



CODE OF CONDUCT

MARCH, 2025

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COCIR COMBINED CODE OF CONDUCT AND Q&A

ON INTERACTIONS WITH HEALTHCARE PROFESSIONALS

20 March 2025

STATEMENT BY ALL COMPANY MEMBERS OF COCIR

COCIR is the European Trade Association representing the medical imaging, radiotherapy, health ICT and electromedical industries. 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 their collective commitment to the highest standards of integrity. It is intended to supplement and not supersede any supranational, national or local laws or regulations or professional codes (including company codes) that may impose particular requirements upon Members or Healthcare Professionals.

Why are COCIR Company Members 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 ensure public confidence in the ethical standards of our industry.

1. INTRODUCTION

This Code of Conduct governs COCIR company members ("Members") interactions with Healthcare Professionals. This Code of Conduct was amended in 2025. This amended Code of Conduct becomes effective on 20 March 2025.

"Healthcare Professionals" refers to individuals who provide healthcare services or who are involved in the decision-making process resulting in the procurement of Members' products or services. It also covers the institutions for which they work.

This includes but is not limited to doctors, nurses, hospital managers, pharmacists, healthcare technicians, purchasers of medical equipments or medical technology and services for or on behalf of medical or clinical personnel including, for example, healthcare data purchasers and healthcare consultants. This also covers individuals working in private practice.

Is the COCIR Code of Conduct applicable to interactions between the pharmaceutical industry and Healthcare Professionals relating to pharmaceutical products?

No, this Code is not applicable to such activities.

Should Members provide copies of this COCIR Code to Healthcare Professionals?

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

This Code applies to interactions with Healthcare Professionals in geographic Europe as defined below.

Where and for whom does the Code apply?

The COCIR Code applies to:

(1) Geographic Europe:

- the European Union: Austria, Belgium, Bulgaria, Croatia, Republic of Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden; and
- the EFTA: Iceland, Liechtenstein, Norway and Switzerland; and
- Albania, Andorra, Armenia, Azerbaijan, Belarus, Bosnia and Herzegovina, Georgia, Kosovo, Moldova, Monaco, Montenegro, North Macedonia, Russia, San Marino, Serbia, Turkey, Ukraine, the United-Kingdom; and

(2) (i) Interactions in Geographic Europe are covered by the COCIR Code, regardless of the place of practice or nationality of the Healthcare Professional.

(ii) Interactions outside Geographic Europe are covered by the COCIR Code if the Healthcare Professional is admitted to practice inside Geographic Europe.

So, if a Healthcare Professional is admitted to practice in Germany, interactions with him/her are covered by the COCIR Code at all times, wherever he/she is in the world.

Likewise, American Healthcare Professionals attending a conference in Geographic Europe will be covered by the COCIR Code for the duration of their stay in Geographic Europe.

If there is any conflict between the COCIR Code and any other code applying to the Healthcare Professional in question, then the stricter code will apply. So, for example, an American Healthcare Professional in Geographic Europe who is subject to a code of conduct will remain subject to it, even while in Geographic Europe.

Members agree to pass on the responsibility to comply with the principles contained in the COCIR Code to their distributors and agents.

What happens if a distributor violates the COCIR Code?

The Members agree to pass on the obligation to abide by the principles contained in the COCIR Code to third parties, such as their distributors, agents, commissionaires and other representatives.

If a Member discovers a violation by a third party, the Member must take appropriate action against that third party.

What should the Members do if someone asks them to do something which would not be in line with the COCIR Code?

In case of potential non-compliance with the COCIR Code, it is recommended to provide the COCIR Code and explain why the COCIR Member cannot comply with the request and that the COCIR Code has been adopted by the entire industry.

If need be, COCIR Member's legal counsel or compliance manager may provide further guidance.

What is the relationship between the COCIR Code and 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.

What is the relationship between the COCIR Code and 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.

What should Members do to ensure internal compliance with the COCIR Code?

Members should adopt an adequate compliance program to ensure conformity with this COCIR Code. This compliance program could involve executive management, legal, compliance and accounting personnel in the following activities:

- (1) educating Member personnel about their obligations under applicable laws and regulations;
- (2) setting procedures for the types of funding, payments, expenses, grants, gifts, donations, compensation, or activities discussed in the COCIR Code;
- (3) conducting due diligence with respect to the activities discussed in the COCIR Code; and
- (4) 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. 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 prevent undue, improper advantages or benefits influencing such procurement decisions.

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 Healthcare Professionals 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 ensures that a Healthcare Professional's decisions are not influenced by other undue considerations.

The Separation Principle safeguards against undue considerations affecting decisions and helps promoting fair competition.

- 2.2** The Transparency Principle – Advantages or benefits provided to a Healthcare Professional should be disclosed to his/her institution's administration or management and to local authorities, if required.

How far does the Transparency Principle extend?

The Transparency Principle extends to all advantages and benefits beyond:

- a) branded promotional items of an insignificant value;
- b) business 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 consultancy agreements and speaking engagements for a conference.

However, please remember that today, local laws and regulations applicable to the Healthcare Professional in question (e.g. the Healthcare Professional's code of conduct or employment rules) are often stricter and must be observed.

2.3 The Proportionality Principle - Any consideration given to a Healthcare Professional in exchange for a service or other performance should not exceed fair market value.

What does fair market value mean?

Fair 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 is not a customer or a potential customer?"

Different valuation methods may be used to establish fair market value. In all instances, a Company should use objective, verifiable criteria. The method or methods used by a Company should be documented.

2.4 The Documentation Principle - The granting of any advantages or benefits to Healthcare Professionals by Members should be documented.

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.

Who is responsible for obtaining the approval - the Member or the Healthcare Professional? Do we need a written statement from the hospital administration?

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

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

What if the Healthcare Professional does not want to disclose the benefit to his/her management?

First, you should review the benefit – if the Healthcare Professional does not want to disclose it, it may indicate that the Healthcare Professional has doubts about the

appropriateness of the benefit.

Second, you can offer to address the Healthcare Professional's administration yourself.

If in the end, there seems to be no way to properly disclose the benefit, you need to retract the benefit offered.

What is the purpose of the four principles?

The four principles are the foundation of the COCIR Code.

Next to these four principles, the COCIR Code also provides more specific rules for particular interactions, but the four principles always remain the cornerstones of these rules.

Whenever you feel that a particular situation is not covered or not well-regulated by specific rules, 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.

3. Meetings - Organised by Members

3.1 Purpose. The meeting should have a genuine educational, scientific or business purpose as its primary purpose and there must be a legitimate reason for inviting each Healthcare Professional to the relevant event.

3.2 Meeting locations. All Member organised meetings should be conducted at an appropriate location and venue.

What is an appropriate location or venue?

An appropriate location or venue 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 at 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.

By contrast, golf courses, ski resorts during the ski season 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.

3.3 Permitted Expenses. Members may pay for reasonable travel and lodging costs incurred by Healthcare Professionals for attending Member organised meetings.

What does "reasonable" mean in the context of travel, lodging costs and hospitality?

The exact meaning of "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, scientific or, to the extent allowed by the Code, business purpose to the meeting. If a European Healthcare Professional can get the same information or training at a Member meeting in Australia or a few weeks later in Germany, it is only appropriate to send him to the Member meeting in Germany. Next, consider that "reasonable" will not always mean the cheapest available, but the economically soundest. Normally, economy class travel will be sufficient. You should consult your own company's internal travel regulations as these will provide a good benchmark. A similar approach applies to the selection of accommodation and food.

3.4 Separation from Sales. It is always inappropriate for Members to organise hospitality for the purpose of inducing Healthcare Professionals to enter into a business transaction. It is also inappropriate for Members to arrange hospitality contingent upon 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 will ensure that their invitations will not be interpreted as extending 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.

What about guests?

To prevent any misunderstandings, all invitations to Healthcare Professionals should clearly state that guests are not included and that the invitee will be responsible for covering any guest expenses (e.g. if his/her spouse stays in the same hotel). Members should take proactive measures to reinforce this policy, such as using personal vouchers or ticket systems for hospitality events to ensure it is clear that guests are not included.

4. Educational or Scientific Events – Organised by Third Parties

4.1 Financial support for Events. Members may support events organised by third parties (the "Third-Party Event(s)"). This article 4.1. is not applicable to Third-Party Procedure Trainings which are covered under other provisions of this Code (i.e. article 4.2). Members may provide financial support to third parties under the following conditions:

- a)** the Third-Party Event is primarily dedicated to promoting objective scientific and educational activities;
- b)** the third party is responsible for and controls the selection of program content, faculty, educational methods, and materials;

- c)** the third party independently invites and selects individual Healthcare Professionals who will participate in the Third-Party Event and determines the payment of their expenses, as the case may be;
- d)** the third party independently selects speakers and determines the payment of their expenses;
- e)** the support of a Third-Party Event by a Member is clearly stated in advance of and at the meeting;
- f)** the support is not specifically granted for any entertainment or hospitality; and
- g)** virtual Third-Party Events are conducted in compliance with the requirements of COCIR Code of Conduct.

What are an appropriate location and venue for a Third-Party Event?

The location and venue of the conference organised by a third party should be appropriate, as described in Q&A related to Section 3.2 for meetings organised by Members.

What is meant by "third party"?

A third party is neither a Member nor an individual Healthcare Professional. For instance, it can be a Healthcare institution, a professional conference organiser, a scientific or medical society.

Do rules mentioned in Section 4.1. (Financial support to Third-Party Events) also apply to trainings organised by third parties?

Yes.

What is the form of a financial support to a non-individual Healthcare Professional?

Financial support to a non-individual Healthcare Professional may be given through an educational grant.

What is the form of a financial support to a Professional Conference Organiser?

Financial support to a Professional Conference Organiser may be given through a sponsorship. A Professional Conference Organiser is an entity whose commercial activity is the management of congresses, Third-Party Events or trainings.

May Members pay specifically for the entertainment elements of a conference or training organised by a third party?

No. Members are only permitted to pay for activities that are conducive to the exchange of information about products, services and scientific information. If a Third-Party Event includes entertainment elements, they must be subordinate to the purpose of the meeting. The name of the Member sponsoring the conference can be mentioned, if it does not correspond to a specific entertainment element.

May a Member select or pay or reimburse a Healthcare Professional, as a speaker, to speak at a Third-Party Event?

No, a Member may neither select the speaker nor pay or reimburse a speaker's fee. However, if the third party asks for a recommendation for names of speakers, without interference from a Member, the latter may recommend names of speakers for a Third-Party Event. In this case, the Member should not have any further role in the selection of the speakers. In contrast, it is possible for a Member to organise a satellite symposium with an agenda independent from a Third-Party Event's main agenda and which should be in the margins of such Third-Party Event and to pay a fee to a speaker invited by the Member for a speaking engagement, at that satellite symposium (see 4.2 (2) below).

4.2 Financial support to individual Healthcare Professionals. Members are prohibited to provide financial support to any individual Healthcare Professional for passive attendance at a Third-Party Event or active participation as a speaker at a Third-Party Event. This includes covering registration fees, travel, lodging costs or honoraria for a speaking engagement.

However, Members may provide financial support to an individual Healthcare Professionals for registration fees, travel or lodging in the following cases:

- a)** Attendance at hands-on procedure training organized by a Third Party, typically conducted in a clinical setting or
- b)** Speaking or providing professional training or a workshop at a satellite symposium organised by a Member alongside a Third-Party Event. In this case, Members may also pay honoraria for such the speaking engagement.

What is a third -party hands-on procedure training?

A third-party hands on-procedure training is a hands-on procedure training whose aim is to provide Healthcare Professionals with training on clinical procedures regarding specific diagnostic, therapeutic rehabilitative procedure or practical demonstrations typically given in a clinical setting.

What is a clinical setting?

A clinical setting is a place suitable for the simulation of medical procedures. It may be, for instance, a hospital or a conference room which is adequately set up to simulate medical procedures.

Does a speaker role also include a chairing role to lead professional debates organised by Member at the satellite symposium?

Yes, it does.

What if a third-party hands-on procedure training takes place nearby and on or around the same time as a Third-Party Event?

Member may pay for registration fee, travel and lodging costs to an individual Healthcare Professional who attends a hands-on procedure training, for the period of time covered by such training. For the avoidance of doubt, Members may neither pay registration fee for the individual

Healthcare Professional to attend the Third-Party Event nor costs related to the attendance of such Third-Party Event. Extra nights at a hotel or a later return ticket of the individual Healthcare Professional may be supported as long as it does not circumvent the ban on direct sponsorship, meets all requirements of the COCIR Code and does not entail additional costs for the COCIR Member. The same rule of absence of support applies to meetings organised by Members, that take place nearby and on or around the same time as the Third-Party Event.

How can a Member financially support the speaker invited to a satellite symposium?

Members may enter into a consultancy agreement with the speaker mentioned in Section 6 (Consultancy) to provide financial support.

If a Member is the sole sponsor for a Third-Party Event, and this third party controls how the funds are spent, is this permitted?

Yes, this is permitted as long as the Member complies with conditions set forth under Section 4.1. (Financial support to Third-Party Events).

5. Hospitality

5.1 In connection with Meetings or Third-Party Events. Members may pay for reasonable hospitality in the form of meals, drinks, and receptions in connection with the program of a meeting or a Third-Party Event. However, any such hospitality should be in accordance with local law and subordinate in both time and focus to the purpose of the meeting or the Third-Party Event.

What is the meaning of "subordinate in time and focus"?

Be mindful that non-business elements in meetings with Healthcare Professionals are a focus of many recent laws and enforcement actions, with some countries outright banning such elements. Even if you are confident they are permitted, consider whether the Healthcare Professionals would still attend the meeting without the non-business component.

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. In addition, a concert, sports or a theater event does not satisfy the test.

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.

5.2 Unconnected with Meetings or Third-Party Events. Members may pay for business meals and drinks that take place in a setting that is conducive to business discussions and is not selected because of its leisure or recreational facilities. However, Members may not pay for any other kind of hospitality.

What is the purpose of this section?

This section aims to allow and regulate business meals and drinks: Members are permitted to pay for such meals and drinks. However, Members should ensure that such hospitality is offered in an appropriate setting, is reasonable in nature, and is occasional.

6. Consultancy

6.1 Agreements in writing. Consultancy agreements between Members and Healthcare Professionals must be in writing, signed by both parties, and specify all the services to be provided. Services may include clinical and scientific advice, speaking engagements, participating in advisory boards, advising on new product development, conducting demonstrations and writing abstracts.

6.2 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 Healthcare Professionals or the institution with which the Healthcare Professional is affiliated or be contingent on past, present or future business transactions.

May a Member ever enter into a consultancy arrangement with a Healthcare Professional as part of a sales transaction?

If a Consultancy agreement is requested by the customer for legitimate reasons, at the time of a sales transaction, then, provided the consulting relationship meets all of the requirements of the COCIR Code and especially Section 6, it may be entered into as a separate agreement contemporaneously with a sales agreement.

6.3 Management approval. Consultancy agreements between Members and Healthcare Professionals must be approved by the administration or management of the institution with which the Healthcare Professional is affiliated.

6.4 Fair market value compensation. Compensation paid to Healthcare Professionals for consultancy should not exceed fair market value for the services provided.

What does fair market value mean?

See above under 2.3

6.5 Legitimate need. Members should only enter into consultancy agreements where a legitimate need and purpose for the contracted services has been identified in advance.

6.6 Consultant qualifications. Selection of consultants should be made on the basis of the Healthcare Professionals' qualifications and expertise to address the identified purpose.

7. Gifts

7.1 Limitation on gifts. Generally, gifts are discouraged. However, if given, they should be in accordance with local law, occasional and of modest or insignificant value, and 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.

What gifts would be acceptable under the Code?

If allowed under national law and provided that they are of modest or insignificant value, acceptable gifts may include promotional or educational items. Promotional or educational items may be branded or non-branded.

Educational items should relate to the Healthcare Professional's practice and benefit patients. They should also serve a genuine educational purpose and not mainly a personal purpose.

Promotional items can be, as an example, umbrellas, disposable pens or mugs.

What does "modest or insignificant value" mean?

This has its common-sense meaning – a gift should not be of notable value.

What is the meaning of "occasionally" in this context?

Gifts should not be routinely offered. This is for the obvious reason that multiple gifts of a modest or insignificant value may quickly add to a level which is more than modest or insignificant and may start to influence the Healthcare Professional in a way which will breach the Separation Principle.

7.2 Never cash or cash equivalent. A gift shall never consist of cash or cash equivalent.

8. Charitable Donations

8.1 Charitable Purpose & Recipient. Members may make donations for a charitable purpose. Donations should be made only to charitable organisations.

What's the difference between a gift and a charitable donation?

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

How can a Member ensure that a charitable organisation is bona fide?

A good test is to check whether the charitable organisation has been properly registered as such according to the requirements (if any) of the country where the charitable organisation has its principal office.

8.2 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 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 contingent upon past, present or future business transactions.

8.3 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.

May a Member consider a request for a charitable donation made in the name of an individual Healthcare Professional?

No. A Member must only consider requests made in the name of the charitable organisation and in accordance with its statutes.

8.4 Evaluation & Documentation. Members are recommended to establish a process whereby they can ensure that requests for charitable donations are evaluated separately from the Member's commercial activities and such requests are consistently documented.

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

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

May a Member make a charitable donation to a charitable foundation if that foundation is also a Healthcare Professional?

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; and

(b) it is not made to induce a Healthcare Professional to purchase, lease, recommend, or use the Member's products or services.

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 Healthcare Professional such as salaries, capital improvements and equipment purchases.

9. Public Procurement

9.1 Main principles. Members value the main principles of the public tendering laws: transparency of tendering processes and fair and equal treatment of all bidders.

9.2 Improper influencing. It is always inappropriate for Members to offer, directly or indirectly, gifts or other benefits in order to improperly influence Healthcare Professionals in the public tendering process. Members shall refrain from any activities that are likely to be seen as aimed at improperly influencing Healthcare Professionals.

9.3 Technical specifications. Members acknowledge that it is important that Contracting Authorities formulate open and objective technical specifications to afford fair and equal access to bidders.

To what extent are Members free to assist contracting authorities in formulating technical specifications?

In general, Members are free to provide technical and product information to Contracting Authorities. However, during the preparation phase of the public tender, they should do so in a way that it does not aim to unjustifiably exclude competitors from the tendering procedure or to unduly favour one supplier.

In particular, Members should not assist contracting authorities to illegally bias technical specifications. Members should not provide award/weighting criteria to contracting authorities, unless expressly requested to do so and in compliance with applicable laws.

9.4 Exemptions from public tendering procedures. Members understand that contracting authorities have only limited possibilities to exempt themselves from public tendering procedures. Members should not encourage contracting authorities to unduly seek such exemptions.

What about exemptions from public tendering procedures?

It is the contracting authorities' obligation to determine whether or not an exemption applies. In cases where the relevant conditions for exemptions from public tendering procedures are clearly not met, Members should take appropriate action before responding to contracting authorities' requests.

How should Members contact the contracting authorities?

Members agree to contact contracting authorities during the tendering procedure only as permitted in such procedure. Members will refrain from taking any actions which could unduly influence the decision-making of the contracting authorities. Contacts with contracting authorities during tendering procedures should be done only through official and transparent ways.

9.5 Consultants, use of third parties. Where a Member, as part of a technical dialogue or otherwise, acts as an independent consultant for the contracting authority, that Member shall do so only in a way that would not violate the principle of equal treatment of bidders.

9.6 Notice of future tenders. More specifically, where a Member, acting in a role of an independent consultant for the contracting authority, is or reasonably should be aware of the likelihood of a future tender arising as a result of the consulting services the Member provides to the contracting party, and which the Member intends to participate in, that Member shall request that the contracting authority issues an appropriate notice of any such future tender so that all potential bidders may have equal and fair notice of that tender opportunity and are aware of the role of the Member in a transparent way.

9.7 Amendments to contract or scope of supply. Members understand that during or after the tendering procedure, contracting authorities will have only limited possibilities to make changes to tender documentation, contractual terms or scope of supply.

What should a Member do if a contracting authority wants to change the contract post award?

Members should not accept significant post-award tender changes unless permitted by public procurement law and/or the tender procedure.

10. Research Agreements

10.1 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.

10.2 Research to be legitimate and 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.

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).

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.

Must the payment for Research be for a specific project?

Yes. Grants for unrestricted R&D, which can be used at the Healthcare Professional'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 Healthcare Professional together. Money may only be paid for work that is or has been performed.

10.3 Separation from sales. The research support should not be contingent upon past, present or future sales of the Member's products or services to the Healthcare Professional. A condition that the research support is contingent upon the Healthcare Professional's purchase of products or services from the Member is only permissible if the said products or services are being purchased for specific use within the research or are requested as part of a tender.

Why does the COCIR Code prohibit research funding that is linked to or contingent on sales of Members' products or services to the Healthcare Professional?

Research funding should not be used to influence a Healthcare Professional'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.

Are Clinical Trial agreements considered Research Agreements?

Yes. Clinical Trial agreements are permitted as 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 a Healthcare Professional'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.

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.

10.4 Management approval. Research Agreements must be approved by the administration or management of the institution with which the Healthcare Professional is affiliated.

10.5 Fair market value compensation. Compensation paid to Healthcare Professionals for research services should not exceed fair market value for the services provided.

11. Educational Grants

11.1 For defined purposes only. Members may make an educational grant to support:

- (a) the advancement of genuine medical, clinical or technological education;
- (b) the advancement of public education, that is, the education of patients or the public about important healthcare topics.

11.2 No grants to individuals. Educational grants should not be made to or for individual Healthcare Professionals.

11.3 Recipient independently controls. The recipient of the grant should independently control and be responsible for the selection of program content, faculty, educational methods, materials, any scholarship awards and any individual Healthcare Professional who may benefit from the grant. The grant may not be used to directly fund endowments of professors, chairpersons of departments or other similar position, nor replace departmental budgets.

May Members define the purpose of educational grant?

Yes, Members may define the purpose of the educational grant. For instance, they can request that educational grants be used for medical education to increase knowledge on a certain disease or to support the attendance of a certain educational or training event by individual Healthcare Professionals, without naming any individual Healthcare Professional.

May Members specify which category of Healthcare Professional they want to sponsor?

Yes, e.g. radiologists or cardiologists, to the extent that the grant is not provided for identified or identifiable Healthcare Professionals.

11.4 Separation from Sales. It is inappropriate for Members to make educational grants for the purpose of inducing Healthcare Professionals to enter into a business transaction. Educational grants should not be contingent upon past, present or future sales of Member's products or services to the Healthcare Professional.

11.5 Evaluation & Documentation. Members are recommended to establish a process whereby they can ensure that requests for educational grants be evaluated separately from Members' commercial activities and such requests be consistently documented.

11.6 Grants must be documented. Members should maintain appropriate documentation in respect of all educational grants made, to show that the grant was used for a genuine educational purpose.

How can Members ensure that the grant was used for a genuine educational purpose?

A Member can include a clause in the grant agreement requiring that the recipient of the grant reports to the Member on the use of the educational grant.

12. Demonstration and Evaluation Equipment

12.1 Limited duration. Members may offer equipment for demonstration and evaluation to Healthcare Professionals free of charge and for a reasonable period of time, which shall normally be less than 6 months. Written approval by Healthcare Professionals' administration or management is required and should be filed alongside the appropriate documentation.

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 Healthcare Professional but is permitted as a temporary measure.

13. Independent third parties

13.1 Use of Independent third parties. Members may use independent third parties for the promotion, importation and sale of their products and services to Healthcare Professionals, such as agents, distributors or consultants.

Why is the COCIR Code relevant to independent third parties?

Members should not use any third parties for actions which they would not be permitted to take or conclude themselves. Members should train their independent third parties on the code and communicate it to them.

13.2 Select with care. In order to find trustworthy individuals or organisations, Members should only select and award business to independent third parties that are committed to act with integrity and comply with applicable laws and regulations.

13.3 Monitor and control. Members should therefore (i) conduct due diligence on proposed independent third parties, (ii) impose obligations in contracts with independent third parties to comply with anti-bribery laws and the duties of the COCIR Code, (iii) monitor independent third parties as part of a Member's regular review of relationships with them and (iv) organise trainings or provide training materials if necessary.

What due diligence should Members carry out?

Not knowing with whom Members do business with, can have serious consequences and may even lead to civil and criminal liability of a Member. For all independent third parties, Members should therefore conduct due diligence on proposed independent third parties 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 independent third parties are trustworthy and will not use unlawful and unethical methods for performing their services for or on behalf of Members.

14. Compliance with the Code

Role of Code of Conduct Committee. COCIR has established a mechanism for anyone concerned that a Member may have breached this Code to report such concerns

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

COCIR has established 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.

Who is responsible for enforcing the COCIR Code?

The Members are responsible for enforcing the COCIR code. This means that they need to make sure that their own employees comply with the code and support other Members in complying with the Code. Ultimately, all Members must comply in order to remain within COCIR.

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, so that the concerns can be properly addressed.

It is the role of the legal or compliance functions inside Members 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 to the Code of Conduct Committee how it has resolved the cases referred to it.

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.

✓ DOs

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

- **SEPARATION BETWEEN BENEFITS AND DECISION-MAKING**
- **PROPORTIONALITY OF REMUNERATION FOR SERVICES PROVIDED**
- **TRANSPARENCY IN THE MANAGEMENT OF HCPS**
- **DOCUMENTATION OF BENEFITS PROVIDED**



MEETINGS, HOSPITALITY & CONFERENCES

- Ensure a legitimate reason for the meeting and appropriateness of location
- Reimburse reasonable travel and lodging expenses to individual HCPs only for educational and scientific conferences organised by Members
- For third-party conference, provide financial support to individual HCPs only if (1) the event organized by the third-party is a third-party procedure training which is a hands-on training typically performed in a clinical environment or (2) if the individual HCP is a speaker or a professional trainer invited by a Member to speak at a satellite symposium organised by the Member in the margins of a third-party conference
- Ensure hospitality related to a meeting is subordinate in time and focus
- Limit meetings and related hospitality strictly to persons having a professional interest in the meeting
- Contribute financial grants to conferences for scientific or educational activities only to conference organiser, be transparent with respect to the support provided

PUBLIC PROCUREMENT

- Allow Contracting Authorities to formulate open and objective technical specifications without interference
- Recognize that Contracting Authorities have only limited possibilities to exempt themselves from public tendering procedures
- Respect the principle of equal treatment of bidders when acting as an independent consultant for a Contracting Authority
- Recognize that Contracting Authorities have limited possibilities to make changes to tender documents or scope of supply

CONSULTANCY & RESEARCH AGREEMENTS

- Ensure a legitimate need for the contracted services based on the HCP's qualifications and expertise
- Specify services and deliverables in a signed contract
- Document approval of HCP's institution
- Compensate consultancy at fair market value

INDEPENDENT THIRD PARTIES (ITPs)

- Select ITPs that are committed to act with integrity and comply with the law
- Conduct due diligence on proposed ITPs
- Impose obligations in contracts with ITPs to comply with anti-bribery laws and the COCIR Code
- Monitor and control ITPs

DEMONSTRATION & EVALUATION EQUIPMENT

- Offer equipment for demonstration/evaluation only for a reasonable period, usually less than 6 months
- Get approval from the HCP's institution

GIFTS & CHARITABLE DONATIONS

- Discourage gifts
- Restrict yourself to occasional gifts of modest value
- Donate only for a charitable purpose to a charitable organisation
- Ensure through your internal evaluation process that donations are not linked to past, present or future business transactions

EDUCATIONAL GRANTS

- Make grants only to advance genuine medical, clinical or technological education or to educate patients or the public about important healthcare topics
- Allow grant recipient to independently (i) control the program content, faculty, educational methods, materials, scholarship awards and (ii) select individual HCPs who may benefit from the grant
- Ensure grants are not contingent upon past, present or future sales
- Ensure to establish a process whereby requests for educational grants be evaluated separately from commercial activities and be consistently documented

SPONSORSHIP

- Make sponsorship for third-party conference or professional training to a professional conference organiser
- Allow the professional conference organiser to independently (i) control the program content, faculty, educational methods, materials, scholarship awards and (ii) select individual HCPs who may benefit from the grant



DON'Ts

DO NOT NEGLECT THE **4 BASIC PRINCIPLES** OF COCIR'S
CODE OF CONDUCT



GIFTS & CHARITABLE DONATIONS

- Treat HCPs with multiple or excessive gifts
- Give cash or cash equivalents
- Donate for non-charitable causes or to non-charitable organisations
- Donate with the intent to influence a business transaction
- Conceal your donation from the HCP's institution

CONSULTANCY & RESEARCH AGREEMENTS

- Engage HCPs without a legitimate need, without consideration of their capabilities and without evaluating their scientific contribution
- Link research funding with sales of members' products (unless product is specifically for use in research or linked by tender)
- Keep deliverables and timelines unclear
- Conceal the agreement from the HCP's institution
- Fix compensation without consideration of the fair market value

DEMONSTRATION & EVALUATION EQUIPMENT

- Loan equipment without a proper reason nor for a period exceeding 6 months
- Conceal the loan from the HCP's institution

PUBLIC PROCUREMENT

- Unduly influence technical specifications
- Offer, directly or indirectly, gifts or other benefits in order to improperly influence HCPs in the public tendering process
- Encourage Contracting Authorities to unduly seek exemptions from public tendering procedures

INDEPENDENT THIRD PARTIES (ITPs)

- Fail to conduct due diligence on proposed ITPs
- Fail to monitor and train ITPs

MEETINGS, HOSPITALITY & CONFERENCES

- Invite to meetings in inappropriate locations
- Pay financial support to individual HCPs to attend third-party conference
- Contribute to conferences with no apparent scientific or educational content or value
- Treat the HCP in a lavish way
- Arrange for hospitality which is excessive in relation to the meeting
- Extend invitations to others in addition to the HCP (e.g. spouses)
- Conceal your contribution from the HCP's institution

EDUCATIONAL GRANTS

- Make grants to individual HCPs
- Use grants to directly fund endowments of professors, chairpersons of departments, the attendance of named individual HCPs or other similar position or replace departmental budgets
- Make grants which are not restricted to medical education with no control of the use of grants by recipients of the grants
- Request the selection of certain speakers or individual HCPs for the third-party conference

SPONSORSHIP

- Request the selection of certain speakers or individual HCPs for the third-party conference



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