Comhairle na nDochtúirí Leighis
Medical Council

CONSULTATION
prior to reviewing 2012 guidance on
Relationships between Doctors and Industry – Frequently Asked Questions

The purpose of the 2012 guidance is to clarify the Medical Council's ethical guidance in relation to doctors' interactions with pharmaceutical and medical device companies.

We want to ensure that the guidance we provide is inclusive, relevant and useful. As a starting point in our review process, we would like to receive feedback from partner organisations about how we can improve our 2012 publication. This is a first step in a thorough consultation process which will seek the views of the public, doctors and partner organisations. We will also invite views on our draft next edition prior to finalisation.

This survey should not take more than 10-15 minutes to complete.

We would appreciate if you could complete this survey **by close of business on Friday, 28th April 2017**.

Privacy in respect of consultation responses:
Following the end of a public consultation, we may publish a summary of responses received. Information people provide in response to our consultations may be disclosed in accordance with the Freedom of Information Acts 1997-2003. If you want the information that you provide to be treated as confidential, please tell us, but be aware that we cannot guarantee confidentiality.

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1. **WHICH CATEGORY BELOW BEST DESCRIBES YOU?**

☐ Interest group / organisation for doctors or healthcare professionals

☐ Employer of healthcare professionals

☐ Government Department

☒ **Healthcare Regulator**

2. **APPROXIMATELY HOW OFTEN HAVE YOU CONSULTED THE GUIDANCE SINCE ITS PUBLICATION IN 2012?**

☐ Weekly

☐ Monthly

☒ **Annually**

☐ Very infrequently

☐ Never

3. **ARE THERE ANY AREAS WHERE THE 2012 GUIDANCE REQUIRES FURTHER CLARIFICATION AND EXPANSION?**

☒ **Yes**

☐ No*

☐ I don't know

***If you answered "No" or "I don't know" to question 3, please skip to question 6.**

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4. PLEASE INDICATE WHICH SECTIONS NEED TO BE AMENDED (tick as appropriate):

Section of the 2012 document	Needs major amendment	Needs minor amendment	No amendment needed
Relevant professional guides, regulations and codes		✓	
Question 1: Is it right for doctors to accept drug samples from pharmaceutical sales representatives?		✓	
Question 2: Is it right for doctors to accept gifts and hospitality from pharmaceutical, medical devices or other commercial companies?		✓	
Question 3. Is it acceptable for doctors to attend promotional or sponsored educational meetings?		✓	
Question 4. Is it acceptable for doctors to charge a fee for a visit by a sales representative?			✓
Question 5. Are you aware of the guidelines and regulations which deal specifically with doctors' interactions with pharmaceutical and medical device companies?	✓		
Question 6. Is it acceptable for a doctor to accept sponsorship from a pharmaceutical, medical devices or other commercial company?		✓	
Question 7. Is educational sponsorship or funding a good idea?			✓
Question 8. Are you using the right sources to keep up-to-date with developments in medication and device safety?		✓	
Relevant sections from *the 2007 Regulations*			✓
Relevant clauses from *the Code*			✓
Codes of practice		✓	

5. PLEASE EXPLAIN WHAT AMENDMENTS ARE NEEDED. (FOR EXAMPLE, ARE THERE ANY AREAS THAT REQUIRE CLARIFICATION/EXPANSION AND HOW? ARE THERE ANY SECTIONS OR PARAGRAPHS THAT COULD BE SHORTENED OR REMOVED?)

Section of the 2012 document	Amendment(s) needed
Relevant professional guides, regulations and codes	The PSI Guidelines referred to in the 2012 iteration of the FAQs have since been updated. The Sourcing and Disposal sections of the *PSI Guidelines on the Sourcing, Storage and Disposal of Medicinal Products* have now been superseded by the following Guidelines (hyperlinked for ease of reference): 1. Guidelines on the Sourcing of Medicinal Products for Sale or Supply by a Retail Pharmacy Business 2. Guidelines on the Disposal of Medicinal Products for a Retail Pharmacy Business Please note that for information pertaining to the Storage of Medicinal Products, the original guideline applies. The FAQs should be amended in light of this. It is suggested that the Health Products Regulatory Authority (HPRA) *Guide to Advertising Compliance* could be included as another reference source/guide for doctors. As a general point, it is worth noting that the Misuse of Drugs Regulations 2017 are due to be enacted in the upcoming days/weeks so this may have implications for codes, FAQs and professional guides already published by the Medical Council.
Question 1: Is it right for doctors to accept drug samples from pharmaceutical sales representatives?	The reference to the PSI Guidelines on the Sourcing, Storage and Disposal of Medicinal Products should be updated

	as explained above, as sections of this guideline have been superseded. Additionally, Regulation 22(2) of the Medicinal Products (Control of Advertising) Regulations 2007 precludes the supply of a sample medicinal product from Schedule 2 of the Misuse of Drugs Regulations 1977, as amended. It is felt that it would be important to continue to reference this regulation in the FAQs. Also it is worth noting that the Misuse of Drugs Regulations are undergoing revision by the Department of Health, and due to be enacted in the upcoming weeks.
Question 2: Is it right for doctors to accept gifts and hospitality from pharmaceutical, medical devices or other commercial companies?	It is thought that the wording pertaining to the 2007 Regulations in the 2012 version of the FAQs could be revised (i.e. the second row of the table). Perhaps further information on the provisions of Regulation 21(2) of the 2007 Regulations could be provided, with reference made to Reg. 21(2) a-c in particular.
Question 3. Is it acceptable for doctors to attend promotional or sponsored educational meetings?	It is recommended that the links provided in the 2012 version of the FAQs to the IMB (now HPRA) and the National Medicines Information Centre (NMIC) be retained, as these organisations can provide medical practitioners with un-biased, independent and evidence-based information.
Question 4. Is it acceptable for doctors to charge a fee for a visit by a sales representative?	
Question 5. Are you aware of the guidelines and regulations which deal specifically with doctors' interactions with pharmaceutical and medical device companies?	Perhaps the wording of the FAQ itself could be amended to read "Where can ~~Are you aware of the~~ guidelines and regulations which deal specifically with doctors' interactions with pharmaceutical and medical device companies be found?" Such an amendment is in keeping with the syntax and tone employed for all the other FAQs provided.

Question 6. Is it acceptable for a doctor to accept sponsorship from a pharmaceutical, medical devices or other commercial company?	When amending the FAQs with the relevant updates from the 2016 Ethical Guide, it might be helpful to make reference to the term 'sponsorship' in the answer provided. This may assist in assuring clarity of message.
Question 7. Is educational sponsorship or funding a good idea?	
Question 8. Are you using the right sources to keep up-to-date with developments in medication and device safety?	Again for this FAQ, when including any updates from the 2016 Ethical Guide, it is recommended that the references to the HPRA and NMIC be retained.
Relevant sections from *the 2007 Regulations*	
Relevant clauses from *the Code*	
Codes of practice	It is suggested that the Health Products Regulatory Authority (HPRA) *Guide to Advertising Compliance* could be included as another reference source/guide for doctors.

6. DOES THE CURRENT GUIDE PROVIDE ADVICE ON ALL RELEVANT ASPECTS OF RELATIONSHIPS BETWEEN DOCTORS AND INDUSTRY?

☐ Yes

☒ **No**

☐ I don't know

***If you answered "Yes" or "I don't know" to question 6, please answer question 7.**

7. PLEASE EXPLAIN WHAT OTHER ASPECTS IT SHOULD COVER, OR ADVICE IT SHOULD PROVIDE.

The references made to the Medicinal Products (Control of Advertising) Regulations 2007, in the FAQs, are clear and concise. Perhaps further information could be provided, regarding Reg. 21(2) **Inducements and Hospitality**. It may be useful to quote what the Regulation states (i.e. hospitality may be offered, provided such hospitality is reasonable in level, is strictly limited to the main purpose or scientific objective of the event and is not extended to persons other than health professionals). This may assist in a clear understanding of the regulations.

Regarding the provision of **free samples** by sales representatives to doctors, perhaps Reg. 22(1) of the Medicinal Products (Control of Advertising) Regulations 2007 could be referenced, specifically Reg. 22 (1) (b). For example, the number of "samples of each product that may be supplied to any one recipient in any one year" cannot "exceed six in number". Additionally, it may be useful to remind doctors to provide a copy of the SmPC for each such product/sample supplied to a patient (see Reg. 22 (1) (g) of the Medicinal Products (Control of Advertising) Regulations, 2007).

As previously mentioned, the Misuse of Drugs Regulations 1988, as amended are undergoing major revision, with new 2017 Regulations expected to be enacted in the upcoming weeks. It may be worthwhile referring to this in the FAQs or in any related documentation published by the Medical Council.

THANK YOU!

NOW YOU'VE COMPLETED THE FORM…

Thank you for taking the time to fill out our survey. We rely on your feedback to help us improve our services. Your input is greatly appreciated.

All comments received will be collated and reviewed by the Medical Council to help decide how to improve the 2012 guidance. We will not be providing individual feedback at this time.

Further consultation will take place once the new guidance has been drafted.

Please email this document to educationandtraining@mcirl.ie or mail it to us at:

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