



COCIR CODE OF CONDUCT
SUPPORTING ETHICAL INTERACTIONS
WITH HEALTHCARE PROFESSIONALS **MAY 2012**

COCIR
SUSTAINABLE COMPETENCE IN ADVANCING HEALTHCARE

European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry



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WHY SUSTAINING A CULTURE OF INTEGRITY AND ETHICAL BUSINESS PRACTICES IS IMPORTANT FOR OUR INDUSTRY?

The long collaborative tradition between the medical technology industry and the healthcare profession has resulted in ground-breaking treatments that have transformed healthcare in general, and more specifically, quality of life for the patient.

COCIR, as the leading voice of the radiological, electromedical and healthcare IT industry in Europe, is keen to support the medical technology industry's commitment to ensuring that this vital interaction adheres to the highest ethical standards.

Recognising that high ethical standards and regulatory compliance are critical to guaranteeing access to modern, innovative and reliable medical technology, COCIR introduced its first formal Code of Conduct in 2009.

The Code of Conduct serves to promote socially responsible behaviour by its corporate members through the provision of an ethical framework within which medical technology companies must work in their relationships with healthcare professionals.

The aim is to ensure that through high standards of integrity of behaviour, healthcare professionals and consumers will have confidence in dealing with the medical technology industry and the medical technologies it provides.

Since 2009, the Code of Conduct has evolved to refine its approach to the key issues which are covered and to introduce guidance Q&As to assist companies in understanding and implementing the Code. Also, the COCIR Code is now available in Dutch, English, French, German, Italian and Spanish, to facilitate efficient deployment to healthcare professionals in Europe and beyond.

Indeed, following the launch of the Code of Conduct, COCIR has received requests from countries all over the world showing interest in adopting its Code. Expansion of the Code of Conduct is particularly important to COCIR's members since they are global companies seeking compliance and harmonisation in international markets.

We encourage the reader to learn more about the COCIR Code of Conduct and also the benefits of working in an ethical, transparent, and socially responsible business environment in the following pages of this brochure.

Nicole Denjoy

COCIR Secretary General



COCIR CODE OF CONDUCT

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STATEMENT BY ALL COMPANY MEMBERS OF COCIR

COCIR is dedicated to the advancement of medical science and the improvement of patient care.

As participants in an industry largely funded from public funds, COCIR company members recognise that adherence to the highest levels of integrity and ethical standards and compliance with all industry laws are critical.

Accordingly, the company members of COCIR adopt this Code of Conduct, which represents our collective commitment to the highest standards of integrity. It is intended to supplement and not supersede any legal requirements and individual member company codes.

1 INTRODUCTION

This Code of Conduct becomes effective 1 October 2009 and governs COCIR company members' ("Members") interactions with Healthcare Professionals.

"Healthcare Professionals" refers to individuals (and the institutions for which they work) involved in the decision making process resulting in the procurement of Members' products or services. This includes doctors, nurses, hospital managers, and consultants employed by hospitals.

This Code applies to Healthcare Professionals in geographic Europe.

The Members agree to pass the responsibility to abide by the principles contained in this Code on to their dealers and agents.

This Code is not intended to supplant or supersede supranational, national or local laws or regulations or professional codes (including company codes) that may impose particular requirements upon Members or Healthcare Professionals.

2 BASIC PRINCIPLES

THE FOLLOWING FUNDAMENTAL PRINCIPLES FORM THE FOUNDATION OF THIS CODE:

- 2.1 The **SEPARATION** Principle – A clear separation should exist between any advantages or benefits granted by Members to Healthcare Professionals and the decision making process resulting in the procurement of Members' products or services. The purpose of this principle is to ensure that such advantages or benefits do not influence business transactions between Members and Healthcare Professionals.
- 2.2 The **TRANSPARENCY** Principle - Advantages or benefits to Healthcare Professionals should be disclosed to their institution's administration or management.
- 2.3 The **PROPORTIONALITY** Principle - Any consideration given to a Healthcare Professional in exchange for a service or other performance should not exceed normal market value.
- 2.4 The **DOCUMENTATION** Principle - The granting of any advantages or benefits to Healthcare Professionals by Members should be documented.

3 MEETINGS

- 3.1 **MEETING LOCATIONS.** All Member organized meetings should be conducted at an appropriate location and venue.
- 3.2 **PERMITTED EXPENSES.** Members may pay for reasonable travel and lodging costs incurred by Healthcare Professionals for attending Member organized meetings or meetings organized by third parties.
- 3.3 **SUBORDINATE HOSPITALITY.** Members may pay for reasonable hospitality in the form of meals, receptions, and entertainment (e.g. a music, sports or theatre event) in connection with the program of a meeting. However, any such hospitality should be subordinate in both time and focus to the educational or training purpose of any meeting.
- 3.4 **SEPARATION FROM SALES.** It is always inappropriate for Members to organize hospitality for the purpose of inducing Healthcare Professionals to enter into a business transaction. It is also inappropriate for Members to arrange hospitality linked to past, present or future business transactions.
- 3.5 **GUESTS.** It is inappropriate for Members to invite to a meeting any other person without a professional interest in the meeting, such as the spouse or guest of a Healthcare Professional. Members should clearly state in all cases that invitations to Healthcare Professionals do not extend to such individuals. It will always be inappropriate for Members to pay for the travel or lodging expenses for such individuals. In addition, it will be inappropriate for Members to pay for the expense of meals and hospitality for such individuals, except in the rare circumstances where such a guest appears at an event (such as dinner) despite not being invited, in which case the reasonable cost of a meal and hospitality may be borne by the Member.
- 3.6 **SPONSORING CONFERENCES.** Members may support conferences organized by third parties. They may provide financial grants to conference organizers to cover costs such as venue hire or catering, under the following conditions:
 - (A) the conference is primarily dedicated to promoting objective scientific and educational activities;
 - (B) the conference organizer is responsible for and controls the selection of program content, faculty, educational methods, and materials;
 - (C) the support of a conference by a Member is clearly stated in advance of and at the meeting.
- 3.7 **FACULTY HONORARIA.** Members may make grants for reasonable honoraria for Healthcare Professionals who are conference faculty members.

4 HOSPITALITY UNCONNECTED WITH MEETINGS

- 4.1 PERMITTED HOSPITALITY RESTRICTED TO MEALS.** Members shall be permitted to pay for meals and drinks which are unconnected with a meeting of the kind described in Section 3. However, Members may not pay for any other kind of hospitality, for example in the form of entertainment (e.g. a music, sports or theatre event), that is unconnected with such a meeting.

5 CONSULTANCY AGREEMENTS

- 5.1 AGREEMENTS IN WRITING.** Consultancy agreements between Members and Healthcare Professionals must be written, signed by both parties, and specify all services to be provided.
- 5.2 SEPARATION FROM SALES.** Consultancy agreements between Members and Healthcare Professionals should not be made on the basis of the volume or value of business generated by the consultants or their affiliates.
- 5.3 MANAGEMENT APPROVAL.** Consultancy agreements between Members and Healthcare Professionals must be approved by the administration/management of the institution with which the Healthcare Professional is affiliated.
- 5.4 FAIR MARKET COMPENSATION.** Compensation paid to Healthcare Professionals for consultancy should be consistent with fair market value for the services provided.
- 5.5 LEGITIMATE NEED.** Members should only enter into consultancy agreements where a legitimate need and purpose for the contracted services has been identified in advance.
- 5.6 CONSULTANT QUALIFICATIONS.** Selection of consultants should be made on the basis of the Healthcare Professionals' qualifications and expertise to address the identified purpose. Selection should not be made on the basis of the volume or value of business generated by the consultants or their affiliates (see Section 5.2).

6 GIFTS

- 6.1 GIFTS SHOULD BE MODEST.** Members may occasionally provide gifts such as branded promotional items to Healthcare Professionals. Any gift from a Member to a Healthcare Professional should be modest in nature and not exceed any amounts specified by the relevant law. Gifts may not be given in the form of cash or cash equivalents.

NOTE. This section on Gifts is not intended to address other types of interactions between Members and Healthcare Professionals that are addressed more specifically elsewhere in this Code or address the legitimate practice of providing appropriate sample products and opportunities for product evaluation.

7 CHARITABLE DONATIONS

- 7.1 CHARITABLE PURPOSE & RECIPIENT.** Members may make donations for a charitable purpose. Donations should be made only to charitable organizations.
- 7.2 SEPARATION FROM SALES.** It is inappropriate for Members to make charitable donations for the purpose of inducing Healthcare Professionals to enter into a business transaction. It is also inappropriate for Members to make charitable donations linked to past, present or future business transactions.
- 7.3 TRANSPARENCY.** The recipient of the donation and the recipient's planned use of the donation should be documented. Members must be able to justify the reason for the donation at all times.
- 7.4 EVALUATION & DOCUMENTATION.** The establishment of a process whereby Members can ensure that requests for Charitable Donations are evaluated separately to the Member's commercial activities and is consistently documented is recommended.

8 RESEARCH AGREEMENTS

- 8.1 RESEARCH SERVICES.** When a Member contracts with a Healthcare Professional for research services, there must be a written agreement specifying all services to be provided, and a written protocol for a genuine research purpose. Well-defined milestones and deliverables must be documented in detail.
- 8.2 RESEARCH TO BE LEGITIMATE & DOCUMENTED.** The research should be legitimate scientific work. Well-defined milestones and deliverables must be documented in a detailed written agreement. Selection of the Healthcare Professional should be made on the basis of qualifications and expertise to address the identified purpose.
- 8.3 SEPARATION FROM SALES.** The research funding should not be linked to or contingent upon past, present or future sales of the Member's products or services to the Healthcare Professional. Conditions linking the research funding with the Healthcare Professional's purchase of products or services from the Member are only permissible if the said products or services are being purchased for specific use within the research or are required to be linked by tender.
- 8.4 MANAGEMENT APPROVAL.** Research Agreements must be approved by the administration/management of the institution with which the Healthcare Professional is affiliated.
- 8.5 FAIR MARKET COMPENSATION.** Compensation paid to Healthcare Professional should be consistent with fair market value for the services provided.

9 LOAN EQUIPMENT

- 9.1 LIMITED DURATION EVALUATION.** Members may offer equipment for demonstration and evaluation to Healthcare Professionals for a reasonable period of time. Written approval by Healthcare Professionals' administration or management is required and should be filed alongside the appropriate loan documentation.



10 MONITORING THE CODE

10.1 CODE OF CONDUCT COMMITTEE. COCIR will establish a mechanism for anyone concerned that a Member may have breached this Code to report such concern directly to COCIR.

Such concerns will be referred to senior legal or compliance officers within the relevant Member for proper investigation, handling and resolution.

COCIR will establish a Code of Conduct Committee consisting of one senior legal or compliance officer from each Member.

The Members shall disclose to the Committee, on an aggregated basis, how concerns relating to that Member have been addressed and resolved.

COCIR QUESTIONS & ANSWERS

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PART 2 COCIR QUESTIONS & ANSWERS¹

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1 GENERAL

1.1 WHY ARE THE COMPANY MEMBERS OF COCIR ADOPTING THIS CODE?

Our industry manufactures and sells products and solutions which improve the lives of millions of patients.

Much of the healthcare sector is financed directly or indirectly by public money. It is essential that our industry, along with all participants in this sector, adhere to certain principles, which embody the high standards we expect of ourselves and which society expects of us.

The COCIR Code is designed to prevent damage to the reputation of our Members and our industry and to ensure public confidence in the ethical standards of our industry.

1.2 WHAT IS THE RELATIONSHIP OF THE COCIR CODE TO OTHER INDUSTRY CODES AND WHAT IF THEY ARE DIFFERENT?

Several industries in the healthcare sector have adopted codes of conduct. There are many common themes, but if you believe more than one code applies to you, and there is a conflict between them, you should apply the stricter code.

1.3 WHAT IS THE RELATION OF THE COCIR CODE TO THE LAW?

The COCIR Code does not replace the law. Where there are legal standards, it is the responsibility of Members to comply with them. Members are expected to comply with the law and with the COCIR Code, whichever is stricter.

Compliance with the COCIR Code will ensure compliance with the law in many countries. But some countries have stricter legal standards and it is the responsibility of Members to ensure they comply with such laws.

¹ This document must be read in conjunction with the COCIR Code of Conduct

1.4 WHERE AND FOR WHOM DOES THE CODE APPLY?

The COCIR Code applies to all doctors admitted to practice or physically present in geographic Europe (which extends from the Atlantic to the Urals).

So, if a doctor is admitted in Germany, he or she is covered by the COCIR Code at all times, wherever he or she is in the world. Likewise, an American doctor who attends a conference in Europe, will be covered by the COCIR Code for the duration of their stay in Europe.

If there is any conflict between the COCIR Code and any other code applying to the doctors in question, then the stricter will apply. So an American doctor in Europe who is subject to the MITA Code of Conduct, will remain subject to it even while in Europe.

1.5 WHAT SHOULD I DO IF SOMEONE ASKS ME TO DO SOMETHING WHICH WOULD BREACH THE COCIR CODE?

If anyone, including a HCP, asks you to breach the terms of the COCIR Code, show them the COCIR Code and explain why you cannot and that the COCIR Code has been adopted by the whole industry.

In appropriate circumstances, you may also choose to involve your own legal counsel or compliance manager, legal counsel for the HCP or other authorities, depending on the nature and seriousness of the improper request.

1.6 WHO IS RESPONSIBLE FOR ENFORCING THE COCIR CODE?

Complying with the COCIR Code will help you ensure that you are complying with the law. Ultimately, all company Members of COCIR must comply in order to remain within COCIR.

1.7 WHAT DOES EUROPE MEAN?

Europe means all the countries of the EU, the EEA and any other countries lying between the Atlantic and the Urals.

1.8 WHAT SHOULD MEMBERS DO TO ENSURE THAT THIRD-PARTIES COMPLY WITH THIS COCIR CODE?

Members may use independent third parties for the promotion, importation and sale of their products and services, such as agents, distributors or consultants (hereafter referred to as "Independent Third Parties", or "ITPs").

Knowing exactly who to do business with can help to protect Members from dealing with individuals or organisations that might be less than trustworthy. Members should only select and award business to ITPs that are committed to act with integrity and comply with applicable laws and regulations.

Not knowing who Members do business with can have serious consequences and may even lead to civil and criminal liability of a Member.

For all ITPs, Members should therefore:

- (I) 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 to use unlawful and unethical methods for performing their services for or on behalf of Members;
- (II) make known their selection policies to ITPs;
- (III) impose obligations in contracts with ITPs to comply with anti-bribery laws and the duties of the COCIR Code;
- (IV) monitor significant ITPs as part of a Member's regular review of relationships with them and subject significant ITPs to audits and financial controls.

1.9 WHAT HAPPENS IF A DEALER VIOLATES THE COCIR CODE?

The Members agree to pass the responsibility to abide by the principles contained in this Code on to their dealers and agents.

If a Member discovers a violation by a dealer or other representative, the Member must take action against that third party and ensure the violation does not recur.

1.10 SHOULD MEMBERS PROVIDE COPIES OF THIS COCIR CODE TO HEALTHCARE PROFESSIONALS (HCP)?

Yes. You are strongly encouraged to provide this COCIR Code to HCPs and to participate in educational efforts to help them to understand the ethical and legal requirements and limitations facing Members.

1.11 WHAT SHOULD MEMBERS DO TO ASSURE INTERNAL COMPLIANCE WITH THIS COCIR CODE?

Members should consider adopting adequate compliance programs to assure conformity with applicable laws and regulations, and this COCIR Code. This compliance program could involve executive management, legal, compliance and accounting personnel in the following activities:

- (I) educating Member personnel about their obligations under applicable laws and regulations;
- (II) setting procedures to approve the types of funding, payments, expenses, grants, gifts, donations, compensation, or activities discussed in the COCIR Code;
- (III) conducting due diligence with respect to the activities discussed in the COCIR Code; and
- (IV) monitoring and auditing the types of funding, payments, expenses, grants, gifts, donations, compensation, or activities discussed in the COCIR Code for compliance with law and regulations.

2 THE PRINCIPLES

2.1 WHAT IS THE PURPOSE OF THE FOUR PRINCIPLES?

The COCIR Code is meant to be principle based rather than rule based. Principles are the foundation of the entire document and will always be a useful guide when you are forming your decisions.

When a situation arises (including one where there is no specific rule given in the COCIR Code or these Q&A for such a situation), you should return to the basic principles for guidance when deciding the correct course of action.

Another question which can be useful is for you to ask "Would I be happy to see what we are doing published on the front page of the newspaper?" This is the so-called "newspaper test" and will often help you decide what is the right course of action.

However, if you have any doubt, we recommended that you ask your legal or compliance department in order to check the local regulations for a specific issue.

2.2 WHAT IS THE AIM OF THE SEPARATION PRINCIPLE?

This fundamental principle concerns the question of separation of benefit from influence. The concept is to ensure that choices by HCPs in business transactions are made only on legitimate grounds.

Proper influence involves solely the objective conditions of the relevant Member's offer, namely price, quality, specifications or service. The Separation Principle ensure that a HCP's decisions are not influenced by other undue considerations. The Separation Principle promotes fair competition.

2.3 HOW FAR DOES THE TRANSPARENCY PRINCIPLE EXTEND?

The Transparency Principle extends to all advantages and benefits beyond branded promotional items of a modest value or reasonable hospitality in the form of meals or other hospitality subordinate in time and focus to the legitimate purpose of a meeting. For instance, it does not extend to branded promotional pens, but it does extend to invitations to conferences, trade fairs etc. Remember, local laws and regulations applicable to the HCP in question (e.g., the HCP's code of conduct or employment rules) have to be observed.

2.4 WHO IS RESPONSIBLE FOR OBTAINING THE APPROVAL? THE MEMBER OR THE HCP? DO WE NEED A WRITTEN STATEMENT FROM THE ADMINISTRATION OF A HOSPITAL?

Both are responsible. You must at least be able to document a confirmation of such approval. You may either address the HCP or his/her administration for such confirmation. However, if only the HCP is addressed, he/she should confirm in writing (e.g. an e-mail) to you that approval has been obtained from the administration.

You should always reserve the right to demand written confirmation from the HCP's administration itself.

2.5 WHAT IF THE HCP DOESN'T WISH TO DISCLOSE THE BENEFIT TO HIS/HER MANAGEMENT?

You should treat this as a sign of a possible violation of the COCIR Code. Many HCPs also have codes of conduct with which they must comply. Transparency is an universal principle. It is in the interest of the HCP to be open about advantages and benefits conferred by Members.

2.6 WHAT DOES MARKET VALUE MEAN?

Market value means a fair rate of pay for the work done – the normal rate in the market for somebody of the experience and qualifications in question.

You should always pose the question “Would you pay the same for somebody who isn't a customer or a potential customer?”

2.7 WHY DO I NEED DOCUMENTATION?

Documentation enables you to prove compliance with the COCIR Code and serves for your own protection. It is also a precondition for transparency.

3 MEETINGS

3.1 WHAT IS AN APPROPRIATE LOCATION OR VENUE?

This means a location which is conducive for the transfer of information, knowledge, training and skills. It must be somewhere where people can actually speak to each other in suitable surroundings.

For example, a training or educational meeting should be the Members' own office facilities, a laboratory, or a conference facility designed for meetings.

It is possible to exchange information meaningfully in some settings which are more overtly social, for example a restaurant.

However, golf links, ski resorts and clubs are not suitable venues for exchanging information. The primary activity is something other than discussion and no real objective benefit can be gained.

3.2 WHAT DOES "REASONABLE" MEAN IN THE CONTEXT OF TRAVEL, LODGING AND HOSPITALITY?

Exactly what is "reasonable" depends on the context.

First, in the case of travel, consider whether the travel is needed at all. There must be a genuine educational purpose to the meeting. If a European doctor can get the same information or training at a congress in Australia and a few weeks later in Germany, it is only appropriate to send him to the congress in Germany.

Next, consider the cost of the travel and lodging. "Reasonable" will not always mean the cheapest available. Normally, economy class travel will be sufficient. However, if, for example, the doctor concerned is a Professor leading a department at a large hospital, it may be reasonable to select business class travel. The same approach applies to selection of accommodation and food. Normally, a restaurant with a Michelin star will not be reasonable. Consider what the individual in question would pay for themselves.

A useful guide here is to look at your own company travel policies for employees and also at policies that the hospitals or institutions follow. Use this guidance in forming your decisions about reasonable in each case.

3.3 WHAT IS THE MEANING OF "SUBORDINATE IN TIME AND FOCUS"?

This is really a measure of the main purpose of the meeting. A meeting during the working day and dinner in the evening satisfies the test that the hospitality is subordinate in time. If the meeting is in the morning and the attendees are allowed to go skiing in the afternoon, this does not satisfy the test.

If you have a two day meeting, or a conference involving a variety of events, then a social event, for example a visit to a concert at the end of the meeting will satisfy the test of being "subordinate". You should also ensure any such event is "reasonable", as described above. It is not appropriate to fly a doctor to a Formula 1 race. It may be appropriate to visit the opera together after a full day meeting at which real work is conducted.

Remember as well that if a ticket to an event has a rarity value which is not reflected in its nominal price, you must consider that in all cases you must avoid influencing the HCP in terms of purchasing equipment as a result of benefits conferred. This is in accordance with the Separation Principle.

You should also consider the frequency of any hospitality – it will not be appropriate to provide frequent events of this nature to the same recipients.

With the exception of reasonable and occasional meals and drinks as described in Section 4 of the Code, entertainment on its own, without any working meeting taking place, is not permitted.

If in doubt, consider the newspaper test.

3.4 WHAT ABOUT GUESTS?

To avoid embarrassing situations, all invitations to HCPs should clearly state that guests are not included and the invitee will have to pay for any guest expenses (e.g. if their spouse stays in the same hotel).

Members should go further and take active steps which make it clear to an HCP that a guest will not be welcome, for example by the use of a personal voucher or ticket systems for hospitality events.

However, if notwithstanding these steps, guests appear uninvited (e.g. the spouse of the HCP), for example at a hospitality event, Members may pay for the reasonable expenses of a meal or related hospitality. The amount should reflect the actual costs.

3.5 WHAT IS MEANT BY “THIRD PARTY”?

A third party is an individual or entity that is neither a Member nor a HCP.

3.6 MAY I PAY SPECIFICALLY FOR THE ENTERTAINMENT ELEMENTS OF A THIRD PARTY CONFERENCE?

No. Members are permitted to sponsor activities that are conducive to the exchange of information about products, services and scientific information. It is for the third party conference provider to organize and pay for entertainment.

3.7 IF A MEMBER PROVIDES 100% OF THE FUNDS FOR AN EDUCATIONAL PROGRAM RUN BY A THIRD PARTY, AND THAT THIRD PARTY CONTROLS HOW THE FUNDS ARE SPENT, IS THIS PERMITTED?

So long as the Member does not control the content of the program or the manner in which the Third Party spends the funds, this is permitted.

3.8 IS IT APPROPRIATE FOR A MEMBER TO PROVIDE A SPEAKER FOR AN EDUCATIONAL PROGRAM SPONSORED BY A HCP, IF THE HCP REQUESTS THE MEMBER TO DO SO?

Yes.

4 HOSPITALITY UNCONNECTED WITH MEETINGS

4.1 WHAT IS THE PURPOSE OF THIS SECTION?

Many meetings between representatives of Members and HCPs will take place in hospitals and clinics.

However, in many European countries, if a meeting is to take place between the representative of a Member and a HCP, it is socially normal for the meeting to include a meal and/or something to drink, for example in a restaurant.

Members are permitted to pay for such meals and drinks. However, Members should ensure that such hospitality is reasonable in nature and occasional.

4.2 CAN MEMBERS INVITE HCP'S FOR THEATRE OR SPORT EVENTS?

HCPs may only be invited for theatre, sports opera or other entertainment events if it is connected to a meeting, and only if the event is subordinate in time and focus to the meeting. Invitations for entertainment events only are not allowed under the Code.

5 CONSULTANCY

5.1 WHAT IS THE MEANING OF “CONSULTANCY” WHAT KINDS OF THINGS ARE COVERED?

This term “consultancy” is very wide. The dictionary definition of a consultant is a professional who provides advice in a particular area of expertise. A consultant is not himself employed by his client, but instead is in business for himself or for a consultancy firm, usually with multiple and changing clients.

A third party HCP who provides any service to a Member for payment will be considered a “consultant”. This would include demos, scientific advice, NPI advice, clinical advice, speaking or writing abstracts.

5.2 MAY A MEMBER EVER ENTER A CONSULTANCY ARRANGEMENT WITH A HCP AS PART OF A SALES TRANSACTION?

A Consultancy should never be awarded solely on the basis of the value of sales, now, in the past or in the future.

However, if a Consultancy agreement is requested by the customer for legitimate reasons, at the time of a sales transaction, then, provided the consulting relationship is transparent, disclosed and for fair market value, in other words it meets the other requirements of the COCIR Code and especially Section 5, it may be entered as a separate agreement contemporaneously with a sales agreement.

5.3 WHAT FORM SHOULD “MANAGEMENT APPROVAL” TAKE?

The approval should be written, but could be in e-mail form. See the commentary on the transparency principle above.

6 GIFTS

6.1 WHAT DOES MODEST MEAN?

Modest has its common sense meaning – it means that the gift should not be particularly noteworthy, but should be of the kind which is normally exchanged in the social setting which applies.

A box of chocolates will be modest. A bouquet of flowers to celebrate an event of significance (such as a wedding or graduation) may be appropriate. A normal bottle of wine will be modest, a case of wine will not be modest.

An expensive item of more than normal value is never appropriate.

6.2 WHAT IS A PROMOTIONAL ITEM?

An item of branded products manufactured by a Member, usually carrying the Member’s branding, for example a disposable pen, an umbrella or a hat.

6.3 WHAT IS THE MEANING OF “OCCASIONALLY” IN THIS CONTEXT?

Gifts should be given only because of specific events, e.g. a noteworthy event where normal manners require that a gift be

offered (e.g. on a wedding or a birth). Gifts should not be routinely offered. This is for the obvious reason that multiple gifts each worth €50 quickly add to a level which is more than normal and may start to influence the HCP in a way which will breach the Separation Principle.

7 CHARITABLE DONATIONS

7.1 WHAT'S THE DIFFERENCE BETWEEN A GIFT AND A CHARITABLE DONATION?

A charitable donation is made to an institution, not an individual.

There are a number of tests to determine what is "charitable", and this varies from country to country. Consult with your legal or compliance Department and follow your company's process for approving such charitable donations.

7.2 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?

No. The general running costs of the HCP are not a charitable purpose.

7.3 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 FOR CHARITABLE PURPOSES?

Yes, provided the donation is clearly separated from Sales, that is, (a) it does not result in the purchase of the Member's products or services (e.g. Members should not fund a gala designed to purchase medical equipment for the HCP or to build a facility to house medical equipment for the HCP); and (b) it is not made to induce an HCP to purchase, lease, recommend, or use the Member's products or services.

7.4 MAY A MEMBER MAKE A CHARITABLE DONATION TO A CHARITABLE FOUNDATION IF THAT FOUNDATION IS ALSO A HCP?

Yes, provide the donation is clearly separated from Sales, that is,
(A) it does not result in the purchase of the Member's products or services; and
(B) it is not made to induce an HCP to purchase, lease, recommend, or use the Member's products or services.

7.5 HOW SHOULD A MEMBER DETERMINE WHETHER THE PROCEEDS WILL BE USED FOR A CHARITABLE PURPOSE?

The Member should conduct due diligence into the proposed charity to determine whether the funds will be used for a bona fide charitable purpose as opposed to being used for the general operating expenses of the HCP such as salaries, capital improvements and equipment purchases.

7.6 MAY A MEMBER FUND AN ENDOWED CHAIR AT A HCP THAT IS ALSO AN EDUCATIONAL INSTITUTION?

Check with your company's legal or compliance department.

8 RESEARCH

8.1 WHAT IS THE MEANING OF LEGITIMATE SCIENTIFIC WORK?

Work where the Member or wider society benefits from the output. You should be genuinely interested in the output of the research as such (i.e. its scientific content).

8.2 WHAT IS THE PURPOSE OF THIS RULE?

The rule enhances transparency of payments for funding for research. Clear separation of research funding from purchases underlines the genuine scientific interest, neutrality and ultimately the quality of the research undertaken.

8.3 MUST THE PAYMENT FOR RESEARCH BE FOR A SPECIFIC PROJECT?

Yes. Grants for unrestricted R&D, which can be used at the HCP's discretion, are not allowed. In such cases, there are no well-defined objectives or deliverables and no expectation on the Member's part of learning or other benefits with regard to product improvement.

To be permitted, an agreement must relate to specific goals, objectives, milestones and deliverables, defined by the Member and the HCP together. Money is paid for work that is performed.

8.4 WHY DOES THE COCIR CODE PROHIBIT RESEARCH FUNDING THAT IS LINKED TO OR CONTINGENT ON SALES OF MEMBERS' PRODUCTS OR SERVICES TO THE HCP?

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

8.5 ARE CLINICAL TRIAL AGREEMENTS CONSIDERED RESEARCH AGREEMENTS?

Yes. Clinical Trial agreements are permitted and necessary to release new products that have been put to the test in a real operating environment and thereby enhance product reliability and patient safety. While Clinical Trial agreements are governed by specific regulatory codes and procedures, they are subject to the same inherent risk of improperly influencing an HCP's decision-making with respect to a purchase of products or services from a Member. Therefore, they must respect the COCIR Code of Conduct in addition to specific regulatory codes and procedures.

8.6 HOW CAN MEMBERS ENSURE SEPARATION FROM SALES?

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.

Members' sales personnel may provide input about the suitability of proposed research funding but sales personnel should not control or unduly influence the decision.

9 LOAN EQUIPMENT

9.1 WHAT IS REASONABLE PERIOD OF TIME FOR A LOAN?

Normally this means less than one year.

9.2 IS LOANING EQUIPMENT AS A REPLACEMENT FOR DEFECTIVE EQUIPMENT OR DELIVERY PROBLEMS PERMITTED?

Yes. This shall be governed by the respective sales or service contract between Member and the HCP but is permitted as a temporary measure.

10 CODE OF CONDUCT COMMITTEE

10.1 WHAT IS THE ROLE OF THE MEMBERS, COCIR ITSELF AND THE CODE OF CONDUCT COMMITTEE?

COCIR's role is to provide a means for any interested party to ensure that concerns about compliance with this Code are referred directly to independent senior staff members in legal or compliance roles inside Member companies, so that the concerns can be properly addressed.

It is the role of the legal or compliance functions inside Member companies to handle and resolve such concerns in accordance with the Member's own compliance processes and procedures. Such resolution will include investigation and appropriate response, including disciplinary action up to termination of employment where appropriate.

Each Member will be responsible for reporting, on an aggregate (i.e. numerical) basis, to the Code of Conduct Committee of COCIR how it has resolved the cases referred to it. For example, how many concerns were verified, what form the response took, how many cases involved disciplinary action and what steps the Member has put in place to prevent recurrence.

It is the role of COCIR's Code of Conduct Committee to monitor the overall trends in terms of number and types of concerns raised. The Committee shall ensure it gives feedback to COCIR on the overall adequacy of the Members' collective compliance with the Code. The Committee shall ensure it gives feedback to each Member on the adequacy of its compliance with the Code.



COCIR DO's & DON'T's

3



DO's



ADHERENCE TO THE 4 BASIC PRINCIPLES OF COCIR'S CODE OF CONDUCT:

- SEPARATION BETWEEN BENEFITS AND DECISION-MAKING
- PROPORTIONALITY OF REMUNERATION FOR SERVICES RENDERED
- TRANSPARENCY TOWARDS HCP'S MANAGEMENT
- DOCUMENTATION OF BENEFITS PROVIDED

MEETING, HOSPITALITY & CONFERENCES

- Ensure appropriateness of location
- Only pay reasonable travel & lodging expenses
- Make sure that hospitality related to a meeting is subordinate both in time and focus.
- Limit meetings and related hospitality to the person of your business partner only
- Contribute financial grants to conferences for scientific or educational activities only to conference organizer, be transparent with respect to the support provided.
- Keep grants for healthcare professionals honoraria at market conditions
- Only pay expenses for meals and drinks in the case of unrelated hospitality activities

LOAN EQUIPMENT

- Offer the equipment for demonstration/evaluation for a reasonable time period
- Get approval from the institution's management
- Document the transaction (recipient and use)

Please refer to the Q&A section for interpretative guidance. Seek advice or report concerns to the COCIR Code of Conduct Committee.

GIFTS AND DONATIONS

- Restrict your activities to occasional gifts of modest value
- Donate only to charitable organisations
- Ensure through internal evaluation process that donations are not linked to past, present or future business
- Document the transaction (recipient and use)

CONSULTANCY & RESEARCH AGREEMENTS

- Have a legitimate need for the contracted services
- Select healthcare partner based on his qualification and experience
- Agree on cooperation on the basis of its scientific contribution
- Specify services, deliverables and milestones
- in a written and signed contract
- Seek for approval by healthcare professional's management
- Compensate the consultancy at fair market value
- No link of research funding with sales of members product (sales only permissible if specific use in research or linked in tender)

DON'T's



NEGLECT TO THE 4 BASIC PRINCIPLES OF COCIR'S CODE OF CONDUCT:
SEPARATION BETWEEN BENEFITS AND DECISION-MAKING
PROPORTIONALITY OF REMUNERATION FOR SERVICES RENDERED
TRANSPARENCY TOWARDS HCP'S MANAGEMENT
DOCUMENTATION OF BENEFITS PROVIDED

MEETING, HOSPITALITY & CONFERENCES

- Invite to meetings in inappropriate locations
- Treat the healthcare professional in a lavish way
- Arrange for hospitality activities which are excessive in relation to the meeting
- Extend invitations to others than the healthcare professional (e.g. spouses)
- Contribute to conferences with no apparent scientific or educational content or value. Hide your contribution.
- Pay honoraria out of line with market conditions to healthcare professionals

LOAN EQUIPMENT

- Lend the equipment without consideration for the scientific need
- Conceal the undertaking towards the institution's management

GIFTS AND DONATIONS

- Treat healthcare professionals with multiple and/or excessive gifts
- Give cash or cash equivalents
- Donate for non-charitable causes or institutions
- Donate with the intent to influence a business transaction
- Hide your donation

CONSULTANCY & RESEARCH AGREEMENTS

- Engage health care professional without need, without consideration of his capabilities and without evaluation of the scientific contribution
- Keep deliverables and timelines unclear
- Keep the agreement secret towards the professional's management
- Fix the compensation without consideration of the market value

Please refer to the Q&A section for interpretative guidance. Seek advice or report concerns to the COCIR Code of Conduct Committee.



COCIR CODE OF CONDUCT COMMITTEE

4



COMPOSITION AND OBJECTIVES

The COCIR Code of Conduct has been complemented by the establishment of a Code of Conduct Committee composed of senior legal and compliance officers of COCIR company members.

The main objectives of the Code of Conduct Committee are to ensure consistent interpretation of the COCIR Code of Conduct and closely monitor compliance by company members.

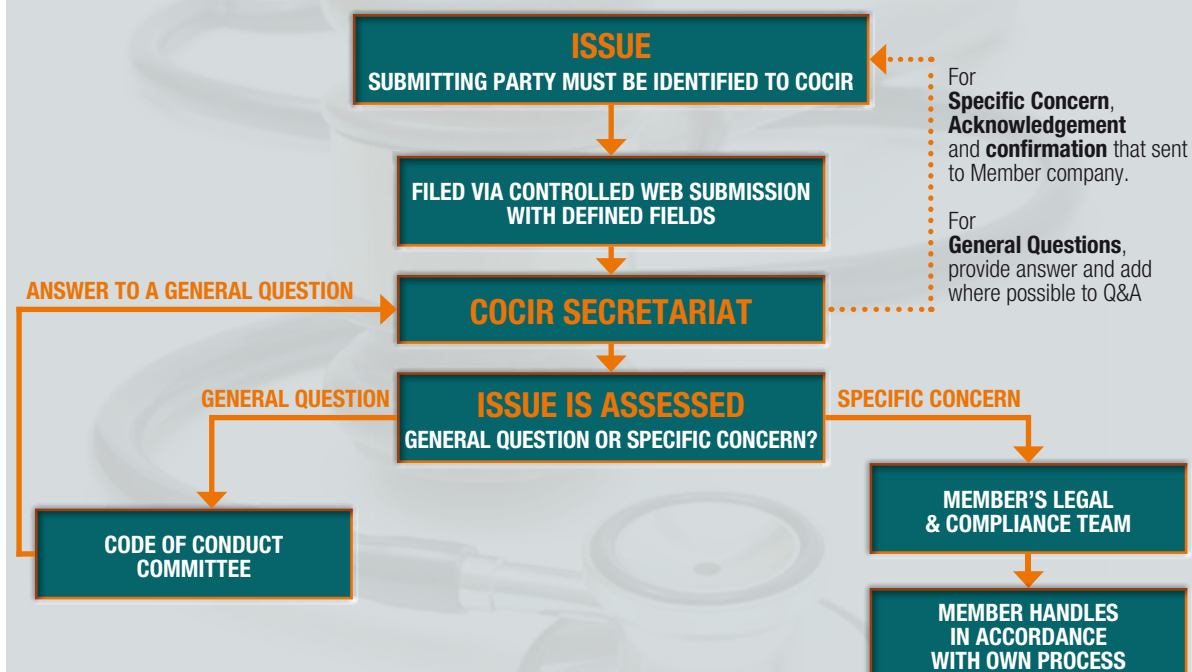
OPERATIONAL APPROACH

In order to assist our member companies in reporting general questions or resolving specific issues related to the Code of Conduct, we have adopted the following approach.

The COCIR Secretariat will refer general questions under the Code of Conduct to the Code of Conduct Committee. Specific concerns will be referred to the Member's Legal & Compliance Team for full investigation and resolution in accordance with their own corporate compliance procedures.

To facilitate and enhance integrity and ethical business conduct in the medical device and healthcare IT industry generally, COCIR shares the results of the work of the Code of Conduct Committee with its national trade association members.

ESCALATION OF QUESTIONS OR CONCERNS UNDER THE CODE



GENERAL INFORMATION ABOUT COCIR

Founded as a non-profit trade association in 1959, COCIR represents the radiological, electromedical and healthcare IT industry in Europe. As such, our members play a driving role in developing the future of healthcare both in Europe and worldwide.

COCIR is committed to supporting its members and communicating with its partners in Europe and beyond on issues which affect the medical technology sector and the health of EU citizens.

COCIR also works with various organisations promoting harmonised international standards and fair regulatory control that respects the quality and effectiveness of medical devices and healthcare IT systems without compromising the safety of patients and users.

We encourage the use of advanced technology to support healthcare delivery worldwide.

COCIR's key objectives include promoting free worldwide trade of medical devices and maintaining the competitiveness of the European health sector.

COCIR COMPANY MEMBERS:



NATIONAL TRADE ASSOCIATIONS MEMBERS:



COCIR HOW TO JOIN US

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