exceed six in number;*
- c. the supply of any such sample is made only in response to a written request, signed and dated, by the recipient;*

- d. *the supplier of such samples maintains an adequate system of control and accountability;*
- e. *each such sample is no larger than the smallest presentation of the product on the market;*
- f. *each such sample is marked “free medical sample — not for sale” or words to the like effect; and*
- g. *each such sample is accompanied by a copy of the summary of product characteristics for each such product.*

(2) *A person shall not supply a sample of a medicinal product which is a controlled drug under section 2 of the Misuse of Drugs Act 1977 or which is an antidepressant, hypnotic, sedative or tranquilliser.*

Relevant clauses from *the Code*

In Clause 14, the Code says that:

“subject to any regulations for the time being in force relating to prices, margins and discounts, no gifts, pecuniary advantages or benefits in kind may be supplied, offered or promised to persons qualified to prescribe or supply by a pharmaceutical company unless they are inexpensive and relevant to the practice of medicine or pharmacy.”

It further says that:

“gifts for the personal benefit of healthcare professionals (such as tickets to entertainment events) should not be offered or provided.”

In relation to educational, research or employment grants, donation or sponsorship of equipment, any such support must be made only in response to a written request and

“must be paid directly to an institution rather than to an individual healthcare professional.”

It is also made clear that:

“any such support must not be linked in any way with product promotion. No commitment must be sought or given in relation to the prescribing, supply or use of the company’s products.”

In relation to hospitality, Clause 16 says that companies may legitimately provide assistance that is directly related to the bona fide continuing education of the healthcare professionals and which genuinely facilitates attendance of the healthcare professional for the duration of the educational aspect of the event. Such support and assistance must, however, always be such as to leave healthcare professionals’ independence of judgement manifestly unimpaired.

It also states at 16(2) that:

“Where appropriate and depending on the time, location and length of the meeting, support to healthcare professionals may cover actual travel expenses, meals, refreshments, accommodation and registration fees.”

At 16 (3) that:

“It should be the programme that attracts delegates and not the associated venue or hospitality. Companies must not organise meetings to coincide with sporting, entertainment or other leisure events or activities. Venues that are renowned for their entertainment or leisure facilities or are extravagant must not be used.”

And at 16(4) that:

“Any hospitality offered to healthcare professionals must:

- i. be reasonable in level and be likely to appear to independent third parties, to be reasonable;*
- ii. be secondary and strictly limited to the main purpose of the event at which it is offered;*
- iii. not exceed the level that recipients would normally be prepared to pay for themselves;*

- iv. *not be extended to spouses or other accompanying persons, unless they are healthcare professionals who qualify as participants in their own right. Travel expenses may not be paid for spouses or other accompanying persons, unless they are healthcare professionals who qualify as participants in their own right;*
- v. *not include sponsoring, securing, organising directly or indirectly any entertainment, sporting or leisure events."*

Codes of practice

"Irish Pharmaceutical Association (IPHA) Code of Marketing Practice."

"Associated Pharmaceutical Manufacturers of Ireland (APMI) Code of Marketing."