



Sustainable Competence
in Advancing Healthcare



COCIR Code of Conduct

Training Course

July 2018



COCIR Code of Conduct

Preface

Welcome to the e-training for the COCIR Code of Conduct

This training is designed to help you learn more about COCIR, the content of the Code of Conduct and the impact of the Code in your daily work



COCIR Code of Conduct

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- Introducing COCIR
- Background to the COCIR Code of Conduct
- Why is a Code of Conduct important?
- What is the scope of the COCIR Code?
- Compliance with COCIR Code
- Code of Conduct main principles and provisions
- Quiz



COCIR Code of Conduct

Introducing COCIR

- Non-profit trade association since 1959
- Voice of European Radiological, Electromedical and Healthcare IT industry
- Represents activities and interests of its Members (National Trade Associations and Companies)
- Communication channel between Members and European institutions, regulatory authorities and other relevant organisations



COCIR Code of Conduct

Background to COCIR Code of Conduct

- COCIR's first formal **Code of Conduct** for the medical technology industry was launched in 2009
- Since 2009, the COCIR Code has evolved and now also includes interpretive guidance in the form of a **Q&A** to assist member companies in understanding and implementing the Code



COCIR Code of Conduct

Why is a Code of Conduct important?

- To ensure the rules on interactions with Healthcare Professionals (HCPs) are clear
- To ensure healthcare decisions are based on the best interests of patients
- To seek compliance and harmonisation in international markets to help eliminate corruption
- To show commitment to ethical corporate behaviour and thereby ensure public confidence in the medical technology industry



COCIR Code of Conduct

What is the scope of the COCIR Code?

The Code of Conduct covers COCIR Member Companies and their relationship with HCPs

- **Member Companies**
 - including employees, agents, dealers, distributors and other third party intermediaries

- **HCPs**
 - individuals or institutions
 - present in or admitted to practice in geographical Europe or
 - that purchase, lease, recommend, use, arrange for the purchase or lease of, or prescribe medical technology products



COCIR Code of Conduct

Compliance with COCIR Code

- The COCIR Code of Conduct **is not intended to replace or supersede** national or local laws or regulations of a country or professional codes (including company codes) that may impose stricter requirements on Members or HCPs who engage in business activities in those countries



COCIR Code of Conduct

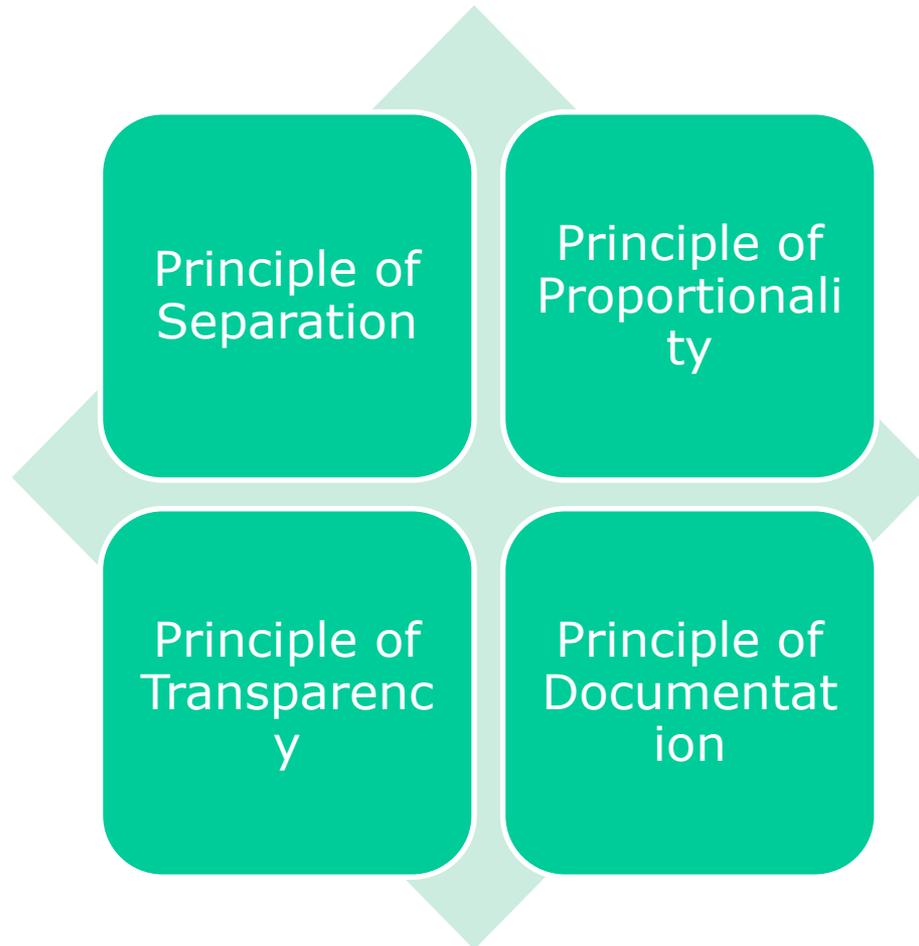
Documents comprising the COCIR Code

- The **COCIR Code on Interactions with Healthcare Professionals** containing the four main principles on which the Code is based and guidance on key areas
- +
- **Interpretive guidance in the form of a Q&A to assist member companies in understanding and implementing the COCIR Code of Conduct**



COCIR Code of Conduct

Based on 4 main principles





COCIR Code of Conduct

4 main principles explained

Principle of Separation

- **Clear separation between any advantage or benefit granted by a Member to an HCP and a business transaction between them**
- **Aim is to ensure the advantage or benefit does not influence the business decision**

Principle of Proportionality

- **Any consideration (eg remuneration) given to a HCP in exchange for a service or other performance should not exceed fair market value**
- **Meals and entertainment should be subordinate in time and focus to the main purpose of a meeting**

Principle of Transparency

- **Advantages or benefits granted to HCPs must be disclosed, and if appropriate, approved by the HCP's employer or employing institution/administration**
- **All approvals must be documented**

Principle of Documentation

- **Advantages or benefits granted to an HCP must be documented preferably in the form of a contract**



COCIR Code of Conduct

Newspaper Test

When a situation arises (including one where there is no specific provision in the COCIR Code), you should **consult** the **four main principles** for guidance on how to decide on the correct course of action

If in doubt, ask yourself:

“Would I be happy to see what we are doing published on the front page of the newspaper?”

If you are not sure the answer would be positive, your actions might **infringe** the **COCIR Code**. Consult your legal or compliance department





COCIR Code of Conduct

Guidance on key areas



1. Meetings – Organised by Members
2. Conferences – Organised by Third Parties
3. Hospitality
4. Consultancy
5. Gifts
6. Charitable Donations
7. Public Procurement
8. Research Agreements
9. Educational Grants
10. Demonstration and Evaluation Equipment
11. Independent Third Parties
12. Compliance with the Code



COCIR Code of Conduct

1. Meetings – Organised by Members

- **Purpose** - meetings must have a genuine educational, scientific or business purpose as their primary purpose
- **Legitimate reason** – there must be a legitimate reason for inviting the HCP to the meeting
- **Permitted Expenses** – only reasonable travel and accommodation costs are allowed
- **Separation from Sales** – Hospitality must not be arranged with the intention to induce the HCP to enter into a business transaction. It is also inappropriate to arrange hospitality contingent on past, present or future business transactions
- **Guests/spouses of HCP** – Meeting invitations must not be extended to any person who does not have a professional interest in the meeting. Inappropriate to pay for travel or lodging costs and hospitality for those people



COCIR Code of Conduct

1. Meetings – Organised by Members (cont.)

- Meeting Locations
 - must be **appropriate for, and conducive to, accomplishing the purpose** of the meeting. A training or educational meeting could be held at a conference facility, clinic, laboratory, hotel or the Member's own offices
 - choice of location must be **based on objective criteria** including logistical, scientific, organisational and economic reasons
 - location **must not become the main attraction of the event**. While resort locations are not automatically excluded, golf clubs, health spas and ski resorts would not be considered appropriate locations for the exchange of business information



COCIR Code of Conduct

1. Meetings – Organised by Members (cont.)

- When inviting HCPs from several countries to attend a meeting, Members must comply with the **specific legal requirements of each country**

For example:

France - invitations must be submitted to the *Ordre des médecins* for prior approval

Belgium - companies must obtain a visa from the Belgian health authority *MDEON*

Norway - invitations to HCPs who work in hospitals must be directed to the Regional Health Enterprises

- If there are **no country-specific legal requirements**, Members must still **disclose** the invitation for approval to the HCP's administration or management of the institution to which the HCP is affiliated



COCIR Code of Conduct

2. Conferences – Organised by Third Parties

- Financial support to Conferences

Members may provide financial support to a third party organised scientific or educational conference if:

- it is primarily to promote **objective, scientific and educational activities**
- the third party **controls** the program content, faculty, educational methods, and materials
- the third party independently selects and contracts with Healthcare Professionals and speakers. Without any involvement of COCIR Members, the Healthcare Professional agrees with the third party on honoraria expenses and the like
- **conference** support by a Member is clearly **stated in advance of and at the conference**
- financial support is **not specifically for entertainment or hospitality**



COCIR Code of Conduct

2. Conferences – Organised by Third Parties (cont.)

- Financial Support to individual Healthcare Professionals

Members may **no longer** provide financial support to individual HCPs to cover the costs of attendance of scientific or educational conferences organised by a third party

This means that Members may neither pay for:

- registration fee,
- travel and lodging costs,
- honoraria

A third party which can organise a conference is for example an hospital, a professional conference organiser, a scientific or medical society



COCIR Code of Conduct

2. Conferences – Organised by Third Parties (cont.)

- Financial Support to individual Healthcare Professionals

Exceptions - Members may provide financial support to individual Healthcare Professionals to:

- attend a hands-on procedure training organised by a third party. Such training is typically performed in a clinical environment which is appropriate for clinical simulation (exception 1)

- speak or provide a professional training at a satellite symposium organised by a Member in the margins of a third-party conference. A satellite symposium refers to any educational event that is independently organised by a Member and held in conjunction with a third-party conference (exception 2)



COCIR Code of Conduct

2. Conferences – Organised by Third Parties (cont.)

- Financial Support to individual Healthcare Professionals

Financial support may be:

1/ for the hands-on procedure training organised by the third-party:

- registration fee, travel and lodging costs to attend the hands-on procedure training
- such expenses should only cover the length of the hands-on procedure training

2/ for the speaker at a satellite symposium:

reasonable honoraria, registration fee (if necessary to access the conference) may be paid in addition to travel and lodging costs



COCIR Code of Conduct

3. Hospitality

- **Linked to a meeting/conference**

Reasonable hospitality in the form of meals, drinks, receptions and entertainment (e.g. a music, sports or theatre event) may be provided

Such hospitality must also comply with local law and be subordinate in time and focus to the meeting (e.g. meeting during the day and dinner in the evening is subordinate in time)

- **Not linked to a meeting/conference**

Hospitality must be limited to a modest meal and drinks, in a setting conducive to business discussions. Hospitality in the form of entertainment is strictly prohibited

Applying the principle of Proportionality

Business meals and entertainment should be subordinate in time and focus to the main purpose of a meeting. The aim is to avoid even the appearance that members may induce HCPs to purchase, prescribe or recommend Members' products



COCIR Code of Conduct

4. Consultancy

- **Consultancy services may include** clinical and scientific advice, speaking engagements, participating on advisory boards, advising on new product development, conducting demonstrations and writing abstracts
- Ensure you have a **written agreement** evidencing a **legitimate need** and **purpose** for the contracted services
- Select HCP on the basis of his/her **qualifications** and **expertise** to address the identified purpose
- **Disclose the consulting arrangement for approval** to the HCP's administration or management of the institution to which the HCP is affiliated
- Pay compensation consistent with **fair market value**

Applying the principle of Separation

Consulting arrangements should not be made on the basis of the volume or value of business generated by the HCP or his/her professional institution or contingent on past, present or future business transactions



COCIR Code of Conduct

5. Gifts

- Gifts are **generally discouraged**
- If given, a gift should be in accordance with the local law, be occasional and of modest value
- A gift must never leave the recipient in a position of obligation or be perceived to affect the outcome of a business transaction or potentially expose the business to undue influence
- A gift shall **never consist of cash or cash equivalent**

Applying the principle of Separation

Gifts should never be intended to influence the recipient's decision



COCIR Code of Conduct

6. Charitable Donations

Members may make donations for a **charitable purpose**

Ensure donations are:

- given to a **charitable organisation**
- **not contingent upon** past, present or future business transactions
- **not given to induce** a HCP to enter into a **business transaction**
- **documented**, disclosing the recipient and recipient's planned use of the donation
- **evaluated separately** from a Member's commercial activities

Applying the principles of Documentation and Separation



COCIR Code of Conduct

7. Public Procurement

- **Do** respect the transparency of the tendering process and the fair and equal treatment of all bidders
- **Do not** engage in activities which could be seen as aimed at improperly influencing HCPs
- **Do not** interfere with Contracting Authorities when they are formulating technical specifications
- **Do not** encourage Contracting Authorities to unduly seek to exempt themselves from public tendering procedures
- **Do not** encourage Contracting Authorities to unduly seek to amend tender documentation, contractual terms or the scope of supply



COCIR Code of Conduct

7. Public Procurement (cont.)

- If acting as an **independent consultant** for a Contracting Authority:
 - **do not** violate the principle of equal treatment of bidders by your actions
 - and if a future tender is likely to arise as a result of acting as an independent consultant, **request** the Contracting Authority to issue **a notice of future tenders** to enable all potential bidders to have equal and fair notice of the tender opportunity



COCIR Code of Conduct

8. Research Agreements

- **Ensure** there is a **written** agreement specifying all the services to be provided including milestones and deliverables and a protocol for a genuine research purpose
- Research must be **legitimate scientific work**
- Ensure research support is **not contingent upon** any business transaction or sale of a Member's products or services. An exception to this rule is if the products or services are requested as part of a tender
- **Disclose the research agreement for approval** to the HCP's administration or management of the institution to which the HCP is affiliated
- Pay compensation consistent with **fair market value**

Applying the principles of Documentation and Separation



COCIR Code of Conduct

9. Educational Grants

- Educational grants **may** be made to **support**:
 - the advancement of genuine medical, clinical or technological education; and
 - to educate patients or the public about important healthcare topics
- The **grant recipient should control** the program content, faculty, educational methods, materials any scholarship awards.
- Educational grants may be used for reasonable honoraria, travel, lodging, and meals for HCPs who are bona fide conference faculty speakers. Members may not select or pay faculty speakers
- Educational grants **may not** be used to directly fund endowments of professors, chairpersons of departments or similar position, nor replace departmental budgets
- Educational grants **should not** be made to individual healthcare professionals



COCIR Code of Conduct

9. Educational Grants

- Members may define the purpose of an educational grant:
 - they can request that educational grants be used for medical education for instance:
 - (i) to increase the knowledge of certain diseases or
 - (ii) to support the attendance to a certain educational event, without naming any Healthcare Professional
 - to ensure that a grant is used for a genuine educational purpose, Members can include in the grant agreement that the recipient of the grant reports on the use of the grant
- Members are recommended to establish a process whereby they can ensure that requests for educational grants be evaluated separately from Members' commercial activities



COCIR Code of Conduct

9. Educational Grants (cont.)

- Ensure requests for educational grants are:
 - **not contingent on** any business transaction or sale of a Member's products or services
 - **documented**, to show (i) the request for grants has been properly evaluated and (ii) used for a genuine educational purpose

Applying the principles of Documentation and Separation



COCIR Code of Conduct

10. Demonstration & Evaluation Equipment

- Members may offer equipment on loan (free of charge) to HCPs for the purpose of **demonstration and evaluation**
- Equipment may be offered only for a reasonable period normally **less than 6 months**
- **Disclose the loan agreement for approval** to the HCP's administration or management of the institution to which the HCP is affiliated.

Applying the principle of Transparency



COCIR Code of Conduct

11. Independent third parties (ITPs)

- Members may use ITPs to promote, import or sell their products or services
- ITPs include agents, consultants, dealers and distributors
- Select and award business to ITPs that are committed to act with integrity and comply with the law
- For all ITPs Members should:
 - Conduct due diligence on proposed ITPs using a risk-based approach, meaning the due diligence procedure and resources employed should be proportionate to the identified risk. The aim is to ascertain that proposed ITPs are trustworthy and will not use unlawful and unethical methods for performing their services for or on behalf of Members
 - Impose obligations in contracts with ITPs to comply with anti-bribery laws and the duties of the COCIR Code
 - Monitor relationships with significant ITPs; and
 - Subject significant ITPs to appropriate controls

See the COCIR Q&A for more information on ITPs



COCIR Code of Conduct

12. Compliance with the Code

- Report concerns about non-compliance with COCIR Code directly **to COCIR via its website**
- COCIR Secretariat will refer concerns **to the Member's legal/compliance teams** for full investigation and resolution in accordance with the Member's corporate compliance procedures
- **Members should disclose** to the Code of Conduct Committee, on an aggregated basis, how concerns relating to that Member have been addressed and resolved



Quiz in 20 questions



COCIR Code of Conduct

Test your understanding

The following multi-choice questions and responses are intended to provide you with a guide to the practical application of the principles articulated in the COCIR Code of Conduct



COCIR Code of Conduct

Test your understanding

Question 1 – Gifts

Which of these items if given as a gift would infringe the COCIR Code of Conduct?

- (a) Company-branded promotional item
- (b) Box of chocolates
- (c) Bouquet of flowers
- (d) Gift voucher to purchase a book



Answer Q1 – Gifts

(d) is the correct answer

Gifts may not be given in the form of cash or cash equivalents. An item that has a specified cash value such as a book token is regarded as a cash equivalent and therefore cannot be given as a gift

The general policy is that gifts are generally discouraged. However, modest gifts (e.g. chocolates, flowers, company-branded promotional items) will not infringe the COCIR Code. “Modest” means moderate in value and of the kind which is normally exchanged in the social setting which applies



COCIR Code of Conduct

Test your understanding

Question 2 – Consultancy

Which of the following would NOT be considered a “legitimate need” when engaging a HCP as a consultant?

- (a) The HCP’s services are required to achieve a proper business objective (e.g. participating on advisory board, writing a scientific abstract)
- (b) The HCP is required to provide clinical research services and in return will receive compensation based on fair market value
- (c) The HCP’s services are required to generate business directly from the HCP
- (d) The HCP has experience of using a specific medical technology and this experience/expertise is necessary to meet the company’s defined need



Answer Q2 – Consultancy

(C) is the correct answer

There are many proper business objectives. However, engaging a HCP for the purpose of generating business directly from such HCP (or a healthcare provider that is affiliated with the HCP) is NOT a proper business objective

Consulting arrangements should be entered into only where a legitimate need for the services is identified in advance and documented. A legitimate need arises when the services of a HCP are necessary in order to achieve a proper business objective

Therefore, BEFORE entering into a consulting arrangement with a HCP you must (a) identify a legitimate need for the services in advance and document this, e.g. clinical research services, speaking at a conference or writing a scientific abstract and (b) select the consultant on the basis of their qualifications and expertise to meet that defined need

The level of consulting services must not exceed the amount that is reasonably necessary to achieve the business objective. Different valuation methods may be used to establish fair market value. In all instances, a Company should use objective, verifiable criteria which the Company should document



COCIR Code of Conduct

Test your understanding

Question 3 – Hospitality

In which of the following circumstances would a business meal associated with a HCP interaction NOT infringe the COCIR Code?

- (a) If the development of general business goodwill is the primary purpose of the meal
- (b) If a business meal is used mainly for entertainment or recreational purposes
- (c) If the business meal takes place at a high-ranked restaurant (e.g. Michelin-starred or renowned chef)
- (d) If the business discussion accounts for most of the time spent during the meal



Answer Q3 – Hospitality

(d) is the correct answer

The business discussion should account for most of the time spent during the meal

Development of general business goodwill should NOT be the primary purpose of a business meal

A business meal should NEVER be used for entertainment or recreational purposes

Business hospitality should be reasonable in nature and occasional. Therefore a moderately-priced restaurant will be acceptable whereas a high-ranked restaurant (e.g. Michelin starred, renowned chef) will not be deemed reasonable.



COCIR Code of Conduct

Test your understanding

Question 4 – Travel Expenses for events organised by Members

You have invited a leading university professor to speak at an educational event organised by your company. According to your company's travel policy economy-class travel would normally be sufficient. However, the professor insists on travelling business-class and says his spouse will accompany him. Which of the following statements is correct?

- (a) Members may pay the reasonable travel costs incurred by HCPs in attending Members' meetings
- (b) "Reasonable" always means the cheapest travel option available
- (c) Members may also pay the reasonable travel costs of a guest accompanying the HCP



Answer Q4 – Travel Expenses for events organised by Members

(a) is the correct answer

The Code of Conduct allows Members to pay the reasonable travel costs incurred by HCPs in attending educational events organised by companies

“Reasonable” does not always mean the cheapest option available. A useful guide is look at your company’s travel policy and the policies of relevant hospitals or institutions. Also, if the HCP concerned is a leading professor responsible for a large hospital department it may be reasonable to select business-class travel. Consider what the individual in question would pay for himself/herself

The Code of Conduct does not permit Members to pay for the expenses of HCP guests that do not have a *bona fide* professional interest in the meeting. “Guests” includes partners and spouses. This is to avoid even the appearance that business courtesies are being given as improper inducements to promote a Member’s medical technologies



COCIR Code of Conduct

Test your understanding

Question Q5 – Travel Expenses for events organised by Third Parties

You have invited Mr. Winner who is a radiologist to attend a hands-on procedure training organised by a third party. This training will cover practical procedures and clinical utility of ultrasounds for thorax. This procedure training will take place at Good Health Hospital in Safeland. At the same time, an educational conference is organised by the College of Radiologists in Safeland

What financial support can you provide to the HCP to attend?

- (a) registration fee, travel and lodging costs to attend the educational conference
- (b) registration fee, travel and lodging costs to attend the hands-on procedure training
- (c) both (a) and (b)



COCIR Code of Conduct

Test your understanding

Answer Q5 – Travel Expenses for events organised by Third Parties

(b) is the correct answer

Member may pay for registration fee, travel and lodging costs to attend the hands-on procedure training that takes place at Good Health Hospital

Member may not pay for registration fee or other costs to attend the educational conference organised by the College of Radiologists of Safeland

If the educational conference has a longer duration than the hands-on procedure training, extra nights at a hotel or later return ticket may not be supported



COCIR Code of Conduct

Test your understanding

Answer Q5 – Travel Expenses for events organised by Third Parties

(a) is incorrect answer

Member should not pay any registration fee, travel and lodging costs to attend the educational conference because of the end of direct sponsorship for educational conference organised by a third party



COCIR Code of Conduct

Test your understanding

Answer Q5 – Travel Expenses for events organised by Third Parties

(c) is incorrect answer

Member should not pay any registration fee, travel and lodging costs to attend the educational conference because of the end of direct sponsorship for educational conference organised by a third party

Registration fee, travel and lodging costs for attendance of a hands-on procedure training would be allowed as it is an exception to the end of direct sponsorship



COCIR Code of Conduct

Test your understanding

Question 6 – Invited speaker at a satellite symposium

Your company has invited Dr. Smith who is a renowned cancer therapist to speak at a satellite symposium. This satellite symposium takes place in the margins of a scientific conference organised by a Third Party

What financial support can you provide to Dr. Smith to speak at the satellite symposium organised by your company?

- (a) registration fee (if necessary to access the satellite symposium) and reasonable honoraria to speak at the satellite symposium
- (b) travel and lodging costs to attend the satellite symposium
- (c) both (a) and (b)



Answer Q6 – Invited speaker at a satellite symposium

(c) is the correct answer

Member can pay for registration fee (if necessary to access the satellite symposium), travel and lodging costs to attend the satellite symposium as well as reasonable honoraria

Note that if Dr. Smith is also the beneficiary of an educational grant (through a HCO for example) to cover his registration fee, travel and lodging costs to attend the third-party scientific conference, your company should not pay for these expenses. In such a case, only honoraria should be paid by your company



Answer Q6 – Invited speaker at a satellite symposium

(a) is incorrect answer

Member may pay travel and lodging costs in addition to registration fee for the day of the satellite symposium (if practicable) and reasonable honoraria

(b) is incorrect answer

Travel and lodging costs may be payable to the HCP as well as registration fee if required to access the conference

Note that if there is a registration fee per day, the day of the satellite symposium should be payable



COCIR Code of Conduct

Test your understanding

Question 7 – Hospitality

A training seminar has been arranged at a hotel which has a renowned golf course. The meeting agenda states that the seminar will be held during the morning and that the afternoon has been left free for participants to make use of the hotel's sporting facility

Does this satisfy the requirement of "*subordinate in time and focus to the purpose of the meeting*"?

- (a) Yes
- (b) No



Answer Q7 – Hospitality

(b) is the correct answer

Members may provide reasonable hospitality and entertainment (including sports and leisure facilities) in connection with a business meeting. However, any such hospitality should be subordinate in both time and focus to the educational or training purpose of the meeting

The meaning of “subordinate in time and focus” is really a measure of the main purpose of the meeting. A meeting agenda should be organised so that healthcare professionals attending the meeting would not be free to make use of the leisure and sporting facilities during any significant part of a normal working day



COCIR Code of Conduct

Test your understanding

Question 8 – Meeting location and venue

You have been asked to organise a seminar on managing global anti-corruption risks in the medical technology industry. Which of the following would NOT be acceptable under the COCIR Code?

- (a) Cruise ship
- (b) A conference centre



Answer Q8 – Meeting location and venue

(a) is the correct answer

When selecting an appropriate venue, Members should take into consideration any implications in terms of potentially negative public opinion resulting from the image created by the event

A cruise ship is renowned for its entertainment facilities and therefore would not be considered conducive to the effective exchange of information



COCIR Code of Conduct

Test your understanding

Question 9 – Accommodation Expenses

May a Member offer to pay for the accommodation expenses of an HCP for a short period extending beyond the duration of a company educational event or hands-on procedure training organised by a third party?

- (a) Yes
- (b) No



Answer Q9 – Accommodation Expenses

(b) is the correct answer

Accommodation support given by Members to HCPs should be strictly tailored to the duration of the event. Therefore, any accommodation expenses relating to an extended stay must be met by the HCP



COCIR Code of Conduct

Test your understanding

Question 10 – Disclosure of advantages to HCPs

You wish to invite HCPs from France and Belgium to attend a hands-on procedure training organised by a third party. Which of the following steps must you take to satisfy the legal requirements relating to conference attendance?

- (a) Disclose the invitation to the administration or management of the institution to which each HCP is affiliated;
- (b) Require each HCP or the administration or management of the institution to which each HCP is affiliated to confirm approval;
- (c) Submit the invitation to the *Ordre des médecins* for prior approval with respect to HCPs licensed to practise in France;
- (d) Obtain a *visa* to attend the meeting from the Belgian health authority MDEON with respect to HCPs licensed to practise in Belgium;
- (e) Steps (a), (b), (c) and (d)



Answer Q10 – Disclosure of advantages to HCPs

(e) is the correct answer

Advantages or benefits granted to a HCP must be disclosed to the administration or management of the institution to which the HCP is affiliated, in addition to complying with the specific legal requirements of each country

All the actions mentioned are valid, but each one by itself is not sufficient to fully comply with the law



COCIR Code of Conduct

Test your understanding

Question 11 – Research Agreements

You have received a request from a HCP for an unrestricted research grant. The HCP tells you that the research proposal will be available in 9 to 12 months. The HCP says if your company agrees to the research request now, he will use his discretion on the best way to use the grant once the research proposal has been made available

If you agree to the request will you infringe the COCIR Code?

- (a) Yes
- (b) No



Answer Q11 – Research Agreements

(a) is the correct answer

There are two main issues:

First, a Member should give a research grant only if it is in support of research that has well-defined objectives, deliverables and milestones. A grant that is unrestricted and which can be used at the HCP's discretion does not fulfil these criteria

Second, the research grant should be made to the organisation or entity that is entitled to receive it under applicable national and local laws and regulations. A research grant should not be made to an individual HCP



COCIR Code of Conduct

Test your knowledge

Question 12 – Selection of conference faculty

Professor Blanc is retained by your company as an expert advisor on certain medical devices. Your management is *insisting* that Professor Blanc be designated as a faculty member and speak at a third-party educational conference

Is this likely to infringe the COCIR Code?

- (a) Yes
- (b) No



Answer Q12 – Selection of conference faculty

(a) is the correct answer

The conference organiser is responsible for and controls the selection of programme content, faculty, educational methods and materials

Under the COCIR Code of Conduct a Member may only recommend a knowledgeable faculty member and only if it is permitted by the conference sponsor's guidelines and requested from the Member by the Conference Organiser



COCIR Code of Conduct

Test your understanding

Question 13 – Independent Third Parties

Does the COCIR Code of Conduct govern the actions of Members' third party intermediaries?

- (a) Yes
- (b) No



Answer Q13 – Independent Third Parties

(a) is the correct answer

Members may use independent third parties (ITPs) for the promotion, importation and sale of their products and services, such as agents, consultants, distributors, representatives or resellers

Members are required to communicate the provisions in the COCIR Code to their ITPs and oblige them to comply



COCIR Code of Conduct

Test your understanding

Question 14 – Charitable Donations

May a Member contribute to or sponsor an event or gala party given by a charitable foundation connected to a HCP, when the proceeds earned from the event or party will be used to purchase specialist medical equipment from the Member?

- (a) Yes
- (b) No



Answer Q14 – Charitable Donations

(b) is the correct answer

A Member may not contribute to or sponsor an event if the motive is to induce the HCP to purchase, lease, recommend, or use the Member's products or services. Donations must be shown to be clearly separated from sales. Here the donation is not clearly separated from sales because it results in the purchase of the Member's specialist medical equipment



COCIR Code of Conduct

Test your understanding

Question 15 – Independent Third Parties (ITPs)

You have been asked to find and select a distributor for your company's products in Romania. Which of the following actions should you take to *fully* ensure that your company is dealing with an individual or organisation that is committed to act with integrity?

1. Conduct due diligence on proposed ITPs using a risk-based approach and/or
 2. Impose obligations in contracts with ITPs to comply with anti-bribery laws and the duties of the COCIR Code; and/or
 3. Monitor significant ITPs as part of a Member's regular review of relationships with them
 4. Subject significant ITPs to appropriate controls
- (a) 1 and 2
- (b) 1, 3 and 4
- (c) 1 and 4
- (d) All of the above



Answer Q15 – Independent Third Parties (ITPs)

(d) is the correct answer

All the actions mentioned are valid, but each one by itself is not sufficient to fully comply with the law

Knowing exactly *who* to do business with can help protect your company from dealing with individuals or organisations that might be less than trustworthy and avoid civil and criminal liability

Therefore for all independent third parties, you should take actions 1-4



COCIR Code of Conduct

Test your understanding

Question 16 – Research Agreements

Is the following statement true or false?

“The COCIR Code prohibits research funding that is contingent upon sales of Members’ products or services to the HCP, unless those products or services are being purchased for specific use in the research or are requested as part of a tender”

- (a) True
- (b) False



Answer Q16 – Research Agreements

(a) is the correct answer

Research funding should not be used to influence a HCP's decision-making with respect to the purchase of equipment from a Member, whether or not the research funding and sales transactions take place concurrently

Members should take organisational measures to ensure that decisions on research funding are taken by departments and/or individuals different and independent from those taking commercial decisions on sales

However, it is permitted to link sales and research if the products or services are specifically being purchased for use in the research or are combined in a public tender and thus requested by the tendering authority



COCIR Code of Conduct

Test your understanding

Question 17 – Charitable Donations

May a Member make a charitable donation to a HCP's event, when the proceeds earned from the event will be used for the general funding of the recipient HCP?

- (a) Yes
- (b) No



Answer Q17 – Charitable Donations

(b) is the correct answer

The general operating costs of the HCP such as salaries, capital improvements and equipment purchases are not a charitable purpose



COCIR Code of Conduct

Test your understanding

Question 18 – Demonstration & Evaluation Equipment

A HCP has requested that a Member provide it with a multiple-use medical device for evaluation

How long can the Member provide the medical device, free of charge, to the HCP?

- (a) less than 6 months
- (b) more than 6 months but less than 1 year
- (c) there is no time limit
- (d) provision of a medical device for evaluation, free of charge, is not permitted under the Code of Conduct



Answer Q18 – Demonstration & Evaluation Equipment

(a) is the correct answer

The length of time reasonably necessary for a HCP to assess a medical device will depend on the frequency of anticipated use, the duration of required training, the number of HCPs who will need to evaluate the product, the length of time necessary to evaluate different product features and similar considerations

A period of less 6 months would be considered sufficient time

A Member should provide a HCP with documentation and disclosure regarding the free of charge status of evaluation equipment



COCIR Code of Conduct

Test your understanding

Question 19 – Consultancy

Your company wishes to engage a HCP as a consultant to conduct clinical research services. Which of the following criteria should NOT be taken into account in assessing “fair market value”?

- (a) the HCP’s experience and qualifications
- (b) the amount of work involved
- (c) the volume or value of business generated by the consultant



Answer Q19 – Consultancy

(c) is the correct answer

Selection of consultants must be on the basis of objective criteria such as the consultant's qualification's and expertise to address the identified purpose

Compensation paid to HCPs engaged as consultants must be the fair market value for the services provided and must not be tied in any way to the volume or value of business generated by consultants, for example, the value of medical devices which consultants may use for their own medical practice



COCIR Code of Conduct

Test your understanding

Question 20 – Public Procurement

Following the award of a public procurement contract to Alpha Medical Technology company, the contracting authority now wants to extend the scope of the contract *considerably* to encompass services not initially covered

The contract only allows for additional services up to 10% of the contract value, and provided they are duly justified. A *considerable* change of scope of more than 10% of the contract value would be classed as a *material* change and therefore result in a new contract

Alpha suggests to the contracting authority that this would not require a new contract

Is Alpha's suggestion compliant with the COCIR Code?

- (a) Yes
- (b) No



COCIR Code of Conduct

Test your understanding

Answer Q20 – Public Procurement

(b) is the correct answer

After the contract has been awarded, the essential terms of it cannot be changed. However, provided the essential terms are not modified, other changes may be made to the contract provided they are within certain limits

If a post-contract change is considered **material** it will result in a new contract. This is because the change is classed as *“materially different in character so as to demonstrate an intention to renegotiate the essential terms of that contract”*

The COCIR Code obliges Members to understand that contracting authorities only have limited possibilities to make changes to the scope of supply. Alpha’s suggestion is not in compliance with the COCIR Code



COCIR Code of Conduct

Test your understanding

Question 21 – Educational Grants

Framex is a medical device company and a recognized leader in the development of both fusion and non-fusion solutions for patients with spinal disorders. It provides educational grants to foster an increased understanding of scientific, clinical or healthcare issues that contribute to the improvement of patient care

Dr Ossein is a bone surgeon and he has applied to Framex for an educational grant to learn more about motion-sparing spine technology. Framex is willing to grant funds directly to Dr Ossein pursuant to his request for an educational grant, on the understanding that he will purchase Framex spinal implants for use in his surgical practice

Is this likely to infringe the COCIR Code?

- (a) Yes
- (b) No



Answer Q21 – Educational Grants

(a) is the correct answer

Two issues would infringe the COCIR Code

Firstly, educational grants should not be made to individual HCPs

Secondly, a surgeon should be free to use any company's products in the practice of medicine. A grant of funds pursuant to a request should not be intended to impact in any way a surgeon's choice of products



COCIR Code of Conduct

Test your understanding

Question 22 – Educational Grants

The European Medical Health Society is a medical society representing oncologists. It requests from you an educational grant for the organisation of a congress on genetics and cancer. Your company is very keen on accepting the request on the condition that Dr. Seraphin and Dr. Marshmallows are invited to the Congress with payment of their attendance costs by the European Medical Health Society. The European Medical Health Society does not intend to sign any educational grant agreement with your company

Is this likely to infringe the COCIR Code?

- (a) Yes
- (b) No



Answer Q22 – Educational Grants

(a) is the correct answer

Two issues would infringe the COCIR Code

Firstly, the European Medical Health society should independently select the individual HCPs who will be invited

Secondly, the request as well as the content of the educational grant should be documented in an agreement between the medical society and your company. This implies that evidence of the request and its handling should be kept. It is important to sign an educational grant agreement to define the educational purpose of the grant. Other terms and conditions of the agreement may include a provision requiring a report on the use of the educational grants with no names of beneficiary HCPs



COCIR Code of Conduct

**THANK YOU
FOR YOUR ATTENTION**

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