COCIR
Advancing Healthcare

COCIR
CODE OF CONDUCT

ON INTERACTIONS WITH HEALTHCARE PROFESSIONALS

November 2020

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

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OPENING REMARKS

HOW TO ENSURE CONTINUOUS IMPROVEMENT OF OUR COCIR CODE?

COCIR members rightly pride themselves on their continuous commitment to sustaining the highest ethical standards in their dealings with healthcare professionals. COCIR provided its first set of guidelines more than 20 years ago and formalised its first Code of Conduct for dealing with healthcare professionals in 2009.

However, the practice of medicine, as well as the way in which all stakeholders engage with healthcare professionals, is constantly evolving. For this reason, COCIR regularly updates its Code of Conduct to ensure it reflects current circumstances and expectations.

Earlier updates have addressed matters such as changes in public procurement, industry support of third-parties' conferences, provision of educational grants and interactions with independent third parties such as agents, distributors and consultants, gifts, demonstration and evaluation of equipment. This latest iteration has been prompted by the decision of COCIR company members to end direct sponsorship. This means that they will no longer cover the registration fees, travel or lodging costs for individual healthcare professionals attending conferences organised by third parties. This will be adopted by all COCIR company members by 1 January 2019.

This will not affect our members' continuing support for medical education. They will continue to fund educational initiatives by healthcare organisations such as hospitals and medical societies. They will also continue to offer sponsorships to professional conference organisers. In future, however, these organisations will be responsible for deciding how funds are allocated for educational purposes. COCIR company members will document all educational grants they provide.

We believe that this latest round of changes will sustain our industry's reputation for maintaining the highest possible ethical standards. In addition, ending direct sponsorship will allow COCIR to further enhance our relationships with healthcare organisations and professional conference organisers.

These latest amendments demonstrate our proactive approach to our Code of Conduct and ensure that we meet or exceed the ethical standards expected of us. As ever, we will continue to monitor the evolution of the healthcare environment and will consider further updates to the Code in future as and when required.

PART 1

COCIR CODE OF CONDUCT

COCIR CODE OF CONDUCT
ON INTERACTIONS WITH HEALTHCARE PROFESSIONALS

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 Company Member codes.

1. INTRODUCTION

This Code of Conduct becomes effective on 1 January 2015 and governs COCIR company members' ("Members") interactions with Healthcare Professionals. This Code of Conduct was amended in 2017. This amended Code of Conduct becomes effective on 1 January 2019.

"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.

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

This Code is not intended to replace 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 prevent undue, improper advantages or benefits influencing such procurement.

2.2 **The Transparency Principle -** Advantages or benefits to Healthcare Professionals should be disclosed to their institution's administration or management and also, if required, to local authorities.

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.

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

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.

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

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.

4. CONFERENCES - ORGANISED BY THIRD PARTIES

4.1 **Financial support to Conferences.** Members may support conferences organised by third parties. Members may provide financial support to third parties under the following conditions:

1) the conference is primarily dedicated to promoting objective scientific and educational activities;
2) the third party is responsible for and controls the selection of program content, faculty, educational methods, and materials;
3) the third party independently invites and selects individual Healthcare Professionals who will participate in the conference or training and determines the payment of their expenses, as the case may be;
4) the third party independently selects speakers and determines the payment of their expenses;
5) the support of a conference by a Member is clearly stated in advance of and at the meeting; and
6) the support is not specifically granted for any entertainment or hospitality.

4.2 **Financial support to individual Healthcare Professionals** Members may not provide financial support to any individual Healthcare Professional for his/her passive attendance or active participation as a speaker in a third-party conference. Therefore, Members may neither pay for registration fee, travel and lodging costs nor for honoraria for a speaking engagement.

However, Members may provide financial support to an individual Healthcare Professional for registration fee, travel and lodging costs to:

1) attend a hands-on procedure training, organised by a third party, which is typically performed in a clinical environment or

2) speak or provide a professional training at a satellite symposium organised by a Member in the margins of a third-party conference; in this case, Member may also pay honoraria for a speaking engagement.

5. HOSPITALITY

5.1 **In connection with Meetings or Conferences.** Members may pay for reasonable hospitality in the form of meals, drinks, receptions and entertainment (e.g. a music, sports or theatre event) in connection with the program of a meeting or conference. However, any such hospitality should be in accordance with local law, subordinate in both time and focus to the purpose of the meeting or conference.

5.2 **Unconnected with Meetings or Conferences.** 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, for example in the form of entertainment as described in 5.1.

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 on 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.

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.

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 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.

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.

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 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.

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 Members' commercial activities and such requests are consistently documented.

9. PUBLIC PROCUREMENT

9.1 **Main principles.** Members value the main principles of 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.

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.

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.

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 a 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.

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.

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:

1) the advancement of genuine medical, clinical or technological education;

2) 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.

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 Members' 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.

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.

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.

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 and (iii) monitor significant independent third parties as part of a Member's regular review of relationships with them and subject significant independent third parties to appropriate controls.

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 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 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.

PART 2

COCIR COMBINED CODE OF CONDUCT & Q&A

COCIR COMBINED CODE OF CONDUCT AND Q&A
ON INTERACTIONS WITH HEALTHCARE PROFESSIONALS

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 Company Member codes.

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 becomes effective on 1 January 2015 and governs COCIR company members' ("Members") interactions with Healthcare Professionals. This Code of Conduct was amended in 2017. This amended Code of Conduct becomes effective on 1 January 2019.

"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.

IS THE COCIR CODE OF CONDUCT APPLICABLE TO ACTIVITIES I.E. RESEARCH AND DEVELOPMENT, MANUFACTURING AND SELLING OF PHARMACEUTICAL PRODUCTS?

No, this Code is not applicable to such activities.

SHOULD MEMBERS PROVIDE COPIES OF THIS COCIR CODE TO HEALTHCARE PROFESSIONALS?

Yes. You 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 Healthcare Professionals in geographic Europe.

WHERE AND FOR WHOM DOES THE CODE APPLY?

The COCIR Code applies to geographic Europe. It is defined as:

> 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, Switzerland and

> Albania, Andorra, Armenia, Azerbaïjan, Belarus, Bosnia and Herzegovina, Georgia, Kosovo, Moldova, Monaco, Montenegro, North Macedonia, Russia, San Marino, Serbia, Turkey, Ukraine, the United-Kingdom.

1) Interactions in geographic Europe are covered by the COCIR Code, regardless of where the Healthcare Professional comes from.

2) Interactions outside geographic Europe are covered by the COCIR Code if the Healthcare Professional is admitted to practise inside geographic Europe.

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

Likewise, an American doctor 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 doctor in question, then the stricter code will apply. So, for example, an American doctor in geographic Europe who is subject to the MITA 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 this 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 this Code to their distributors and agents.

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

WHAT SHOULD I DO IF SOMEONE ASKS ME TO DO SOMETHING WHICH WOULD NOT FOLLOW THE COCIR CODE?

If anyone, including a Healthcare Professional, asks you not to follow the terms of the COCIR Code, show them the COCIR Code and explain why you cannot do so 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 of the Healthcare Professional or other authorities, depending on the nature and seriousness of the improper request.

This Code is not intended to replace 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.

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.

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 promotes fair competition.

2.2 **The Transparency Principle -** Advantages or benefits to Healthcare Professionals should be disclosed to their institution's administration or management and also, if required, to local authorities.

HOW FAR DOES THE TRANSPARENCY PRINCIPLE EXTEND?

The Transparency Principle extends to all advantages and benefits beyond:

1) branded promotional items of a modest value;

2) 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 doctor 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 avoid embarrassing situations, all invitations to Healthcare Professionals should clearly state that guests are not included and that 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 a Healthcare Professional that a guest will not be welcome, for example by the use of a personal voucher or ticket system for hospitality events.

4 CONFERENCES - ORGANISED BY THIRD PARTIES

4.1 **Financial support to Conferences.** Members may support conferences organised by third parties. Members may provide financial support to third parties under the following conditions:

1) the conference is primarily dedicated to promoting objective scientific and educational activities;
2) the third party is responsible for and controls the selection of program content, faculty, educational methods, and materials;
3) the third party independently invites and selects individual Healthcare Professionals who will participate in the conference or training and determines the payment of their expenses, as the case may be;
4) the third party independently selects speakers and determines the payment of their expenses;
5) the support of a conference by a Member is clearly stated in advance of and at the meeting; and
6) the support is not specifically granted for any entertainment or hospitality.

WHAT ARE AN APPROPRIATE LOCATION AND VENUE FOR A THIRD-PARTY CONFERENCE?

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 such as a hospital, a professional conference organiser, a scientific or medical society.

DO RULES MENTIONED IN SECTION 4.1. (FINANCIAL SUPPORT TO CONFERENCES) 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, conferences or trainings.

MAY MEMBERS PAY SPECIFICALLY FOR THE ENTERTAINMENT ELEMENTS OF A CONFERENCE OR TRAINING ORGANISED BY A THIRD PARTY?

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

MAY A MEMBER PAY A HEALTHCARE PROFESSIONAL, AS A SPEAKER, TO SPEAK AT A CONFERENCE ORGANISED BY A THIRD PARTY?

No. A Member may neither select the speaker nor pay or reimburse a speaker's fee. In contrast, it is possible for a Member to organise a satellite symposium in the margins of a third-party conference and to pay a fee for a speaking engagement, to the speaker invited by the Member (see 4.2 (2) below).

4.2 **Financial support to individual Healthcare Professionals.** Members may not provide financial support to any individual Healthcare Professional for his/her passive attendance or active participation as a speaker in a third-party conference. Therefore, Members may neither pay for registration fee, travel and lodging costs nor for honoraria for a speaking engagement.

However, Members may provide financial support to an individual Healthcare Professional for registration fee, travel and lodging costs to:

1) attend a hands-on procedure training, organised by a third party, which is typically performed in a clinical environment or
2) speak or provide a professional training at a satellite symposium organised by a Member in the margins of a third-party conference; in this case, Member may also pay honoraria for a speaking engagement.

WHAT IS A THIRD-PARTY HANDS-ON PROCEDURE TRAINING?

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

WHAT IS A CLINICAL ENVIRONMENT?

A clinical environment is a place suitable for the simulation of medical procedures.

It may be, for instance, a hospital as well as a conference room, which are 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 AT THE SAME TIME AS AN EDUCATIONAL CONFERENCE ORGANISED BY A THIRD PARTY?

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 educational conference organised by the third party nor costs related to the attendance of such educational conference. If the educational conference has a longer duration than the hands-on procedure training, extra nights at a hotel or a later return ticket of the individual Healthcare Professional may not be supported.

HOW CAN A MEMBER FINANCIALLY SUPPORT THE SPEAKER INVITED TO A SATELLITE SYMPOSIUM?

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

IF A MEMBER IS THE SOLE SPONSOR FOR AN EDUCATIONAL CONFERENCE RUN BY A THIRD PARTY, 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. (Conferences organised by third parties).

5. HOSPITALITY

5.1 **In connection with Meetings or Conferences.** Members may pay for reasonable hospitality in the form of meals, drinks, receptions and entertainment (e.g. a music, sports or theatre event) in connection with the program of a meeting or conference. However, any such hospitality should be in accordance with local law, subordinate in both time and focus to the purpose of the meeting or conference.

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

Be aware that non-business elements of meetings with Healthcare Professionals are in focus of many recent laws and enforcement actions, and that in many countries, such elements are completely forbidden in any case.

Even if you are sure that non-business elements of meetings are allowed, consider whether the Healthcare Professionals would attend the meeting without the non-business element.

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.

Remember as well that if a ticket to an event has a rarity value which is not reflected in its nominal price, you should consider the ticket as being of a much higher value.

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 Conferences.** 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, for example in the form of entertainment as described in 5.1.

WHAT IS THE PURPOSE OF THIS SECTION?

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

WHAT GIFTS WOULD BE ACCEPTABLE UNDER THE CODE?

If allowed under national law and modest, acceptable gifts may include company branded promotional items, items that relate to the Healthcare Professional's practice, items that benefit patients and items that serve a genuine educational purpose.

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.

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 retirement or an anniversary). 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 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 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 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 A 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 Members' 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:

1) it does not result in the purchase of the Member's products or services; and
2) 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 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 MEMBERS 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 a 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.

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:

1) the advancement of genuine medical, clinical or technological education;

2) 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 Members' 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 and (iii) monitor significant independent third parties as part of a Member's regular review of relationships with them and subject significant independent third parties to appropriate controls.

WHAT DUE DILIGENCE SHOULD MEMBERS CARRY OUT?

Not knowing with whom Members do business 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 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 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 Members, 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.

COCIR DO's

PART 3
COCIR DO's & DON'T's

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

MEETING, 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 organised by the third party is a 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

CONSULTANCY & RESEARCH AGREEMENTS

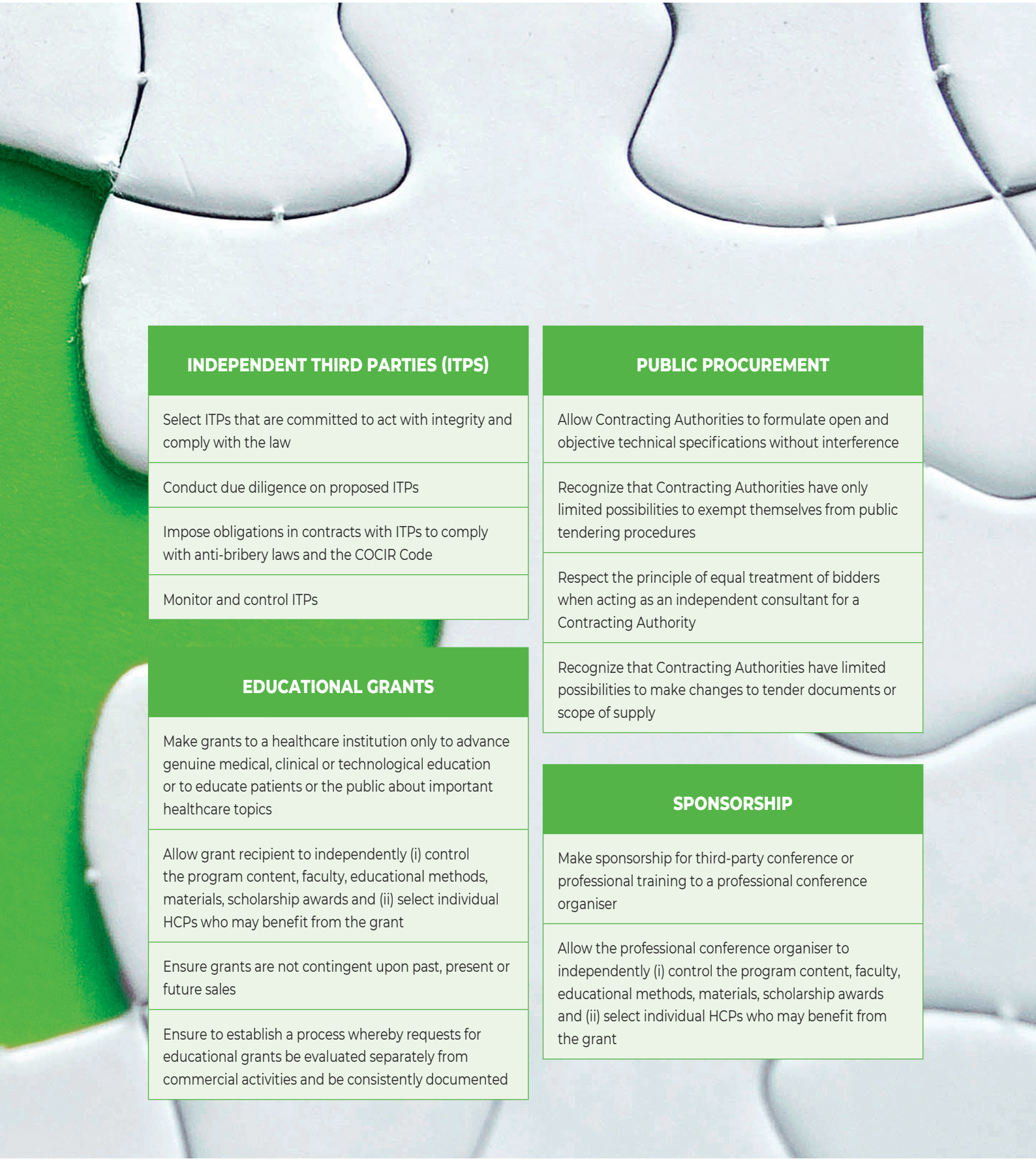
- Ensure a legitimate need for the contracted services based on the HCP's qualifications and expertise
- Specify services and deliverables in a signed contract
- Document approval of HCP's institution
- Compensate consultancy at fair market value

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



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

EDUCATIONAL GRANTS

- Make grants to a healthcare institution 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

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

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

COCIR DON'T's

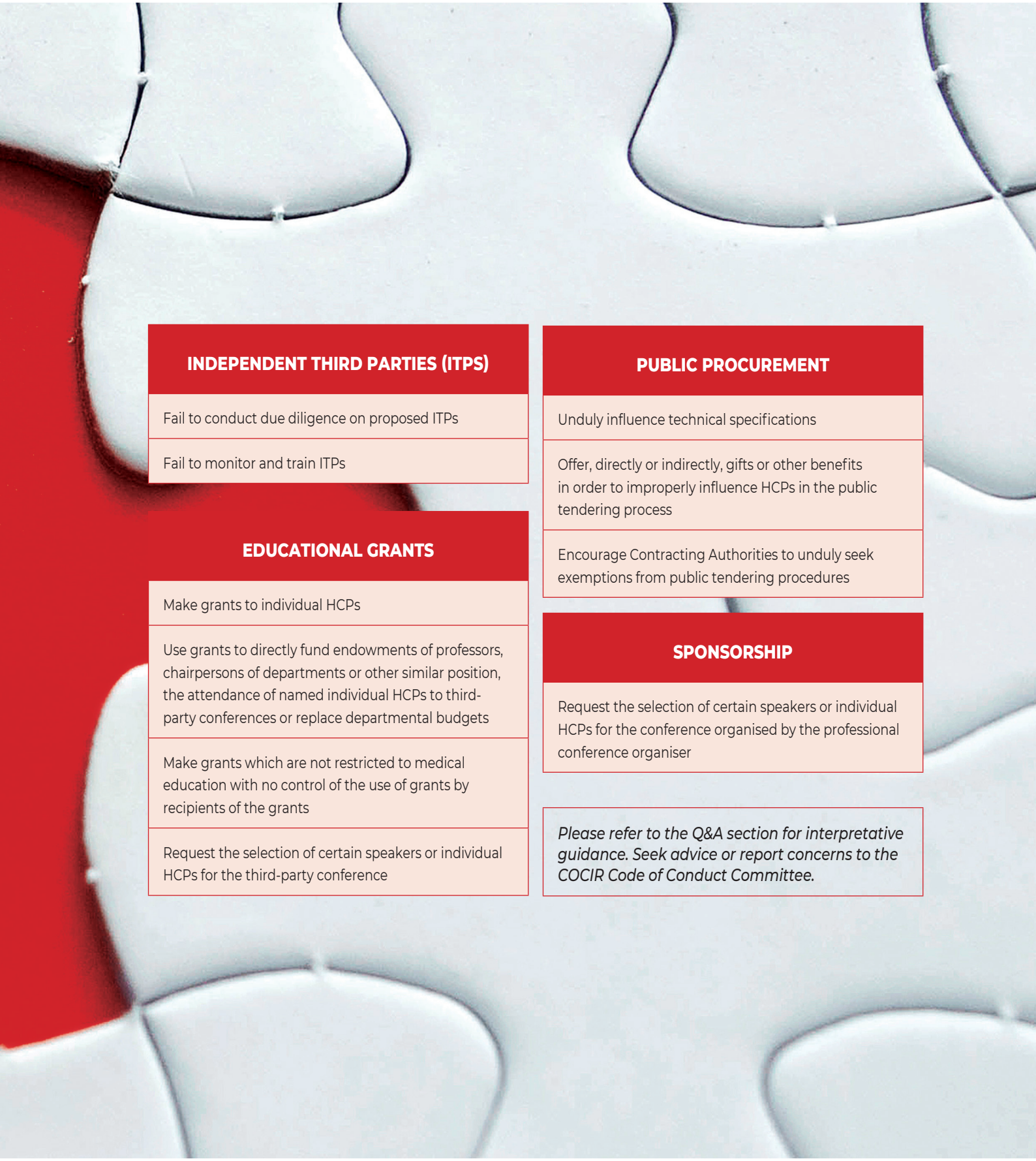
DO NOT NEGLECT THE **4 BASIC PRINCIPLES** OF COCIR'S CODE OF CONDUCT
SEPARATION BETWEEN BENEFITS AND DECISION-MAKING
PROPORTIONALITY OF REMUNERATION FOR SERVICES PROVIDED
TRANSPARENCY IN THE MANAGEMENT OF HCPS
DOCUMENTATION OF BENEFITS PROVIDED

MEETING, HOSPITALITY & CONFERENCES
Invite to meetings in inappropriate locations
Pay financial support to individual HCPs to attend third-party educational conference
Contribute to conferences with no apparent scientific or educational content or value
Treat the HCP in a lavish way
Arrange for hospitality for Member's meeting or third-party procedure training 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

DEMONSTRATION & EVALUATION EQUIPMENT
Loan equipment without a proper reason nor for a period exceeding 6 months
Conceal the loan 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

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



INDEPENDENT THIRD PARTIES (ITPS)

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

EDUCATIONAL GRANTS

- Make grants to individual HCPs
- Use grants to directly fund endowments of professors, chairpersons of departments or other similar position, the attendance of named individual HCPs to third-party conferences 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

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

SPONSORSHIP

- Request the selection of certain speakers or individual HCPs for the conference organised by the professional conference organiser

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

PART 4

GUIDELINES GOVERNING COCIR MEETINGS & TELECONFERENCES

GUIDELINES GOVERNING COCIR MEETINGS AND TELECONFERENCES

COCIR'S MISSION

COCIR's aim is to represent the interests of its radiological, electromedical, radiotherapy and healthcare IT industry members in Europe and abroad. COCIR also provides services to its members and acts as a communication channel for key stakeholders including the European institutions and other regulatory bodies.

COCIR operates in Europe and has an office in China. COCIR also covers matters of common interest to its members beyond Europe.

COCIR seeks to promote the development of harmonised international standards and regulatory control which respect the quality and effectiveness of medical devices and healthcare IT systems without compromising the safety of patients and users and promote the free worldwide trade in these products.

GUIDELINES

COCIR offers a neutral platform that allows its members to discuss matters of common interest. However, meetings or teleconferences at which competing COCIR members participate give rise to a risk of competition law infringement.

These guidelines provide a general summary of the competition law rules and do not intend to be exhaustive. They are provided for informational purposes only and cannot be considered as legal advice. For further assistance or clarification, please contact a specialised lawyer.

BEST PRACTICE

DO ensure that for any meeting organised by COCIR that an official COCIR representative is present.

DO ensure that meetings and teleconferences have a legitimate purpose.

DO ensure that agendas are agreed and circulated in advance of any formal meetings, and that accurate minutes are circulated thereafter.

DO ensure that the attendance list is signed at the beginning of each physical meeting, and in the case of a teleconference, that it is properly documented.

DO ensure that membership of working groups / participation criteria to meetings are transparent and non-discriminatory.

DO inform the COCIR meeting organiser if you have competition law concerns about the appropriateness of any discussion and/or any topic on the agenda.

DO stop the discussion of any topic if you reasonably believe that it does not comply with competition/antitrust laws until such concerns can be ruled out, either during the meeting or afterwards. If efforts to stop the discussion are not successful, leave the meeting under protest and request that your protest be documented in the minutes.

WHAT MAY BE DISCUSSED

AMONG OTHERS, THE FOLLOWING MAY BE DISCUSSED:

- Non-confidential, technical issues relevant to the industry, such as standards, environmental concerns, matters related to corporate social responsibility, health and safety matters, regulatory policy developments.
- Public policy, educational and scientific developments.
- Publicly available information (e.g. trade press, newspapers and company websites) on industry trends or general market conditions, provided the information is not company specific and relates to the industry as a whole.

- Benchmarking exercises or market surveys provided these activities do not result in an exchange of competitively and/or commercially sensitive information among the participants; results must be presented in an aggregated form which does not allow the identification of individual companies.

DO NOT DISCUSS

Any discussions, whether in a formal or informal context including mere information exchanges, could constitute an anti-competitive agreement or practice.

To avoid liability, **DO NOT** reach understandings or agreements or even discuss any of the following commercially sensitive matters:

- Pricing strategies including price ranges, margins, discounts, rebates or any other element of pricing.
- Supply costs, operating costs or other overhead costs.
- Invoicing practices and payment terms.
- Market partitioning such as the allocation of customer groups, types of products or territories between competitors.
- Markets for expansion and investment.
- Commercial business plans, marketing or sales initiatives, development roadmaps and product portfolio plans.
- Any arrangement to avoid direct competition, or joint action to exclude competitors or new entrants to the market and/or to COCIR.

GUIDELINES ON MARKET STATISTICS INFORMATION EXCHANGE

COCIR collects market statistics data and strict confidentiality rules govern what information may be exchanged.

The exchange of statistical information is typically **PERMITTED** when:

- only aggregated statistical information is shared with individual companies; and
- it does not allow the identification of individual companies.

However, it is **PROHIBITED** to exchange company-specific information between competitors, such as data on prices, costs, market shares, order and sales volumes (by units and/or values), marketing plans or inventories.

GENERAL INFORMATION ABOUT COCIR

COCIR is the European Trade Association representing the medical imaging, radiotherapy, health ICT and electromedical industries.

Founded in 1959, COCIR is a non-profit association headquartered in Brussels (Belgium) with a China Desk based in Beijing since 2007. COCIR is unique as it brings together the healthcare, IT and telecommunications industries.

Our focus is to open markets for COCIR members in Europe and beyond. We provide a range of services in the areas of regulatory, technical, market intelligence, environmental, standardisation, international and legal affairs.

COCIR is also a founding member of DITTA, the Global Diagnostic Imaging, Healthcare IT and Radiation Therapy Trade Association (www.globalditta.org).

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