

Code of Ethics



European Diagnostic Manufacturers Association

EDMA represents the interest of the European In Vitro Diagnostic (IVD) industry to various stakeholders namely European governmental agencies, healthcare professionals who use or rely on our products, patient groups and general public.

EDMA believes that high quality, cost-effective IVD medical devices and related services can make a significant contribution to the safety and well-being of patients and the improvement of healthcare systems.

EDMA's members recognise that compliance with applicable laws and regulations and adherence to ethical standards are both an obligation and a critical step to the achievement of the aforementioned goals and can enhance the reputation and success of the IVD industry.

This **Code of Ethics** is intended to provide guidance on the interactions of EDMA members with individuals or entities that purchase, lease, recommend, use, arrange for the purchase or lease of, or prescribe members' IVD medical devices ("Healthcare Professionals") in Europe and, generally, elsewhere.

There are many forms of interactions between EDMA members and healthcare professionals that advance medical science or improve patient care, including:

- **Advancement of Medical Technology:** The development of innovative medical devices and improving existing products are often the result of collaborative processes between members and Healthcare Professionals. Innovation and creativity are essential to the development and evolution of medical devices, often occurring outside the facilities of medical device companies.
- **Safe and Effective Use of IVDs:** The safe and effective use of medical technology often requires members to offer Healthcare Professionals appropriate instruction, education, training, service and technical support. Regulators may also require this type of training as a condition of product approval.
- **Research & Education:** Members' support of *bona fide* medical research, education, and enhancement of professional skills contribute amongst others to patient safety and increases access to new technology.

EDMA members recognise that adherence to ethical standards and compliance with applicable laws are critical to the medical technology/devices industry's ability to continue its collaboration with Healthcare Professionals. Members should encourage ethical business practices and socially responsible industry conduct related to their interactions with Healthcare Professionals. Members should also respect the obligation of Healthcare Professionals to make independent decisions regarding treatment.

This code sets out the standards appropriate to various types of relationships with Healthcare Professionals. **This code is not intended to supplant or supersede national laws or regulations or professional codes (including company codes) that may impose particular requirements upon members or Healthcare Professionals who engage in certain activities in those countries. All members should independently ascertain that their interactions with Healthcare Professionals comply with all current national and local laws, regulations and professional codes.**

The associations that are members of EDMA ensure that their respective codes of practice, if any, are compatible with the EDMA Code of Ethics

The Code represents an act of self-discipline. EDMA members should also acknowledge that the Code is to be applied in the spirit, as well as in the letter. Any non-member involved in the IVD industry within Europe is invited to accept and observe the Code, because it is considered that high ethical standards should be followed throughout the whole industry if it is to maintain the confidence of all the interests which it serves.

EDMA members should ensure all relevant employees (such as sales & marketing, customer service, technical support and service engineers) are aware of the Code and their obligations to the complying with it.

I. Member-sponsored product training & education

Where appropriate members should make product education and training available to healthcare professionals to facilitate the safe and effective use of certain *in vitro* diagnostic devices. Such education and training programs should occur at appropriate locations taking account of the convenience of the attendees and the nature of the training. In particular:

- Programmes and events should be conducted in clinical, laboratory, educational, conference, or other appropriate **settings**, including members' own premises or commercially available meeting facilities, that are conducive to effective transmission of knowledge and any required "hands on" training. The **training staff** should have the proper qualifications and expertise to conduct such training.
- Members may provide attendees with modest meals in connection with the programme, and, for educational programmes necessitating overnight stays, additional **hospitality** may be appropriate. Any hospitality should be modest in value, subordinate in time and focus to the educational purpose of the training and in compliance with the regulations of the country where the Healthcare Professional is licensed to practice.
- Members may pay for reasonable **travel and lodging** costs incurred by an attending Healthcare Professional, in compliance with the regulations of the country where the Healthcare Professional is licensed to practice.
- Members should not, however, pay for travel or other expenses for **spouses or guests** of Healthcare Professionals, or for any other person who does not have a *bona fide* professional interest in the information being shared at the meeting. It may be appropriate for spouses or guests to participate in group hospitality, provided that incremental costs to members are nominal.

II. Supporting third party educational conferences

Independent, educational, scientific, or policy-making conferences promote scientific knowledge, medical advancement and the delivery of effective healthcare. These typically include conferences organised by national, regional, or specialty medical associations or accredited continuing medical education providers. Members may support such conferences in various ways:

- **Conference Support.** Members may provide financial grants to cover conference costs and reasonable travel and lodging expenses of Healthcare Professionals (and medical students, residents, fellows, and others who are Healthcare Professionals in training) when the conference is primarily dedicated to promoting objective scientific and educational activities. **Such support should be consistent with the regulations of the country where the Healthcare Professional is licensed to practice.** The conference organiser should be responsible for and control the selection of programme content, faculty, educational methods, and materials. The support by a member should be clearly stated in advance of, at the meeting and in the proceedings.
- **Modest Hospitality.** Members may provide financial support to the conference organiser in the form of modest meals and hospitality for programme attendees. Any meals and hospitality should be modest in value and should be subordinate in time and focus to the purpose of the conference.
- **Faculty Expenses.** Members may make grants for reasonable honoraria, travel, lodging, and meals for Healthcare Professionals who are *bona fide* conference faculty members.
- **Advertisements and Demonstration.** Members may purchase advertisements and lease booth space for company displays at conferences.

III. Sales & promotional meetings

In the countries where it is appropriate for members to meet with Healthcare Professionals **to discuss product features, contract negotiations, and sales terms**, these meetings should, as a general rule, occur at or close to the Healthcare Professional's place of business. In connection with such meetings, members may pay for modest meals and hospitality for Healthcare Professional attendees.

Members may also pay for reasonable travel costs of attendees when necessary (e.g., for plant tours or demonstrations of non-portable equipment). However, it is not normally appropriate to pay for meals, travel, or other hospitality of Healthcare Professional's guest or any other person who does not have a *bona fide* professional interest in the information being presented at the meeting.

IV. Arrangements with Consultants

Healthcare Professionals may serve as consultants to members, providing valuable *bona fide* consulting services, including research, participation on advisory boards, presentations at member-sponsored training, and product collaboration. It is appropriate to pay Healthcare Professionals reasonable compensation for performing these services.

The following factors support the existence of a *bona fide* consulting arrangement between members and Healthcare Professionals:

- Consulting arrangements with Healthcare Professionals should be written, signed by the parties and specify all services to be provided. **Such arrangements should be consistent with the regulations of the country where the Healthcare Professional is licensed to practice.**

- Compensation to Healthcare Professionals consultants should be based on the nature of and commensurate to the services provided and not on the value of *in vitro* diagnostic devices which consultants may use for their own practice; **it should be paid based on services actually provided and in accordance with applicable tax and other legal requirements.** Members may pay for reasonable expenses incurred by consultants in carrying out the subject of the consulting agreement.
- Consulting agreements should be entered into only where a legitimate purpose for the services is identified in advance.
- Selection of consultants should be on the basis of the consultant's qualifications and expertise to address the identified purpose.
- The venue and circumstances for member meetings with consultants should be appropriate to the subject matter of the consultation. Member-sponsored hospitality that occurs in conjunction with a consultant meeting should be modest in value and should be subordinate in time and focus to the primary purpose of the meeting.
- When a member contracts with a Healthcare professional acting as a consultant for research services, there should be a written research protocol and all required consents and approvals should be obtained.



V. Gifts

Members occasionally may provide modest gifts to Healthcare Professionals, but these should be modest in value and in accordance with the regulations of the country where the Healthcare Professional is licensed to practice. As a general rule, gifts should benefit patients or take a genuine educational form.

In addition, members may occasionally give Healthcare Professionals branded promotional items of minimal value related to the Health Care Professional's work or for the benefit of patients. Gifts should not be given in the form of cash or cash equivalents.

This section is not intended to address the legitimate practice of providing appropriate sample products and opportunities for product evaluation.

VI. Provision of reimbursement & other economic information

Members should support accurate and responsible billing to reimbursement authorities and other payors. In doing so, they may provide economic efficiency and reimbursement information to Healthcare Professionals and third-party payors regarding members' products.

This information should be limited to identifying appropriate coverage, coding or billing of member products, or procedures using those products, or to encouraging the economically efficient delivery of member products.

This section is not intended to address the legitimate practice of providing technical or other support intended to aid appropriate use or installation of the member's products. Information being shared at the meeting. It may be appropriate for spouses or guests to participate in group hospitality, provided that incremental costs to members are nominal.

VII. Donations for charitable & philanthropic purposes

Members may make donations (including grants) for a charitable or other philanthropic purpose, such as supporting genuine independent medical research for the advancement of medical science or education, indigent care, patient education, public education, or the sponsorship of events where proceeds are intended for charitable purposes. Donations should be made only to organisations or entities entitled to receive them under applicable local laws and regulations. All donations should be appropriately documented.

Examples of appropriate donations and related considerations are:

- **Advancement of Medical Education.** Members may make grants to support the genuine medical education of medical students, residents, and fellows participating in fellowship programmes, which are charitable or have an academic affiliation or, where consistent with the preamble to this section, other medical personnel. (For additional considerations regarding educational grants, see Section II, Supporting Third Party Educational Conferences.)
- **Support of Research with Scientific Merit.** Members may make research grants to support genuine medical research. The purpose of the grant should be clearly documented. (For guidance as to the limitations that apply when a member contracts with a Healthcare Professional to provide research on behalf of a member, see Section IV, Arrangements with Consultants.)
- **Public Education.** Members may make grants for the purpose of supporting education of patients or the public about important healthcare topics.

PART B – Competition Law Compliance Guidance

The following practical guidelines are designed to ensure that neither EDMA staff nor EDMA corporate members knowingly or wilfully enter into any activity which might violate the competition laws of the European Union, with particular emphasis on conduct at EDMA meetings

Article 81(1) EC Treaty

Article 81(1) of the EC Treaty prohibits agreements between companies and decisions by associations of companies which have as their object or effect the restriction of distortion of competition within the European Union. The concepts of “agreement” and “decision” are very broad, and will include tacit agreements and passive acceptance of anti-competitive conduct.

If these rules are not complied with, whether at formal EDMA meetings or at more informal gatherings, your company may be at risk from significant fines – up to 10% of total world-wide annual sales.

The following points are given as examples.

Basic Do’s and Don’ts

DON’T AGREE with your competitors or anyone else:

- To fix prices or conditions of sales of your products.
- To limit your production, agree production quotas, or otherwise limit the supply of any product reaching the market.
- To divide up the market or sources of supply, either geographically or by class of customer.
- To blacklist or boycott customers, competitors or suppliers.
- To limit or control your investments or technical developments in the market.

DON’T DISCUSS OR EXCHANGE INFORMATION with your competitors on any subject relating to the issues mentioned above.

In other words, DO NOT have formal or informal discussions on the following:

- Individual company prices, price changes, terms of sales, etc.
- Industry pricing policies, price levels, changes, etc.
- Price differentials, price mark-ups, discounts, allowances, credit terms.
- Costs of production or distribution, cost accounting formulas, methods of computing costs.
- Individual company figures on sources of supply, costs, production, inventories, sales, etc.
- Information as to future plans of individual companies concerning technology, investments, or the design, production, distribution or marketing of particular products including proposed territories or customers.
- Matters relating to individual suppliers or customers, particularly in respect of any action that might have the effect of excluding them from the market.

CONDUCT AT EDMA MEETINGS is particularly important. By virtue of your membership, you accept EDMA’s rules and conduct. Consequently, if EDMA engages in any anti-competitive behavior, even unwittingly, members can be held liable for such conduct.

- EDMA seeks to ensure that draft agendas are checked on issues which could raise EU competition law concerns. EDMA members should not hesitate, however, to seek legal advice on any given topic.
- If during an EDMA meeting, discussions are held on any of the competition-sensitive matters listed in this memorandum, individual members may request that the Chairman suspend and postpone the debate for as long as it takes to obtain legal advice on the matter.
- Members may alternatively feel free to refrain from participating in discussions on the particular agenda point.
- The individual member should make sure that his/her objection and departure from the meeting are recorded in the minutes.
- Individual members should react in the same way if attempts are made to debate clearly improper topics such as price-fixing or market-sharing.

PART C – Commercial Activities

I. Promotion

The companies that are members of EDMA undertake to ensure that they observe the following principles in promoting their company and its products to their customers:

- The products or services of other companies should not be disparaged, either directly or by implication, unless in the context of independent publications in the public domain.
- The clinical and scientific opinions of the medical and allied professions should not be disparaged either directly or by implication.
- Methods of promotion must never be such as to bring discredit upon, or reduce confidence in the IVD industry.

II. Diagnostic Industry representatives

Note: The term representative is used hereafter within this Code to apply to all employees of EDMA members and not just to those engaged in direct sales activities

- Diagnostic representatives must be adequately trained and possess sufficient technical knowledge to present information on the company’s products in an accurate and responsible manner.
- Diagnostics representatives should at all times maintain a high standard of ethical conduct in the discharge of their duties.
- The requirements of the Code which aim at accuracy, fairness, balance and good taste apply to all representations as well as printed material.
- Unfair or misleading comparisons, or comparisons implying product performance advantage which is not in fact justified must be avoided by diagnostics representatives.
- Diagnostics representatives must not employ any inducement or subterfuge to gain an interview. No payment of a fee should be made for the grant of an interview.
- Diagnostics representatives must endeavour to ensure that the frequency, timing and duration of calls on pathology laboratories, or on hospitals, together with the manner in which they are made, are conducted in a reasonable manner. The wishes of an individual customer, or an arrangement in force at any particular establishment, must be observed by diagnostics representatives.
- Diagnostics representatives must take adequate precautions to ensure the security of diagnostic products in their possession.

PART D – Compliance

Those who feel that the actions of a member company violate this Code should contact the Director General of EDMA.

If the complaint is clearly set out and supported by explanatory documents, the Director General shall submit the complaint as soon as possible to the EDMA Executive Committee (with exclusion of any individuals in direct competition with, or employed by one of the parties involved). The Director General will ensure that they receive evidence from all parties involved in the complaint. The Executive Committee will investigate the complaint and advise the parties involved of the outcome.

If the decision and any recommendations from the Executive Committee are not accepted then the dispute shall be taken to an independent council formed by EDMA. The party requesting this will be required to place a deposit with EDMA to cover any costs incurred.

The Council shall consist of five members, namely:-

- An independent Chairman, such as the President of EDMA or a past President.
- The Chairman of the Professional association associated with the market sector from which a product complaint arises
- A representative from another trade association
- Two nominees from the EDMA Executive Committee appointed by the Committee.

On the basis of the advice of the Council, the Executive Committee of EDMA will decide on any action to be taken. If the complaint is well founded, the Executive Committee will seek to secure the assurance of the company in question that they will institute immediate action and observe the Code in future. In extreme cases, it may mean the expulsion of the company from membership of EDMA, but the company will have the right to appeal to the General Assembly of Members, whose decision will be deemed final. The Director General of EDMA will inform in writing all parties to the complaint of the final decision and the action to be taken.



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