Comhairle na nDochtúirí Leighis
Medical Council

Guide to Professional Conduct and Ethics
for Registered Medical Practitioners

Relationships between doctors and industry
Frequently Asked Questions

Relationships between doctors and industry – Frequently asked questions

About this document

The Medical Council regulates registered medical practitioners (doctors) 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 aims to answer your questions about what is ethically acceptable when dealing with pharmaceutical and medical devices companies. It clarifies the ethical guidance the Medical Council gives to doctors in relation to their dealings with such companies.

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

The Medical Council's Guide to Professional Conduct and Ethics (8th Edition 2016) states that you should not rely solely on promotional literature distributed by pharmaceutical companies for information about particular drugs or medical devices. Instead, you should source independent, evidence-based information on the benefits and risks of all medication and medical devices before you prescribe them.

Plain English
Approved by NALA

Contents

Useful publications – Relevant professional guides and regulations

Guide to Professional Conduct and Ethics for Registered Medical Practitioners, 8th Edition, 2016.

(In this document, we will refer to this publication as 'the Guide'.)

Medicinal Products (Control of Advertising) Regulations 2007 (S.I. 541 of 2007).

(In this document, we will refer to this publication as 'the 2007 Regulations'.) This legislation applies to people or bodies advertising medicinal products.

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

Questions and Answers

Question 1

Should a doctor accept gifts and hospitality from a pharmaceutical, medical devices or other commercial company?

You should not accept gifts (including hospitality) from pharmaceutical, medical devices or other commercial enterprises. You should be aware that even low-value promotional materials can influence prescribing and treatment decisions.

This does not prevent you attending educational meetings or receiving payment of reasonable fees and reasonable hospitality for professional services as part of a contract with a commercial company.

This should:

- be strictly limited to the main purpose or scientific objective of the event, and
- not be extended to people other than healthcare professionals.

The reason the Medical Council gives this advice is to guard against the risk that a doctor's professional judgement might be, or might be perceived to be, affected by accepting gifts or hospitality.

Question 2

Should doctors 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 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. Doctors should source independent, evidence-based information on the benefits and risks before prescribing.

Useful resources for independent, evidence-based information are the

Health Products Regulatory Authority (http://www.hpra.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 advises that these payments should go through unrestricted Education and Development Funds made available by the sponsoring company to the institution or the conference organiser hosting the meeting. Unrestricted Education and Development Funds are not linked to or controlled by the organisations that contribute to them. Healthcare institutions can choose to spend the funds any way they see fit.

It is, however, permissible for companies to specify how they want their support and sponsorship to be used, provided that it is in line with the Medicinal Products (Control of Advertising) Regulations 2007 legislation.

Question 3

Should doctors charge a fee for a visit by a sales representative?

The Guide does not give specific guidance on this matter. However, it is likely that the Medical Council would view the charging of fees for visits by sales representatives as unacceptable.

Question 4

Should doctors 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 their patients, their employers, and any other institution where

they see or treat patients about any relationship they have with a company.

If the relationship involves medical research, the doctor must make sure that the relationship does not influence the study, design or interpretation of the research information, or affect the research or education in any way. The doctor should also tell the relevant ethics committee about the relationship.

The Medical Council fully endorses and expects doctors to be transparent in their workings with pharmaceutical, medical devices and other companies.

Question 5

Is it acceptable for a doctor to have a financial interest in an organisation, or to own a patent on a product that they are recommending to patients?

Paragraph 63 of the Guide deals with conflicts of interest. Doctors must not let financial considerations influence, or appear to influence, their management of patients. They must tell patients if they, or a close family member, have a financial interest in a private clinic, hospital, pharmacy or other institution to which they wish to refer a patient for investigation or treatment.

For example, a doctor who owns a patent for a new technology which they are recommending for the patient (for example, a particular type of artificial joint) must tell the patient that they have a financial interest in that product.

Question 6

Is educational sponsorship or funding acceptable?

Paragraph 62.5 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.

It is, however, permissible for companies to specify how they want their support and sponsorship to be used, provided that it is in line with the Medicinal Products (Control of Advertising) Regulations 2007 legislation.

There are voluntary regulation codes that a number of pharmaceutical companies sign up to and follow, such as the Irish Pharmaceutical Association (IPHA) Code of Marketing Practice, and the Associated Pharmaceutical Manufacturers of Ireland (APMI) Code of Marketing.

Question 7

Should doctors accept drug samples from pharmaceutical sales representatives?

The Guide does not deal directly with the issue of doctors receiving drug supplies. However, doctors should practise evidence-based medicine, rather than relying on free samples and complimentary medication.

The advertising of medicinal products including the supply of free samples to doctors is regulated under the following legislation:

S.I. No. 541/2007 - Medicinal Products (Control of Advertising) Regulations 2007

Paragraph 22(2) refers to Free Samples:

"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."

The Pharmaceutical Society of Ireland (PSI) currently has guidance on the sourcing, storage and disposal of medicinal products. This guidance can be viewed here:

www.thepsi.ie/Libraries/Publications/Guidelines_on_the_Sourcing_Storage_and_Disposal_of_Medicinal_Products.sflb.ashx

Question 8

What are the guidelines and regulations which deal specifically with doctors' interactions with pharmaceutical and medical device companies?

The Medical Council's Guide and the 2007 Regulations set out the recommended codes of conduct relating to a doctor's 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.

The Medical Council fully endorses doctors' transparency in their dealings with pharmaceutical, medical device and other companies.

Relevant paragraphs from the 2016 Guide

Paragraph 5.8 – Conflicts of interest

Conflicts of interest may happen where doctors, or their close family members, have financial interests in health or care providers, or in the medical devices or pharmaceutical industries. You should identify and try to avoid conflicts of interest that may affect, or be seen to affect, your clinical judgement. If you cannot avoid a conflict of interest, you should tell the patient, and anyone else who may be affected by the decision, about your financial (or other) interest.

Paragraph 25 – Clinical Trials and Research

Paragraph 25.6 – 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 the payment does not influence your study design or interpretation of research data.

Paragraph 25.7 – If you are paid, directly or indirectly, by pharmaceutical, medical device or other commercial companies or organisations in connection with medical research, you must address any potential conflict of interest and disclose the payment in any publication of research results. You should also follow the guidance on conflict of interests in paragraph 62.

Paragraph 25.8 – If you act as an investigator in a clinical trial or any form of medical research, you must submit and receive approval from the relevant research ethics committee before the research begins. You must make sure that the trial conforms to the Declaration of Helsinki[1] and any relevant national legislation.

[1] https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/

Paragraph 42 – Prescribing

Paragraph 42.5 – As far as possible, you should make sure that any treatment, medication or therapy prescribed for a patient is safe, evidence-based and in the patient's best interests. Where possible, when prescribing[2] drugs avoid the use of brand names – unless there is a good reason for using them. You should be particularly careful when prescribing multiple medications in case the combination might cause adverse reactions, and you should liaise with the pharmacy to clarify any issues or concerns you may have. You should take special care when prescribing for patients who may have an impaired ability to metabolise the medication prescribed. You should weigh up the potential benefits with the risks of adverse effects and interactions when deciding what to prescribe. You should review patients' treatment regimes periodically.

Paragraph 42.6 – You should keep up to date with developments in medication safety. You should seek independent, evidence-based sources of information on the benefits and risks associated with medicines before prescribing.

Paragraph 62 – Managing Conflicts of Interest

Paragraph 62.3 – You should not accept gifts (including hospitality) from pharmaceutical, medical devices or other commercial enterprises. This does not prevent you attending educational meetings or receiving payment of reasonable fees for professional services to commercial enterprises. You should be aware that even low-value promotional materials can influence prescribing and treatment decisions.

Paragraph 62.5 – If you are responsible for education activities in your hospital or any other institution, you should make sure that any funding from commercial enterprises is channelled through unrestricted Education and Development Funds and managed without influence from the commercial enterprise.

[2] Health (Pricing and Supply of Medical Goods) Act 2013: http://www.irishstatutebook.ie/eli/2013/act/14/enacted/en/pdf

Paragraph 62.6 – Conflicts of interest may arise if you get financial support or other resources from pharmaceutical companies or related enterprises in connection with professional activities including lectures, presentations, publications, development of clinical services or research. In these circumstances, you should tell patients and any other relevant party about any professional relationship you have with these companies[3].

Paragraph 62.7 – If you are involved in any way in promoting or endorsing specific healthcare products or services, you must declare any financial or commercial interest you have in the organisation or company providing the products or services.

3 See Medical Council guidance on Relationships between Doctors and Industry – Frequently Asked Questions http://www.medicalcouncil.ie/News-and-Publications/Publications/Professional-Conduct-Ethics/Relationship-between-doctors-industry.pdf

Relevant sections from the 2007 Regulations

Section 21 says that:

(1) "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.

Useful guides

- HPRA (2017): Guide to Advertising Compliance.
- Medical Council and Pharmaceutical Society of Ireland. (2017): Safe Prescribing and Dispensing of Controlled Drugs: Joint Guidance.