



CODE OF CONDUCT

ON INTERACTIONS WITH HEALTHCARE PROFESSIONALS

QUESTIONS & ANSWERS

GENERAL

1. **Why are the company Members of COCIR adopting this Code?**

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

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

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

2. **What is the relationship of the COCIR Code to other industry codes and what if they are different?**

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

3. **What is the relation of the COCIR Code to the law?**

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

them. Members are expected to comply with the law and with the COCIR Code, whichever is stricter.

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

4. Where and for whom does the Code apply?

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

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

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

5. What should I do if a someone asks me to do something which would breach the COCIR Code?

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

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

6. Who is responsible for enforcing the COCIR Code?

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

7. What does Europe mean?

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

8. What happens if a dealer violates the COCIR Code?

The Members agree to pass the responsibility to abide by the principles contained in this Code on to their dealers and agents. If a Member discovers a violation by a dealer or other representative, the Member must take action against that third party and ensure the violation does not recur.

9. Should Members provide copies of this COCIR Code to Healthcare Professionals (HCP)?

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

10. What should Members do to assure internal compliance with this COCIR Code?

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

- (i) educating Member personnel about their obligations under applicable laws and regulations;
- (ii) setting procedures to approve the types of funding, payments, expenses, grants, gifts, donations, compensation, or activities discussed in the COCIR Code;
- (iii) conducting due diligence with respect to the activities discussed in the COCIR Code; and

- (iv) monitoring and auditing the types of funding, payments, expenses, grants, gifts, donations, compensation, or activities discussed in the COCIR Code for compliance with law and regulations.

THE PRINCIPLES

1. What is the purpose of the four principles?

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

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

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

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

2. What is the aim of the Separation Principle?

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

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

The Separation Principle promotes fair competition.

3. How far does the Transparency Principle extend?

The Transparency Principle extends to all advantages and benefits beyond branded promotional items of a modest value or reasonable hospitality in the form of meals or other hospitality

subordinate in time and focus to the legitimate purpose of a meeting.

For instance, it does not extend to branded promotional pens, but it does extend to invitations to conferences, trade fairs etc.

Remember, local laws and regulations applicable to the HCP in question (e.g., the HCP's code of conduct or employment rules) have to be observed.

4. Who is responsible for obtaining the approval? the Member or the HCP? Do we need a written statement from the administration of a hospital?

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

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

5. What if the HCP doesn't wish to disclose the benefit to his/her management?

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

6. What does Market Value mean?

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

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

7. Why do I need documentation?

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

MEETINGS

1. What is an appropriate location or venue?

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

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

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

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

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

Exactly what is "reasonable" depends on the context.

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

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

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

3. What is the meaning of “subordinate in time and focus”?

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

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

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

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

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

If in doubt, consider the newspaper test.

4. What about guests?

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

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

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

5. What is meant by "third party"?

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

6. May I pay specifically for the entertainment elements of a third party conference?

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

7. If a Member provides 100% of the funds for an educational program run by a Third Party, and that Third Party controls how the funds are spent, is this permitted?

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

8. Is it appropriate for a Member to provide a speaker for an educational program sponsored by a HCP, if the HCP requests the Member to do so?

Yes.

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HOSPITALITY UNCONNECTED WITH MEETINGS

1. What is the purpose of this section?

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

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

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

2. Can Members invite HCP's for theatre or sport events?

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

CONSULTANCY

1. What is the meaning of "Consultancy" – what kinds of things are covered?

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

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

2. May a Member ever enter a consultancy arrangement with a HCP as part of a sales transaction?

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

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

3. What form should "Management Approval" take?

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

GIFTS

1. What does modest mean?

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

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

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

2. What is a promotional item?

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

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

Gifts should be given only because of specific events, e.g. a noteworthy event where normal manners require that a gift be offered (e.g. on a wedding or a birth). Gifts should not be routinely offered. This is for the obvious reason that multiple gifts each worth €50 quickly add to a level which is more than normal and may start to influence the HCP in a way which will breach the Separation Principle.

CHARITABLE DONATIONS

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

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

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

2. May a Member make a charitable contribution to a HCP's golfing event or gala party, when the proceeds earned from the event or party will be used for the general funding of the recipient HCP?

No. Either the general running costs of the HCP are not a charitable purpose or else such a donation is bound to breach the requirement for Separation.

3. May a Member contribute to or sponsor an event or gala party given by a charitable foundation connected to a HCP, when the proceeds earned from the event or party will be used for charitable purposes?

Yes, so long as: (a) the charitable foundation is truly a separate charitable organization independent of the HCP; (b) the charitable purpose will not likely result in the purchase of the Member's products or services (e.g. Members should not fund a gala designed to purchase medical equipment for the HCP or to build a facility to house medical equipment for the HCP; and (c) the donation is not made to induce the HCP to purchase, lease, recommend, or use the Members products or services.

4. 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 (such as education) as opposed to being

used for general operating expenses of the HCP such as salaries, capital improvements and equipment purchases.

5. May a Member fund an endowed chair at a HCP that is also an educational institution?

Check with your company's legal or compliance department.

RESEARCH

1. What is the meaning of legitimate scientific work?

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

2. What is the purpose of this rule?

The rule enhances transparency of payments for funding for research.

3. Must the payment for Research be for a specific project?

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

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

4. Why does the COCIR Code prohibit research funding that is linked to or contingent on sales of Members products or services to the HCP?

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

5. Are Clinical Trial agreements considered Research Agreements?

No. However, Clinical Trial agreements are permitted and necessary to release new products that have been put to the test in a real operating environment and thereby enhance product reliability and patient safety. They fall outside the scope of this

COCIR Code of Conduct but are governed by regulatory codes and procedures.

LOAN EQUIPMENT

1. What is reasonable period of time for a loan?

Normally this means less than one year.

2. Is loaning equipment as a replacement for defective equipment or delivery problems permitted?

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

CODE OF CONDUCT COMMITTEE

1. What is the role of the Members, COCIR itself and the Code of Conduct Committee?

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

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

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

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