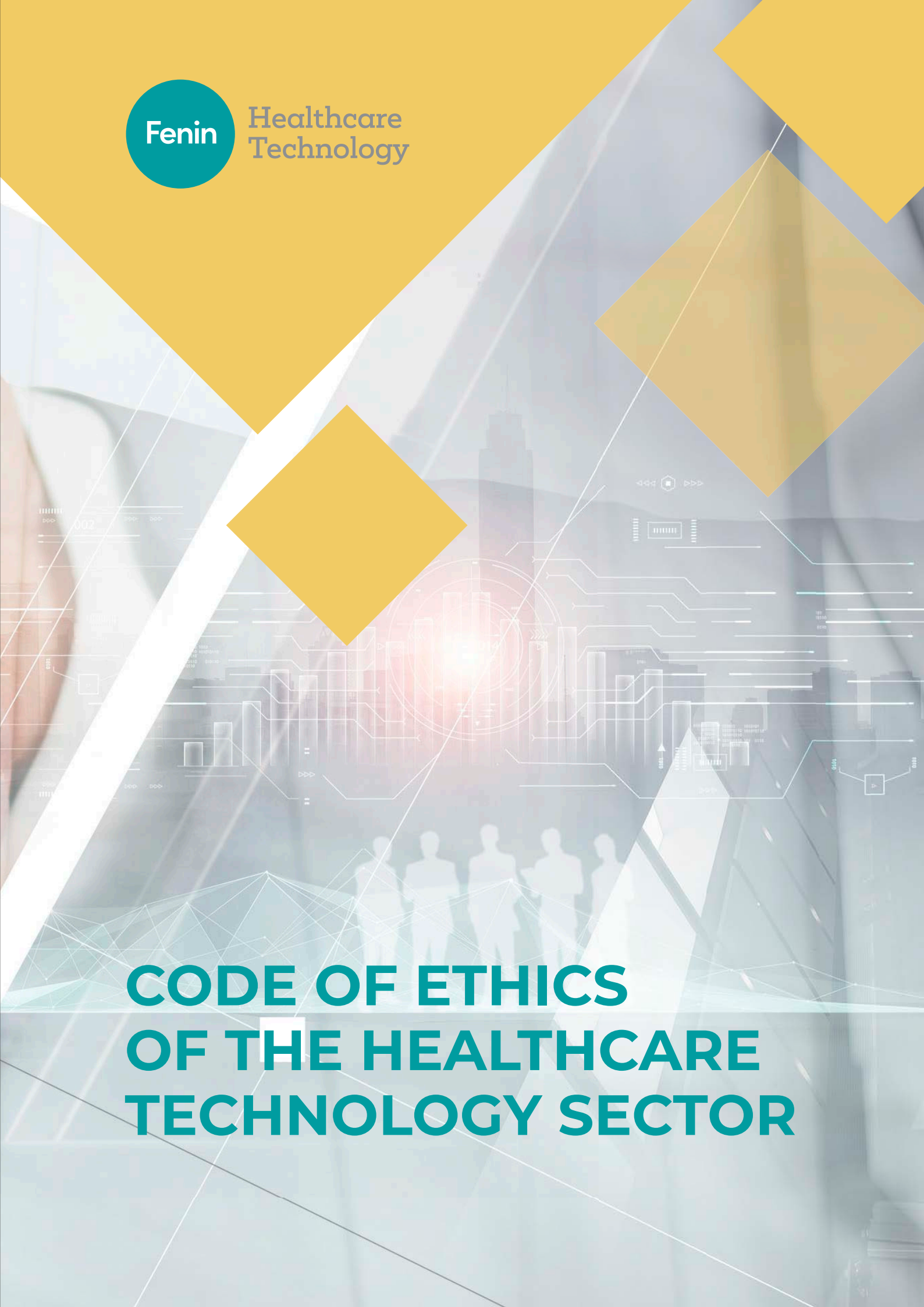
Fenin Healthcare Technology



CODE OF ETHICS OF THE HEALTHCARE TECHNOLOGY SECTOR

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01

INTRODUCTION

INTRODUCTION

The Spanish Federation of Healthcare Technology Companies (Fenin) is the business association that represents the medical technology industry, manufacturers, distributors, and importers. Its mission is to represent and promote the interests of the sector at all levels, highlighting its value, encouraging its rational use, fostering the progress of medical technology in Spain, and promoting an ethical industry.

Without the necessary collaboration between healthcare professionals, healthcare organizations, patient organizations, and the medical technology industry, technological advances applied to healthcare, new technologies for the diagnosis and treatment of diseases, and the development of healthcare technologies that improve the health and quality of life of patients would not have been possible.

If the technological innovations on which the business sector is betting are to have a positive impact on healthcare services, it is essential to understand the clinical needs, the experience of patients and professionals, and the healthcare needs of health centers.

A sector as innovative as medical technology, which continuously develops new solutions and generates new opportunities for clinical practice, represents a challenge for medical educational, which must follow up to apply in practice the innovations and techniques developed by the advancement of science.

The development of a collaborative framework between healthcare professionals, patient organizations, healthcare institutions, and the industry to implement new solutions to improve patient health and guarantee the educational of healthcare professionals in new technologies must be carried out with the highest ethical standards.

To improve ethical standards, the medical technology sector must measure up to social demands by applying the utmost rigor and socially responsible conduct in all areas of its activity in Spain, so that decisions related to the use and acquisition of medical technology are fulfilled in compliance with the ethical principles that guarantee the quality of the National Health System for the benefit of patients.

The behavior of the medical technology sector, a key player in the healthcare system, must be exemplary in complying with the applicable national and international legislative and regulatory provisions, especially in the areas of safety, quality and performance, advertising and promotion, data protection, anti-corruption, environmental health and safety, and competition.

This compliance should not be limited only to laws and regulations. Therefore, this Code demonstrates the commitment of the business sector to transparency and ethics by providing itself with self-regulation that guarantees compliance with the highest ethical standards in its relations with healthcare professionals, patients, and healthcare institutions, which directly or indirectly may purchase, recommend, use, or endorse medical technology.

The Code of Ethics of the medical technology sector is an integral and inalienable part of the rules of Fenin and its member companies, as well as of all the entities that voluntarily decide to adhere to it. It embodies the commitment to respect and promote the principles established in the Code in their relations with healthcare professionals, patients, and healthcare institutions.

To ensure effective compliance, the Code applies not only to those who have pledged to implement and apply it, but also to all their employees, delegates, distributors, sub-distributors, agents, third-party intermediaries, and any type of representatives.
The latest version of the Code includes updates to the ethical framework of the sector to comply with new European standards, set out in the Code of Ethical Business Practices of MedTech Europe, the European-level employers' association of the sector, of which Fenin is a member.

With this objective, the Board of Directors and the General Assembly of Fenin, in the meeting held on December 20, 2022, have agreed to approve this new version of the Code of Ethics of the medical technology sector.

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SCOPE OF APPLICATION

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The Code applies to the relations of companies in the medical technology sector with healthcare professionals, patients, patient organizations, and healthcare organizations in Spain or abroad.

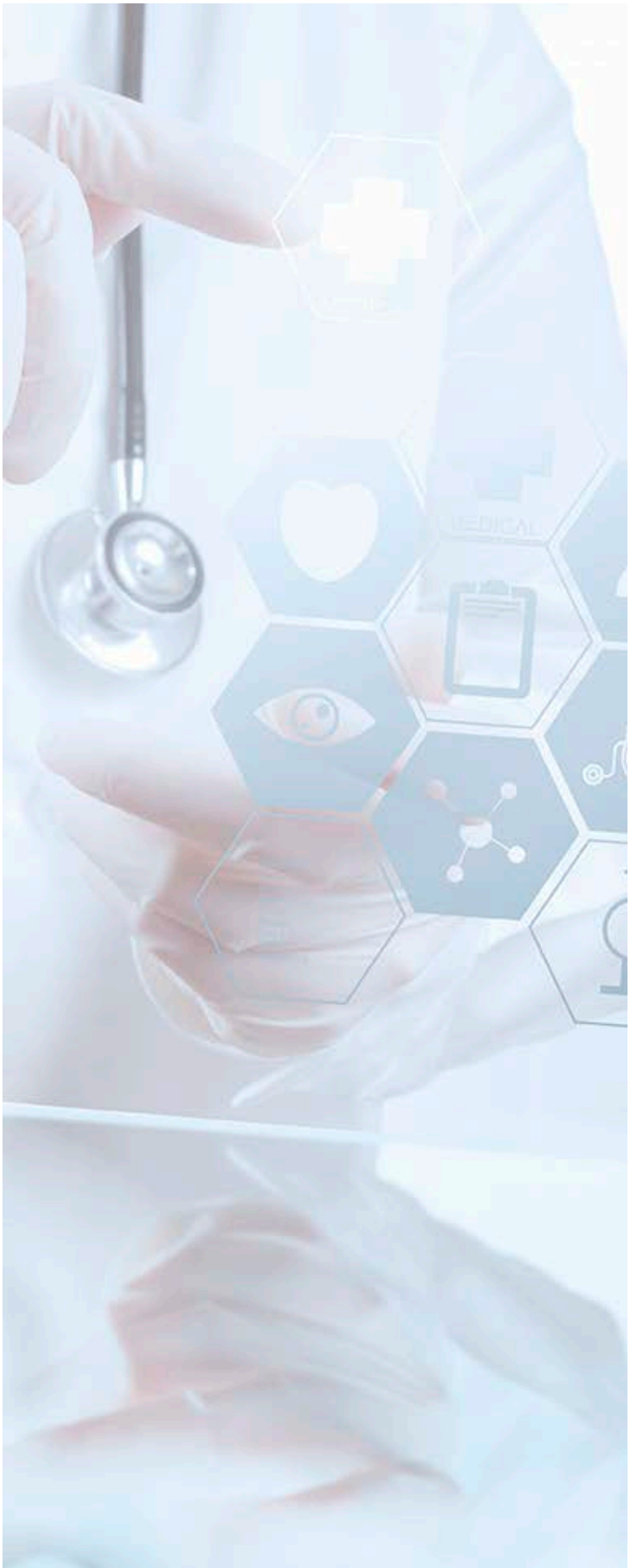
When the interaction with health professionals, healthcare organizations, and/or patient organizations takes place abroad, local codes regarding lodging and/or hospitality criteria will be considered as they are deemed to be in line with the reality and prices in force in that country.

Companies with affiliates, subsidiaries, or parent companies in other countries shall ensure and be responsible for compliance with the Code when working in Spain, and their interactions with healthcare professionals, patients, patient organizations, and healthcare organizations operating in Spain.

All Fenin associates, as well as all those entities or institutions that voluntarily adhere to the Code, will be obliged to comply with it, and are responsible for their employees and collaborators, delegates, distributors, sub-distributors, agents, sellers, and other channels. To honor this objective, clauses that formalize this commitment and provide educational and information on their content must be included in all contracts.

Companies adhering to the Code shall always respect the obligations of their customers and suppliers with their codes of ethics and conduct.

The Code applies to the relations of companies with health professionals who perform their activity in the public and private sphere, as well as to the relations with healthcare organizations and patient organizations of public, private, or mixed nature.



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GLOSSARY

GLOSSARY

CHARITABLE DONATIONS: Any type of delivery with a transfer of ownership and without consideration or intent to influence, of money, equipment, or products intended exclusevily for charitable or philanthropic purposes. The company has no control over the use of the donation by the organization receiving it. They can only be made to charitable and non-profit organizations.

CODE: The Code of Ethics of the medical technology sector, as well as any document that may develop it (Q&A document, application guide, etc.).

CLINICAL RESEARCH: SA type of research that studies tests and treatments and evaluates their effects on human health. This includes interventional and non-interventional clinical research or clinical performance studies in which individuals volunteer to test medical interventions, including drugs, cells, and other biological products, surgical procedures, radiological procedures, devices, behavioral treatments, and preventive care.

For the purposes of this Code, this definition includes any activity or investigation with a research o training scope done by a health professional.

CLINICAL TECHNIQUES AND PROCEDURES TRAINING EVENTS ORGANIZED BY THIRD PARTIES: Training events organized by third parties without following company guidelines or instructions, intended primarily to train healthcare professionals on the safe and effective performance of one or more clinical procedures. Training fields include:

- Therapeutic procedures, diagnostic and/or rehabilitation procedures on clinical methods and/or techniques (instead of the use of specific products or medical technologies).
- Demonstrations and/or training for healthcare professionals, where most of the training program is done in a clinical environment, that is, practices in the operating room, practices with animals, with human anatomical samples, simulators, and other environments associated with the practical execution of the procedure.

Short-term training in which healthcare professionals go to other institutions to train others or receive training (proctorship and preceptorship) are not included in this definition.

COMPANY(IES), BUSINESS(ES), OR ADHERED COMPANY(IES): Legal entities that execute their activities in Spain and are subject to the Code. This includes all the companies associated with Fenin, as well as those that, without being members, voluntarily and formally adhere to the Code.

COMPANY EVENTS: Medical technology educational events and other meetings aimed at healthcare professionals, healthcare organizations, and/or patient organizations, organized, financed, managed, and executed in whole or in part, by or on behalf of the company.

COMPANY TRAINING EVENT IN CLINICAL PROCEDURES AND/OR USE OF MEDICAL TECHNOLOGIES: Training session organized by a company whose objective is to provide healthcare professionals with specific education and training for:

- the safe and effective use of medical technologies, therapies, and/or related services;
- the safe and efficient operation of clinical procedures; and
- related medical and/or clinical pathologies or conditions.

In all cases, the information and/or training must refer to medical technologies, therapies, and services related to the activity of the company.

GLOSSARY

CONFERENCE VETTING SYSTEM: centralized decision process that validates the compliance of international educational events organized by third parties with the MedTech Code of Ethical Business Practices and is managed independently by Medtech Europe (http://www.ethicalmedtech.eu), or, for those that fall outside the above scope and refer to events in Spain, it is the conference vetting system of the Ethics and Compliance Unit of Fenin (http://www.fenincodigoetico.org).

DELEGATE: Healthcare professional who attends an event passively or as a spectator, not as a speaker or as a healthcare professional providing services to a company for the specific event.

DEMONSTRATION PRODUCTS: Reusable or single-use products provided free of charge by or on behalf of a company to healthcare organizations or healthcare professionals who have the necessary qualifications and facilities to use them. Demonstration products may only be provided for the time necessary for their intended purpose, which is to demonstrate the safe and effective use and adequate functionality of a product and may not be used for clinical use in patients.

The following are not considered demonstration products:

- samples
- products for evaluation
- products intended for clinical research and/or training aids
- products subject to charitable donations
- products provided at no additional cost as part of the overall purchase price in commercial agreements, or as substitute products under a warranty agreement.

EDUCATIONAL CONFERENCES ORGANIZED BY THIRD PARTIES: Any independent, educational, or scientific activity, aimed at promoting scientific knowledge, medical advances, and/or health management, consistent with the relevant guidelines established by professional societies and patient organizations. The organizer will have the accreditation provided for in the Code.

EDUCATIONAL EVENT: Educational session. It can be organized directly by the company or by third parties.

EDUCATIONAL EVENTS ORGANIZED BY THIRD PARTIES: Any scientific or educational activity in which the means and budget are managed and executed, in whole or in part, by or on behalf of a person or entity other than the company without following guidelines or instructions from the company. The organizer may have the accreditation provided for in the Code.

EDUCATIONAL GRANTS: Provisions of funds, products, or services for healthcare organizations to be used exclusively to support and promote specific health educational for health professionals, patients, and/or the general population. Educational programs will be based on subjects of interest to the therapeutic areas in which the company operates and will be focused on clinical, scientific, and/or health management topics.

EMPLOYER NOTIFICATION: Prior written notification made to the manager and/or supervisor of the health professional, of the collaboration between a company and any health professional, which must be fulfilled following this Code.

Although it does not require express authorization, the notification must be made in writing before the activity and in time for the institution to object if it deems it necessary.

It is not mandatory to include the detail of expenses incurred by the company. The notice intends to inform the practitioner's employer of the existing relationship between the company and the practitioner.

EVENT: Own event or an event organized by third parties.

FAIR MARKET VALUE: Value of specified services (or products, if applicable) that the company would pay to the other party (e.g., a healthcare professional or healthcare organization), each negotiating under the same conditions in an open and unrestricted market, and where neither party is forced to buy or sell, and both parties have reasonable knowledge of the relevant facts.

GLOSSARY

FINANCIAL HARDSHIP: Severe and unavoidable financial problems of healthcare organizationscaused by elements or circumstances beyond their control that affect their activity and jeopardize patient care.

Financial difficulties that are a result, in whole or in part, of mismanagement of the healthcare organization are taken into account.

Financial difficulties must be objectively justified and documented.

GRANTS FOR TRAINING COURSES OR STAY: Economic collaborations carried out by or on behalf of a company and established with health organizations exclusively aimed at supporting the training of health professionals. These include fellowships for graduate health professionals and scholarships for students in health professions.

GUEST: Spouse or person in a similar affective relationship, relative, or guest of the healthcare professional, or any other person who does not have a genuine professional interest in the information to be shared during the event.

HEALTHCARE ORGANIZATION: Any legal entity or body (regardless of its legal or organizational form) that is a health, medical or scientific association or organization, which has a direct or indirect influence on the prescription, recommendation, purchase, ordering, supply, dispensing, use, sale, or transfer for use (free or for payment) of medical technologies and related services, including but not limited to hospitals, purchasing organizations, clinics, laboratories, pharmacies, research institutions, foundations, universities or any educational entity or professional or scientific society (except patient organizations and/or foundations), through which one or more health professionals provide their services. They may be of a public, private or mixed nature.

This definition includes the concept of a healthcare institution, understood as any organization considered a health center according to the provisions of the Royal Decree 1277/2003, of October 10, 2003, which establishes the general bases for the authorization of health centers, services, and establishments, as well as any organization that, without being defined by said Royal Decree, is active in the field of healthcare, such as, for example, health services, scientific and/or professional societies.

HEALTHCARE PROFESSIONAL (PROFESIONAL DE LA SALUD): Any individual (whether or not they have a healthcare function, are a public employee or representative of any public sector entity, or an employee or representative of any private sector entity, including, but not limited to, healthcare professionals, research personnel, research coordinators or purchasing personnel) who in the course of their activities may directly or indirectly purchase, use, recommend, administer, supply, dispense, purchase or influence the purchase, acquisition, or may prescribe medical technologies.

HEALTHCARE PROFESSIONAL (PROFESIONAL SANITARIO): Any person recognized as such in Law 44/2003, of November 21, 2003, on the regulation of the health professions, or any regulation that may replace it.

IN-KIND SUPPORT: Granting of subsidies, charitable donations, and other types of support in the form of goods or services other than money, including the provision of labor, rented, or donated goods, or rented or donated services (e.g., catering services for events, provision of venue space, company products and other services).

GLOSSARY

LEGITIMATE BUSINESS INTEREST: A current and actual business objective pursued by a company, such as the advancement of medical education, clinical research, and/or the safe and effective use of the company's medical technology.

Involving a healthcare professional or healthcare organization to influence the prescribing, recommending, purchasing, ordering, supplying, using, selling, or leasing of medical technologies or related services directly or indirectly by a healthcare professional or healthcare organization is never considered a legitimate business interest.

LEISURE AND ENTERTAINMENT ACTIVITIES: Activities not directly related to the educational or scientific activity of health professionals, as well as any recreational activity.

These include, but are not limited to, dancing or activities where live music is the main attraction, sightseeing tours, theater plays, sporting events (skiing, golf or football matches, etc.), visits to museums, monuments or historic buildings, and other types of recreational activities. Background music during an event shall not be considered a leisure and entertainment activity.

MEDICAL TECHNOLOGY: For the purposes of this Code, these are those products (reusable or single-use) and/or services marketed by the companies, including, but not limited to, medical devices, in vitro diagnostic medical devices, therapy services, software, remote services, maintenance services, management services, and user training services.

Under this Code, medical technology refers to medical devices and in vitro diagnostic medical devices as defined in Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices and Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices, as amended from time to time.

PANEL OF EXPERTS: A group of individuals with provable expertise in a particular area (e.g., therapy, reimbursement, procurement process) who come together to provide unbiased advice and guidance to a company within a defined scope. The group's expertise complements the company's internal knowledge. Expert panels are commonly used to support product development or the development of new indications for a product or to support the development of commercial strategies.

PATIENT ORGANIZATIONS: Non-profit organizations in which patients or caregivers (if patients cannot represent themselves) are a majority in decision-making bodies. Includes e.g., patient organizations and patient advocacy groups, etc.

PRODUCTS FOR EVALUATION: Medical technologies provided free of charge by or on behalf of a company to healthcare organizations or health professionals who have the necessary qualifications and facilities to use them for their evaluation to obtain specific data or information from users for the necessary period of time under the conditions of use and intended purposes, according to the conditions of commercialization in Spain.

GLOSSARY

The following products are not considered products for evaluation

- demonstration products
- samples
- products that are part of a charitable donation
- products intended for clinical research and/or training aids
- products provided at no additional cost as part of the overall purchase price in commercial agreements, or as substitute products under a warranty agreement.

PROFESSIONAL CONFERENCE ORGANIZER (PCO): A non-profit or for-profit legal entity that manages events, congresses, conferences, seminars, and similar events. An accreditation provided for in the Code shall be available.

RESEARCH GRANTS: Any contribution, by or on behalf of a company, of funding, products, equipment, and/or services to any organization that conducts research solely to support the development or promotion of scientifically valid and legitimate research on behalf of the recipient of support; and whose goal is the advancement and knowledge of science, medicine and/or healthcare, medical technologies and/or clinical techniques designed to improve patient outcomes.

SALES, BUSINESS, AND/OR PROMOTIONAL MEETINGS: Any type of event or meeting organized by the company to promote the sale of its medical technologies or related services, as well as those aimed at promoting the company's brand(s). This includes meetings to discuss product features, the benefits of using the product, and/or the commercial conditions of the product.

SAMPLES: These are reusable or single-use products (consumables, equipment, implantable devices, etc.) provided free of charge by or on behalf of a company to healthcare organizations or healthcare professionals who have the necessary qualifications and facilities to use them to enable healthcare professionals and patients to become familiar with the products in clinical use.

The following free products are not considered samples:

- demonstration products
- products for evaluation
- products that are part of a charitable donation
- products intended for clinical research and/or educational grants
- products provided at no additional cost as part of the overall purchase price in commercial agreements, or as substitute products under a warranty agreement.

SATELLITE SYMPOSIUM: A company's event. The common elements of a satellite symposia are:

- they are held at a third-party event and are part of the official program of the third-party event (i.e., it is not focused on the marketing of specific products);
- the company is responsible for the content subject to review by the organizer when required;
- they are open to any attendee, not just selected individuals; and
- they have the company's branding, and the company can promote the satellite symposium to customers and third-party event attendees.

SERVICE AGREEMENTS: Provision of services by a healthcare professional, healthcare organization, or patient organization for or on behalf of a company. These arrangements include but are not limited to, consulting, marketing, and clinical research activities, providing technical expertise for the development, testing, etc. of medical technology, providing feedback on post-commercialization evaluations and market research, providing speaking services at events, providing training on the use of the company's medical technology, participating in research related meetings, etc.

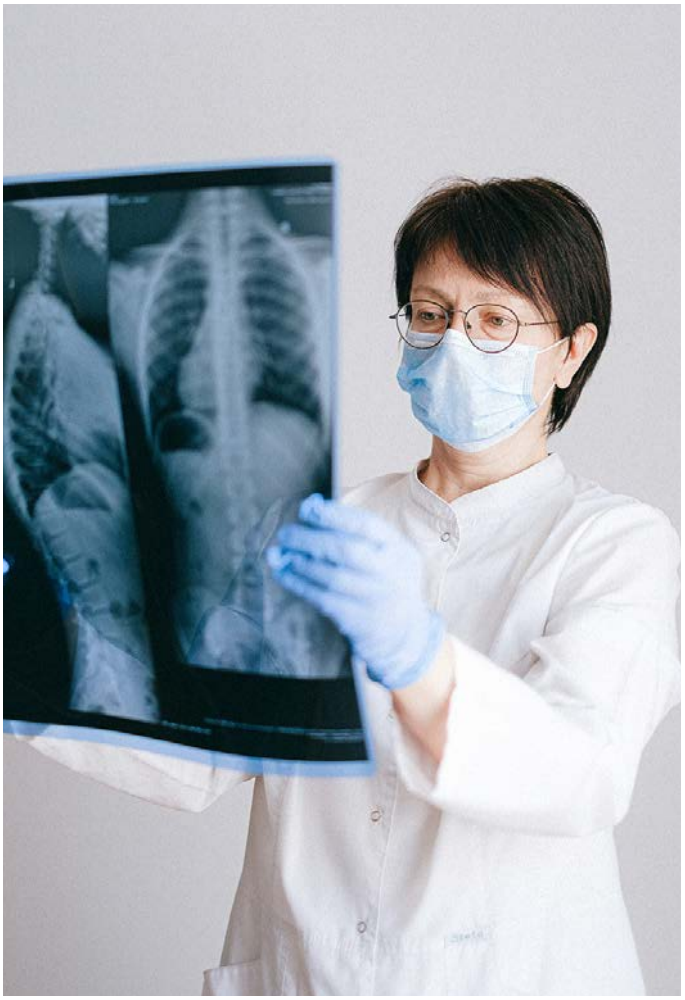
GLOSSARY

SPEAKER: Speaker, moderator, or panel member, who presents during an event. Authors of scientific communications, whether by abstract or poster, will not be considered speakers.

THIRD-PARTY INTERMEDIARY: Legal entity or person who markets, sells, promotes, or otherwise provides to end users and/or healthcare professionals the products or related services of companies of the healthcare technology sector, and may include distributors, wholesalers, distribution or sales agents, marketing agents, brokers, and independent sales representatives.

Retail stores such as pharmacies, orthopedics stores, etc., are not considered third-party intermediaries.

VIRTUAL EVENT: It is an event organized by third parties or an own event characterized by the exclusive remote attendance of health professionals and/or patients. Consequently, it is not linked in any way to an in-person event.



04

CODE PRINCIPLES

CODE PRINCIPLES

The Code is based on and must be interpreted according to the following principles:

PRINCIPLE OF ADVANCEMENT OF MEDICAL TECHNOLOGY: The development, advancement, and innovation of medical technology requires the collaboration of healthcare professionals, healthcare organizations, and the industry. Advances in medical technology allow new solutions to be found for patients' diseases, providing important benefits for the National Health System.

PRINCIPLE OF SAFE AND EFFECTIVE USE OF MEDICAL TECHNOLOGY: To avoid risks in the use of medical technology and to ensure maximum effectiveness, companies must provide patients, patient organizations, healthcare professionals, and healthcare organizations with appropriate instruction, education, training, and service and technical assistance.

PRINCIPLE OF RESEARCH AND EDUCATION: Corporate support for research and education must serve to improve the clinical skills of healthcare professionals and thus contribute to patient access to new technologies and healthcare services in maximum safety conditions.

PRINCIPLE OF IMAGE AND PERCEPTION: Companies should always and in any situation consider the image and perception of the medical technology industry, which should be protected when there are interactions and relationships with professionals, patients, and healthcare organizations.

PRINCIPLE OF SEPARATION: Relationships between industry and healthcare professionals and healthcare organizations should in no case compromise the autonomy and impartiality of each of them, generate advantages in purchasing decisions and procedures, or encourage recommendations by healthcare professionals.

PRINCIPLE OF TRANSPARENCY: Industry relationships with patients, healthcare professionals, and healthcare organizations must be transparent and comply with applicable laws, regulations, and codes of ethics.

PRINCIPLE OF HONESTY: Trust, professionalism, and rigor must preside over the relationships between the industry and the rest of the agents of the healthcare system, acting with loyalty and good faith, with the aim of improving the skills of healthcare professionals and improving patient health and safety.

PRINCIPLE OF EQUIVALENCE: The remuneration paid by the companies to the health professionals for the services rendered must be proportional and in accordance with the market value of the services rendered.

PRINCIPLE OF DOCUMENTATION: Company interactions with healthcare professionals and healthcare organizations should be documented by a written agreement that sets forth, among others, the purpose of the interaction, the services to be performed, the payment or reimbursement of expenses, as well as the paid remuneration. In any case, all activities must be documented. All documentation must be kept by the company for a reasonable period to justify the necessity of the service performed, the materiality of the service, as well as the reasonableness of the remuneration paid.

PRINCIPLE OF LEGALITY: The industry's relations with patients, healthcare professionals, and healthcare organizations must, at all times, respect the legislation in force.

PPRINCIPLE OF LEGITIMATE INTEREST: Relationships between industry and healthcare professionals, healthcare organizations, and patient organizations should be developed in a field related to the company's area of activity.

PRINCIPLE OF INTEGRITY AND TRUST: Any relationship of the medical technology industry must have a legitimate reason, including an identified benefit for patients, and should never be used to induce or encourage the use of company products or services, nor to seek improper information, and should pursue the objective that corresponds to the nature of the collaboration (educational, research, or even commercial...) always for the benefit of the development of medical technology and patients.

05

QUALITY OF PRODUCTS AND SERVICES

QUALITY OF PRODUCTS AND SERVICES

Companies should ensure that:

01.

Products are manufactured and sold or put into service, and services are rendered in full compliance with current legislation and officially recognized national and/or international standards.

02.

Sold products, not yet regulated by national or European legislation, have technological and quality attributes that make them suitable and valuable for the intended usage they were created for.

03.

The technical characteristics of each product are those indicated on the labels, illustrative brochures, promotional materials, and the product's instructions, according to current legislation.

04.

The services offered are designed to meet the needs of users to obtain satisfactory results, through continuous improvement and always within the framework of compliance with current regulations and subject to the highest quality standards.

06

GENERAL CRITERIA FOR EVENTS

GENERAL CRITERIA FOR EVENTS

The criteria and requirements included in this section shall apply to company events (both educational and promotional) and educational events organized by third parties, to which the companies give any kind of direct or indirect support (educational aids, support to health professionals for attendance to events, and promotional activities).

Companies, in general, cannot directly award educational grants to cover the attendance of healthcare professionals at educational events organized by third parties.

Companies can only indirectly support the participation of healthcare professionals in educational events organized by third parties in accordance with the provisions of Chapter XV of the Code regarding educational aids.

As an exception, companies may support the direct participation of health professionals in the following cases:

- Events organized by third parties for training in techniques and procedures (procedural training), provided that the requirements established in the Code are met.
- Company-organized medical technology education and training events.
- Healthcare professionals who participate as speakers in a symposium organized by the company within the framework of an educational conference organized by a third party as part of a service provision agreement, within the limits outlined in Chapter XV.

EVENT PROGRAM

LOCATION AND VENUE OF THE EVENT

GUESTS

HOSPITALITY

TRAVEL

REIMBURSEMENT OF EXPENSES

TRANSPARENCY

VIRTUAL EVENTS

GENERAL CRITERIA FOR EVENTS

EVENT PROGRAM:

The program of the event must be directly related to the specialty and/or medical or professional practice of the healthcare professional attending the event or be relevant enough to justify attendance.

In the case of educational events organized by third parties, although companies may suggest program content and speakers when requested by the organizers, the final decision on the content rests solely with the organizer.

The detailed program should be available well in advance, with a clear schedule and without excessive breaks between sessions for face-to-face or hybrid events. In these cases, the minimum duration of an event should be 6 hours for a full day and 3 hours for a half day, including reasonable breaks.

To qualify as a half-day event, it must take place only in the morning or afternoon, before or after lunch, or before or after 3:30 p.m. (including a short lunch of no more than one hour).

Likewise, the speakers for each session should be identified in the program when it is first published. Promotional materials (brochures, websites, etc.) will be consistent with the scientific or promotional nature of the event.

Companies cannot organize their company events, nor shall they provide financial or other support to events organized by third parties that include social, sporting, or other forms of recreational activities.

The above prohibition does not include welcome cocktails, working lunches, and official dinners that usually appear in the programs of the events, provided that they meet the requirements referred to in Section 4 below and do not incorporate additional elements (cultural, recreational, or entertainment, etc.).

LOCATION AND VENUE OF THE EVENT:

When considering hosting or sponsoring an event, companies should always consider the following regarding the location and venue (hotel, conference center, etc.):

- The location of the event and the venue should not become the main attraction of the event.
- Possible negative public perception of the location and venue. The perceived image of the location and the venue should not be ostentatious, oriented towards vacation tourism, or a place linked with recreational activities.
- The venue must have the necessary and appropriate infrastructure for the program of the event (space, furniture, and audiovisual equipment).
- Venues should be selected based on ease of travel and cost for most participants. Therefore, the location and venue of the event must be close to an airport or train station with adequate connections depending on the point of origin of the attendees, and with adequate ground transportation infrastructure for travel to the event venue. In this sense, companies may not organize or sponsor events outside of Spain, unless it makes more sense from a logistical point of view because:
  - most participants are from abroad; or because
  - relevant knowledge or resources that cannot be easily transferred to Spain and that are the main subject of the event are located abroad.
- The event must be in or near a city that is a recognized business and/or scientific location, suitable for the organization of a conference that allows the exchange of ideas and the transmission of knowledge.

  In general, the venue of the events must be a center related to the professional's activity or a convention center. In the case of using hotels as a venue for events in Spain, they must not exceed four stars. The use of five-star or similar hotels will be allowed if it can be proven that there are security or availability reasons that

require it, and their main activity is not leisure. Under no circumstances will five-star grand luxury accommodations be allowed.

- Companies should consider the season of the year during which the event will be held. The date should not clash with the tourist season in the chosen geographic location. In this sense, the tourist season is set between June 1 and September 30 for summer destinations, and between December 1 and March 31 for winter destinations.

  This does not apply to provincial capitals which may host events during any time of the year (summer or winter tourist season). In the rest of the locations, the seasonality criterion will be taken into account, as well as the rest of the general requirements for events.

GUESTS:

Companies cannot, directly or indirectly, pay and/or facilitate meals, transportation, lodging, or other related services to guests of health professionals, or to any other person who does not have a genuine professional interest in the information to be exchanged during the event, even in the case of shared services (transportation from the lodging to the venue of the event).

"Facilitate" means to book and/or arrange meals, transportation, lodging or other related services for or on behalf of a healthcare professional's guest by or on behalf of the company.

To promote scientific exchange, in no case will the presence of guests be acceptable at any time during the event, including scientific sessions and/or working breakfasts, lunches, dinners, and refreshments, even if the health professional or guest assumes the expenses.

HOSPITALITY:

The Code seeks to strike a balance between the companies' professional and formal treatment of healthcare professionals and the desire to avoid even the slightest appearance that the provided hospitality may be used by companies as a means to induce healthcare professionals to purchase, prescribe, or recommend their medical technologies.

Companies may pay for moderate hospitality expenses for healthcare professionals in the context of in-person events (including travel before, during, and after the event). Hospitality should be subordinate in time and scope to the main purpose of the event and should avoid situations that could create an inappropriate image for the sector.

No food, beverages, or other types of hospitality may be sent to virtual events.

As a result, companies must determine what is "reasonable" in each specific situation, accepting variations depending on the location of the event and, in any case, must comply with the applicable regulations. The term "hospitality" includes both meals and lodging and in all cases excludes leisure and entertainment activities.

- **LODGING**

  Accommodation will be considered reasonable if the hotel has up to four stars and is not intended primarily for leisure (spas, golf clubs, resorts, casinos, boutiques...). The use of five-star or similar hotels will be allowed if it can be proven that there are security or availability reasons that require it, and their main activity is not leisure. Under no circumstances will five-star grand luxury accommodations be allowed.

  Lodging and other associated hospitality may not exceed the official duration of the event. In this regard, arrangements should be made for participants to return on the next available transport that can be found.

- **MEALS**

  In Spain, a meal (lunch or dinner) that does not exceed the amount of 80 euros per diner, including taxes, is considered moderate. For events held outside Spain, the maximum amount will be set by law or by the national association of the country hosting the event.
  Business lunches should be subordinate to the main purpose of the meeting, and therefore their location should facilitate productive and efficient discussion and exchange of information (and, where appropriate, audiovisual presentations and/or medical technology products).

GENERAL CRITERIA FOR EVENTS

In this case, they may not include, even partially, recreational activities (musical shows, performances, art exhibitions, tastings, etc.). Companies will only be responsible for the meals of active participants in the sales, business, and/or promotional meetings.
Companies may not in any case be responsible for:

- meals not related to events, such as Christmas lunches and dinners, anniversaries, etc.;
- meals at which company representatives are not present; and
- alcoholic beverages, except wine and/or beer during the meal.

REIMBURSEMENT OF EXPENSES:

Companies will be directly responsible for paying the necessary expenses for health professionals to attend events. Under no circumstance shall health professionals be reimbursed in cash for such expenses. Exceptionally, in the absence of a valid alternative, minor travel expenses (cabs, mileage, short-distance transportation, parking, etc.) may be reimbursed to health professionals upon justification.

Payment for any leisure and entertainment activities are excluded, as well as travel allowances, i.e., any expenses that are covered or reimbursed by the company must be independently justified.

TRAVEL:

Companies shall only be responsible for actual travel that coincides with the start and end dates of the event, except in the case of impossibility and never beyond the day before or after the event, provided that it is justified. Health professionals who wish to extend their stay must personally cover any additional costs incurred (additional accommodation and meals, extra transportation costs, etc.).

Companies will only pay for economy or tourist class for health professionals traveling by plane unless the flight lasts more than 5 hours (including connection times) in which case business class will be allowed. First class will not be allowed in any case. In the case of connections or delays of more than 3 hours, companies may cover the cost of access to premium lounges, if not covered by the ticket.

For train journeys the básico (basic) fare must be used. In journeys longer than 1 hour the elige (pick and choose) fare may be used. In no case can the prémium (premium) fare be used.

GENERAL CRITERIA FOR EVENTS

TRANSPARENCY:

Whenever a company pays for a healthcare professional's expenses for attending an in-house or third-party educational event on clinical techniques and procedures, the healthcare professional's manager, or supervisor at the healthcare facility where he or she provides services must be notified in advance in writing of the scope and purpose of the assistance. Scope is defined as the purpose for which the aid is given (support for attendance to a training course) and purpose is defined as the specific purpose of the aid (registration, accommodation, and/or travel).

VIRTUAL EVENTS:

Virtual events must comply with any part of the Code that by its nature applies to them. Therefore, companies may provide financial and/or in-kind support (e.g., company medical technology) to virtual events following the rules of this Code.

Support for the participation of health professionals in virtual events organized by third parties shall be in accordance with the provisions of Chapter XV.

07

EDUCATIONAL EVENTS ORGANIZED BY THIRD PARTIES

EDUCATIONAL EVENTS ORGANIZED BY THIRD PARTIES

Companies can financially support in cash or in-kind (through medical technologies, etc.) the holding of educational events organized by third parties in accordance with the rules of this Code. Such events can be:

01.
Educational conferences organized by third parties.

02.
Events organized by third parties for training in clinical techniques and procedures (procedural training).

01.
Educational conferences organized by third parties:

Companies may support in cash or in-kind the holding of educational conferences organized by third parties provided that:

- Chapter VI of the Code (General Criteria and Requirements for Events) is complied with; and
- have the approval of the conference vetting system.

The aforementioned support may be provided through the following grants and/or collaborations:

a. Educational grants:

Companies may provide educational grants for educational conferences organized by third parties.

Such support shall be provided to the organizer of the activities. If the organizer is a health professional in a personal capacity, without any legal entity, such as a technical secretariat, the support granted can only be in-kind and companies will take special care to ensure strict compliance with the principles of the Code.

This type of support carries significant risks for all parties involved, which must be managed with care, even when such an event complies with all other aspects of the Code, including the prohibition on supporting the attendance of identifiable healthcare professionals.

Educational grants for healthcare professionals can be used for attending educational conferences hosted by third parties. However, companies cannot provide these grants directly to individual healthcare professionals, they must be given through healthcare organizations.

In such cases, the healthcare organization receiving the educational grant shall be solely responsible for the selection of participants, which shall be expressly reflected in writing in the grant agreement. In it, companies may define the professional profile of the healthcare professional who may benefit from the aid, but not in a way that makes him/her identifiable.

In the case of educational events aimed at patients, grants may also be awarded exclusively for the organization of the event.

b. Promotional activities:

Companies may contract advertising and visibility services, such as advertising space, exhibition stands, etc. Companies shall ensure that a professional overall image is projected by promotional activities at educational congresses or conferences organized by a third party. In no case should they cause discredit or undermine confidence in the medical technology sector.

The activity carried out at the stands should be mainly aimed at informing about the company's products and services and related literature. Other activities may be carried out on a limited basis and non-alcoholic beverages such as water, coffee, and soft drinks may be offered in a context that may serve to facilitate meetings or the exchange of information.

In educational events aimed at patients, the promotion of products shall be limited exclusively to those authorized by health legislation to be promoted to the general public.

EDUCATIONAL EVENTS ORGANIZED BY THIRD PARTIES

c. Satellite workshops/symposia:

Companies can contract satellite workshops/symposia related to the subject of the educational conference organized by third parties. Companies can decide the content and speakers for these workshops/symposia.

Companies can cover the expenses of satellite workshops or symposia speakers to attend the conference, including travel, lodging on the day of the workshop, and, if necessary, registration fees for access to the conference venue, which must be included in the contract with the healthcare professional.

Workshops and satellite symposia should not interfere with the program of the event.

02.
Events organized by third parties for training in clinical techniques and procedures (procedural training):

These are eminently practical, small-group training events in clinical or specially enabled environments. To be considered as such, at least 50% of the program must be hands-on practice on patients, cadavers, animals, skin models, synthetic bones, simulators, etc. This part must be done in person.

In the case of practical sessions with visualization, it would be valid if at least 33% of the total duration of the event corresponds to hands-on sessions and the rest, up to 50%, is complemented with streaming visualization or real case studies.

Third-party procedural training courses are usually organized in a clinical setting, which includes venues suitable for the simulation of medical procedures, and not only for the medical treatment of real patients.

Examples of clinical environments include hospitals or clinics, where medical treatment can be applied to real patients; as well as conference rooms that are properly set up to simulate medical procedures, for example, with the presence of medical technologies used on cadavers, skin models, synthetic bones...

Companies may financially support events organized by third parties for training in clinical techniques and procedures either by means of educational aids or by directly financing the healthcare professional's costs related to his/her attendance at the event in question, provided that the following rules are complied with:

- Financial support must comply with the criteria included in Chapter VI (General Criteria and Requirements for Events). In this case, companies may directly pay for travel, accommodation, hospitality, and registration fees of health professionals.
- The events organized by third parties for training in clinical techniques and procedures must be validated by the conference vetting system applicable in each case.
- Companies must meet the requirements governing conduct and attendance to such events in the country where the healthcare professional practices, complying also with the requirements in the country where the event is held.
- They are independent events, not adjacent nor complementary to another main event. If they are organized within the framework of a congress or other type of course, they do not qualify for training in techniques and procedures and therefore it would not be possible to grant aid directly to professionals.
- If the practical part of a third-party procedure training is canceled or becomes virtual, the event itself will cease to be a third-party procedure and technique training. Therefore, companies may only support such events through educational grants and by paying the registration/access fee for the recording of such events. Travel expenses will not be covered.

EDUCATIONAL EVENTS ORGANIZED BY THIRD PARTIES

CONFERENCE VETTING SYSTEM:

The conference vetting system is the online, binding, and centralized decision-making process to assist companies in reviewing compliance of educational events organized by third parties with the Code.

The Ethics and Compliance Unit of Fenin manages it. It is the body of Fenin that, with full independence from the governing bodies of the Federation, is responsible for ensuring compliance with the Code of Ethics (Chapter XIX of the Code), and its decisions are subject to review by the Ethics Committee.

The approval of the conference vetting system is required for companies to support third-party organized educational events for healthcare professionals, which are held in-person or hybrid.

Educational events that take place entirely virtually will not be subject to the conference vetting system. However, they must abide by the Code in those aspects that apply to them, and aids for the participation of professionals may be granted, in any case, according to the provisions of Chapter XV of the Code.

If there is a conference vetting system decision concerning a specific third-party organized educational event, this decision binds all companies.

SEAL OF ADHERENCE TO THE CODE OF ETHICS OF THE MEDICAL TECHNOLOGY SECTOR FOR ORGANIZERS OF EDUCATIONAL EVENTS:

Entities organizing educational events for health professionals, or entities managing educational grants, may apply for the Seal of Adherence to the Code of Ethics of the medical technology sector for organizers of educational events, as a guarantee of its commitment to the principles and ethical provisions of the sector.

Fenin will publish on its web page the list of entities that have the Seal of Adherence to the Code of Ethics of the medical technology sector.

To do so, an e-mail request must be submitted at selloetico@fenin.es with the required documentation attached:

Declaration signed by the legal representative of the entity in the format approved by Fenin, stating the following information and pledges:

- Adherence to the Code of Ethics of the sector, its principles, and requirements, particularly concerning aspects related to the organization of events:
  - Educational program and deadlines for communication to interested parties
  - Location
  - Headquarters
  - Hospitality
  - Entertainment and recreational activities
  - Guests
  - Conference vetting system
  - Other
- Insurance that those involved in applying the Code of Ethics within the organization are aware of and trained in the Code of Ethics.
- Treatment of company data to which they may have access in the management of the event with the utmost confidentiality, refraining from sharing or disseminating such information among other companies or with third parties.
- Establishment of appropriate policies and procedures to ensure compliance with the principles and requirements of the Code of Ethics.
- Profile descriptions, in advance, of the beneficiaries of the educational grants and their selection method, if these grants are intended to cover the participant's cost of attendance to various educational events. The selection process must be documented.
- Allocation of the funds provided by the companies for the educational of health professionals exclusively for this purpose, applying criteria of non-discrimination, opportunity, and reasonable need for the selection of the beneficiaries of the training, guaranteeing the non-interference of the company that granted them.

EDUCATIONAL EVENTS ORGANIZED BY THIRD PARTIES

- Publication, before managing of events, of the amount to be deducted from the educational grants received, as management expenses. It cannot exceed 10%.
- Reimbursement of the companies that have granted educational grants for any remainder that may be left over after the end of the event. The reimbursement will be made by applying the percentage corresponding to the contribution of each company.
- Submission of the audit procedure established by Fenin, whose objective is to verify compliance with this declaration and the Code of Ethics.
- Identification of a contact person for the entity's compliance with the Code.
- Possession of the necessary organizational and management capacity to comply with this declaration.
- Submission to the procedure for withdrawal of the Seal in the event of non-compliance with the declaration or the Code of Ethics.
- Agreement to cooperate in good faith and actively with the Ethics and Compliance Unit regarding educational grants, providing the statistical information required, and verifying actual compliance with the obligations assumed by adhering to the Code.

Powers of attorney of the signatory of the Declaration.

The Seal may be removed:

- At the request of the interested party, by e-mail from the legal representative of the entity, including its powers of attorney.
- 2. In case of non-compliance with the Code of Ethics and/or its declaration of adherence, the following procedure will be carried out, which may be initiated as a consequence of the results of the audit or through a complaint from the company adhering to the Code, which must be brought to the attention of Fenin's Ethics and Compliance Unit.
- 3. The Ethics and Compliance Unit:
  - Will verify that the application meets the requirements set forth above.
  - When the request is valid, it will grant five working days for the entity denounced to present allegations.
  - Will resolve the complaint within a maximum period of 10 working days from the receipt of the allegations or the expiration of the time limit to submit them.
  - Will communicate the resolution to the entity within two working days and publish it on Fenin's website when it implies the withdrawal of the Seal.

08

COMPANY EVENTS

COMPANY EVENTS

1. GENERAL PRINCIPLES:

Companies may invite, and assume the related costs of health professionals in the following company events:

- In-house health technology training events and educational events.
- Sales, business, and/or promotional meetings.

The events must in any case comply with the requirements referred to in Chapter VI (General Criteria and Requirements for Events).

Provided there is a legitimate reason, company events may take place totally or partially in facilities used by the company, even when these are outside the healthcare professional's country of residence (manufacturing and/or distribution facilities, demo rooms, maintenance workshops, etc.) or in facilities owned by a healthcare organization, which may be a reference center of the company.

2. COMPANY TRAINING EVENTS IN MEDICAL TECHNOLOGIES:

Where appropriate, to support the safe and effective use of existing medical technologies or to educate about new uses or therapies, companies will provide training to healthcare professionals in need of such training, whether they are customers of the companies.

Companies shall ensure that the persons who provide training in the aforementioned events have the necessary experience and technical knowledge.

3. EDUCATIONAL EVENTS ORGANIZED BY THE COMPANY:

Educational events organized by the company are aimed at medical educational and the improvement of professional skills.

The objective of educational events is to communicate information directly related to the use of the companies' medical technologies, e.g., information about disease states and the benefits of medical technologies for specific patient populations. In all cases, the information and/or training must be directly related to the company's medical technologies, therapies, and/or related services. This means that a company must meet the general criteria for events (Chapter VI).

In addition, the companies' educational events must meet the following requirements:

- The program must be scientifically and/or pedagogically rigorous. This means that its content must include current scientific information of a nature and quality suitable for the health professionals attending the event.
- The program must be genuinely educational and bona fide, and therefore cannot have a primary sales and marketing objective. This means that the educational part should be the main part of the program.
- The information on the program must indicate the name of the company organizing the event and must be available enough in advance so that invited health professionals can form a reasoned judgment on the rigor and quality of the program.
- In principle, the program should be a full-day program, with most of the morning and afternoon devoted to scientific and/or educational sessions, unless the event is a half-day event, begins or ends at noon, or lasts less than half a day. These half-day or shorter sessions are acceptable, but no non-scientific or non-educational events or activities should be organized for the rest of the day. In addition, there should be no significant gaps in the program that would allow health professionals to engage in non-scientific or non-educational activities.

COMPANY EVENTS

3.1 Company events that take place in the context of educational events organized by third parties:

Companies cannot directly cover the travel and/or lodging or other expenses of health professionals participating as attendees in company events that coincide (during or around) the date and place of another training event organized by a third party.

If operational reasons are justified, company events or meetings (including service delivery arrangements) may be organized during or around an educational event organized by a third party for reasons of convenience and efficiency, given the attendance of healthcare professionals at that event.

In these cases, the company may only pay the contractual remuneration and expenses agreed upon for the provision of services by healthcare professionals at the educational event organized by the company.

In no event shall the partner company pay for additional costs related to the attendance of healthcare professionals at the educational event organized by a third party, such as registration, hospitality, additional travel, or lodging costs.

In the case of satellite symposia or presentations with consultants at the company's event within a third-party organized educational event, payment of the conference registration fee is allowed exclusively limited to the company's activity and may cover lodging and travel costs related exclusively to the company's event. Some flexibility in travel may be offered to allow the consultant to attend the entire third-party educational event if there are no incremental costs.

In addition, healthcare professionals should play an active role in the event organized by the company, rather than being mere passive attendees. Companies will not provide support to healthcare professionals attending an educational event organized by the company as mere attendees when it is organized in or around an educational event organized by a third party.

3.2 Specific rules for certain corporate events organized in the context of educational events organized by third parties:

The registration fee of healthcare professionals for third-party organized educationals events may be covered only if the access of healthcare professionals to the satellite symposium or booth at the third-party organized educational event is conditional upon the payment of the registration fee.

Travel and accommodation expenses can only be covered if the health professional does not already benefit from a scholarship that covers his/her attendance at the event.

3.3. Hospitality at corporate events organized in the context of educational events organized by third parties:

If a company wishes to organize a business or scientific meeting including lunch or dinner with certain healthcare professionals in the context of a third-party organized educational event, the following conditions must be met when covering hospitality expenses:

- The meeting must have a legitimate business or scientific purpose and the lunch or dinner should not be the primary purpose of the invitation but should be subordinate to the purpose of the meeting.
- The invitation to the lunch or dinner should be made to a reduced number of participants and proportional to the number of company representatives or delegates, to ensure an effective contribution through knowledge transfer, discussion, and exchange among participants, in line with the legitimate business or scientific purpose of the meeting. In no case may a company issue a general invitation to all participants in the third-party educational event, but only to those who have a genuine interest in the content of the meeting.

In all cases, companies should pay particular attention to instances where healthcare professionals may be benefiting from educational support that already covers all forms of hospitality; and be aware of the impact their interactions with healthcare professionals may have on the image and perception of the industry as a whole.

COMPANY EVENTS

4. SALES, BUSINESS, AND/OR PROMOTIONAL MEETINGS:

When appropriate, companies may organize business meetings for selling and/or promoting their medical technologies, including, but not limited to, meetings to discuss the characteristics, advantages, and use of their medical technologies, negotiate the terms and conditions of their supply, and/or manage the business relationship.

In addition to the requirements of point 1 (general principles), they must meet the following requirements:

- As a general rule, these meetings should take place at or near the practitioner's place of work.
- It is not acceptable for companies to assume the travel and lodging costs of healthcare professionals, except when necessary for the demonstration of non-portable healthcare technologies, in which case the requirements of Chapter VI (General Criteria and Requirements for Events) shall be met.

09

SERVICE AGREEMENTS

SERVICE AGREEMENTS

GENERAL PRINCIPLES:

Companies may engage healthcare professionals, healthcare organizations, and patient organizations to provide consulting and other services, including, but not limited to, research, participation in expert panels, presentations at proprietary events, and product development meetings.

Companies may pay health professionals, healthcare organizations, and patient organizations the remuneration corresponding to the services rendered, which must be monetary, reasonable, and follow the fair market value.

In any case, service provision agreements must comply with applicable laws and ethical codes.

These principles apply to all consulting agreements between healthcare professionals, healthcare organizations, patient organizations, and companies, including those in which the healthcare professional or healthcare organization, and/or patient organizations, decline to receive remuneration for the provision of their services.

Remuneration must be received by the professional or entity that has effectively provided or contracted the services and not by third parties.

Service agreements shall not create, involve, or imply an inducement for the actual or potential future purchase, lease, recommendation, prescription, dispensing, use, supply, or acquisition of the company's products or services.

To select consultants, companies must previously enable independent decision-making processes that allow them to identify, prevent, and mitigate bribery risks and potential corruption risks arising in connection with the hiring of consultants. For example, the decision to engage a specific healthcare professional, healthcare organization, or patient organization for the provision of a service may not be motivated by sales. If the company's sales department must be involved in the decision of engaging a healthcare professional, healthcare organization, or a specific patient organization, the independent decision-making/review process should eliminate the risk of these decisions being improperly motivated.

These processes should document the prior assessment of any of these associated risks and relevant background information, as well as information relating to each consultant.

CRITERIA APPLICABLE TO SERVICE PROVISION AGREEMENTS:

In addition to the principles of the previous point, the agreements that regulate the provision of services must comply with the following criteria:

- Agreements should only be entered into when there is a legitimate business need for the services identified in advance of their selection.
- The number of professionals or entities should not be greater than the number reasonably necessary to achieve the identified legitimate business need.
- The selection of the contracted health professionals should be based on criteria directly related to the need identified by the company, as well as the training and experience of the consultant/service provider to address the identified need. The impact on the business generated by a study already carried out by the consultant or entity in which he/she carries out his/her professional activity is not a relevant criterion. On the other hand, years of experience in clinical research, experience in presentations and publications, or familiarity with a specific product, technique, or service are relevant criteria.
- Service agreements must be documented in a written agreement, signed by the parties prior to the commencement of the provision of services. Such a contract shall specify the services to be rendered and their remuneration.
- Recruitment must not represent an incentive for the purchase, lease, recommendation, prescription, dispensation, use, supply, or acquisition of the company's products or services. When collaborating with a healthcare professional, healthcare organization, or patient organization, companies must consider any potential conflict of interest that may arise from the specific project or from the engagement of that particular professional or organization.

SERVICE AGREEMENTS

- Remuneration for rendered services must comply with applicable laws and regulations, be monetary, reasonable, and reflect the fair market value of the services rendered.

- Companies should maintain records and documentation of the services and products associated with the work performed by the service provider as well as the company's use of such services and products. Some examples of documentation are the presentation, invitation, agenda, minutes, list of attendees, etc.

- The venue and all other aspects related to the hospitality provided to the service provider (travel, meals, hotels, etc.) must follow the provisions of Chapter VI (General Criteria and Requirements for Events).

REMUNERATION FOR SERVICES:

The remuneration of health professionals, healthcare organizations, and patient organizations contracted by companies shall be adjusted to the fair market value of the services rendered, which shall be determined in accordance with a duly documented internal method. Among others, the contractor's qualifications, experience, and the services to be rendered will be considered.

They shall not incentivize or reward healthcare professionals in their professional practice for the purchase, lease, recommendation, prescription, dispensation, utilization, supply, or acquisition of the company's technologies and/or services. Likewise, they may not have these effects on the healthcare organizations in which they carry out their activities.

Any payment made for these services must respect the law and include taxes. Companies may pay consultants for reasonable expenses incurred in providing the services covered by the engagement or in attending meetings with or on behalf of the company, including reasonable travel, meal, and lodging expenses. The agreement should detail in writing what expenses may be claimed by the consultant and the basis for payment by the company.

TRANSPARENCY:

Companies shall ensure that they comply with all applicable legislation, regulations, and professional codes of conduct requiring any publication, disclosure, or approval when engaging healthcare professionals, healthcare organizations, and patient organizations. Companies shall have consents, approvals, or notifications if required, including those of the health center, the relevant administration, or its manager and/or supervisor.

If there are no legal requirements, companies shall maintain appropriate transparency by notifying the practitioner's management or superior in the healthcare organization for which he/she provides professional services by disclosing the purpose and scope of the service delivery agreement.

Companies will also impose appropriate transparency obligations on consultants to ensure that they have participated in research in the scientific publication where the results of the research are disclosed, as well as in any publication or presentation of the research.

Companies shall include in the service agreement the obligation that healthcare professionals, healthcare organizations, or patient organizations declare they provide services to the company whenever they write or make public statements regarding the object or result of the agreement.

EXPERT PANELS:

In addition to the requirements set forth in the preceding paragraphs, expert panels shall comply with the following rules:

- The participation of healthcare professionals shall not be used for the promotion of the company's products to healthcare professionals.

- The object of the panel of experts must be limited in the contract to specific projects of a fixed duration prior to the commencement of the work and may not be extended indefinitely.

- The expert panel shall document the outcome of their work in writing and record the individual contribution of each member during working sessions.

- The number of members of the panel must be reasonable and necessary to achieve its objectives.

10

THIRD PARTY INTERMEDIARIES

THIRD PARTY INTERMEDIARIES

Companies should be aware that they may be liable for the activities of third-party intermediaries that interact with healthcare professionals, healthcare organizations, and patient organizations in connection with the sale, promotion, or other activities involving the companies' products and/or services.

Accordingly, when entering into such agreements, and provided that local laws and regulations allow it, companies shall ensure that the relevant contractual documentation imposes an obligation on third-party intermediaries to comply with the provisions set forth in the Code and other applicable guidelines, as well as adequate supervision to ensure that this is duly complied with.

RISK ASSESSMENT

Companies should evaluate the risk profile of proposed and/or contracted third-party intermediaries, including, for example, the assessment of:

- The risk in the relevant country, as well as the specific risk profiles of the third-party intermediaries.
- Information on the legal and ethical requirements of the local market.
- Information available from public or internal sources for potential risks associated with third-party intermediaries.
- Subcontracting by third-party intermediaries of other operators for the development of the contracted activity.

DUE DILIGENCE

Before engaging a third-party intermediary, companies should conduct a robust, risk-based pre-engagement and renewal due diligence process to identify, prevent and mitigate risks related to the market in which the third-party intermediary is engaged to operate, as well as any specific activities that the third-party intermediary may undertake on behalf of the company.

The risk assessment to determine the necessary due diligence may consider aspects such as the degree of control, influence, or dependence of the third party; and the activities that the third party will carry out in relation to marketing or selling products, negotiating contracts, and obtaining licenses or permits.permisos.

Companies should also consider conducting due diligence checks during the term of the contract to continuously update any relevant information regarding the third-party intermediary, and in any case whenever required by local laws and regulations.

TRAINING

Companies shall consider current regulations regarding the incorporation and training of third-party intermediaries and maintain and update their training materials accordingly.

It is therefore recommended that companies maintain an up-to-date assessment of the training needs of all third-party intermediaries with whom a company has contracts and ensure that they are regularly trained on new rules, requirements, and standards applicable to the activity they perform for or on behalf of the company.

CONTRACTUAL DOCUMENTATION

Companies shall encourage agreements to include commitments to have adequate controls and compliance with the implementation of the company's anti-corruption policy, such as the following:

- Compliance with applicable laws, industry or professional codes, best practice principles, and policies of the member company.
- The right to independent audits, including, if available, access to relevant books and records.
- Early termination rights for non-compliance with applicable laws, industry or professional codes, best practice principles, and/or company policies.

THIRD PARTY INTERMEDIARIES

SUPERVISION

Companies should, when appropriate, make reasonable efforts to carry out monitoring, audits, or other evaluation activities.

The type and periodicity of these monitoring activities will be based on the potential risk of non-compliance with applicable laws, industry and professional codes, best practice principles and company policies, and relevant contractual terms.

APPROPRIATE CORRECTIVE ACTIONS

Companies shall apply the necessary and appropriate corrective measures, according to applicable local legislation, if a third-party intermediary fails to comply with applicable legislation, industry or professional codes, best practice principles, company policies, and/or applicable contractual terms, or engages in other misconducts.

EDUCATIONAL GRANTS

In accordance with the provisions of Chapter XV. Companies are responsible for compliance by third-party intermediaries with the provisions outlined in this Code regarding their interactions with healthcare professionals, healthcare organizations, and patient organizations.

In this sense, the provisions of Chapters VI, VII, and XV regarding the development of educational events and educational grants for health professionals are applicable and must also be followed by third-party intermediaries of the companies.

11

RESEARCH

RESEARCH

Companies may engage healthcare professionals and/or healthcare organizations to conduct company-promoted studies, and support investigator-initiated studies through research grants or collaborative research, following the specific rules contained in this chapter, with any general rules applicable to interactions with healthcare professionals, and also abiding by the general principles of the Code.

01.
Research studies promoted by the company.

02.
Postmarket studies promoted by a company.

03.
Studies initiated by third parties - research grants.

04.
Collaborative research.

05.
Organization and promotion of studies through prizes and contests.

01. Research studies promoted by the company:

When there is a legitimate business need to do so, companies may promote, conduct, manage, and finance scientific studies to generate data, either before or after the commercial launch of medical technology. In this context a legitimate business need is understood as the generation of data to satisfy, including, but not limited to:

- Medical needs, including patient safety.
- Research and development.
- Scientific purposes, including the generation and testing of performance indicators and the comparison of objective scientific parameters.
- Regulatory compliance, including the medical device surveillance system, safety, reimbursement, and economic analysis, including clinical data and cost-effectiveness, and resulting data relevant to health technology assessment and reimbursement decisions.

When a company engages a healthcare organization and/or healthcare professional to provide advisory or consulting services, such as to conduct a study on behalf of the company (i.e., acting as principal investigator), the company must ensure that such advisory or consulting agreement is in full compliance with Chapter IX Service Provision Agreements.

Under the documentation principle, any agreement reached by a company to provide itself with research-related services must be formalized through a written agreement that must include, as part of its content:

- the research protocol
- the work timeline
- as well as all the necessary consents, approvals, and authorizations that must be obtained before the start of the study (ethics committees, etc.).

The company shall in any case have written approval before the start of the study from the relevant healthcare organization when:

- the main investigator, or any person involved in the development of the study, is an employee of the company;
- the study uses its resources (including, but not limited to, material and/or personal resources and/or data); and/or
- the study is carried out at the company's facilities.

Remuneration paid by the company must be commensurate with the services actually rendered by the healthcare professional and/or the healthcare organization (taking into account, time spent, work performed, complexity, and responsibilities assumed) and with the purposes of the study. It must correspond to market values, be monetary, and be subject to the corresponding taxes and/or withholdings of legislation in force.

Companies should ensure that their research activities comply with all applicable national laws and regulations, codes of ethics, and codes of conduct of investigators, as well as with applicable good clinical practice standards.

In accordance with the principles of the Code, companies must also ensure appropriate transparency in trials and studies in relation to their research activities and their results, including the disclosure of adequate information about the companies' clinical trials (public records, specialized scientific journals, etc.). To this effect, companies must clearly publicize their participation as promoters in the publication of the studies.

When companies engage third-party intermediaries to conduct research (contract research organizations - CROs), they must ensure that the work performed by these third parties on behalf of the company is conducted according to all applicable legal and ethical requirements, including applicable requirements pursuant to this Code.

Under no circumstances should these studies be undertaken as a procedure for the promotion of medical technology or to induce the purchase, lease, recommendation, prescription, dispensation, use, request for supply, and/or acquisition of medical technology marketed by the companies.

The contracting company must request the delivery by the health professional and/or healthcare organization of documentary support of the services performed, as well as the results generated, and its custody is recommended for a reasonable time following the legal precepts in force, and in no case less than five years.

02. Postmarket studies promoted by a company:

When there is a legitimate business need to do so, companies may promote third-party performances of health technology assessment studies after their commercial launch. To this end, companies may provide medical technologies for evaluation under a written service contract, to obtain the evaluation by a user employed by a healthcare organization.

When the products for evaluation are reusable, the time required to evaluate them will depend on:

- the expected frequency of use
- the nature of the evaluation
- the required training
- and reasonable considerations in the context of the evaluation.

Companies shall in all cases ensure that they retain ownership of reusable evaluation products and have a process in place for their removal from the site at the end of the evaluation period unless they have been purchased or leased by the healthcare organization.

Medical technologies for evaluation can be provided free of charge as part of the evaluation performed by health professionals at healthcare organizations, all of which must be formalized by written contract, which will include the applicable protocol and/or questionnaire to be completed by users.

The contracting company must request the delivery by the health professional and/or healthcare organization, once the evaluation has been carried out, of documentary support of the services performed as well as the results generated.

The provision of products for evaluation and/or related services shall not induce and/or encourage healthcare professionals and/or healthcare organizations to purchase, lease, recommend, prescribe, dispense, administer, use, request the supply, and/or purchase of medical technology marketed by the companies or constitute an undue advantage to the healthcare professional, healthcare organization, and/or persons associated with them.
Any supply of products for evaluation must always be in full compliance with applicable laws, regulations, and professional and industry codes of conduct (including, but not limited to, this Code).

Companies must always have written approval before initiation of the study from the relevant healthcare organization when:

Companies must always have written approval before initiation of the study from the relevant healthcare organization when:

- the main investigator, or any person involved in the conduct of the study, is an employee of the company;
- the study uses its resources (including, but not limited to, material and/or personal resources and/or data); and
- the study is carried out at the company's facilities.

If the evaluation is remunerated, it must be proportionate to the services actually rendered by the health professional and/or the healthcare organization in accordance with the fair market value and for the purposes of the study. It must be monetary and subject to the corresponding taxes and/or withholdings of the legislation in force.

03. Studies initiated by third parties - research grants:

Companies may provide research grants to support studies initiated by clearly defined third parties for research programs, in therapeutic areas in which the company is interested and/or involved.

They may take the form of financial or in-kind support for documented and legitimate expenses/services, as well as reasonable amounts of product at no charge and limited to the duration of the research.

Any support provided by companies (human, in-kind, or monetary) may only be destined or used for the specific study for which the research grant has been awarded, excluding the use of such support or resources in the ordinary activity of the beneficiary institution.

Companies providing such aid must ensure that they do not influence the research. However, to guarantee that the aid is granted for a specific investigation, they shall know the scope of the research and the purposes for which the aid is requested and shall ensure that the agreement with the recipient healthcare organization includes the company's right to verify that the aid is applied only for the use foreseen in the agreement. This verification may include a documentation request related to the study, such as a copy of the research protocol, the ethics committee approval, and the study report at the completion or early termination of the research.

Research grants, which are reimbursement-based, must be awarded for a specific project, with the requirements established in the Code. On the other hand, any support for research whose purpose is to assume the expenses generated by the research teams is not in accordance with the provisions of the Code and should not be offered or granted by companies.

All applications for research grants must be received in writing and must at least detail the type, nature, and objectives of the research, the milestones and budget, the approximate duration of the research, and, if applicable, the requirements for ethics committee approval or other authorizations. Bearing in mind that the researcher is responsible for complying with local legislation and regulations, companies may consider an application for research grants before the research project has the approval of the relevant ethics committee.

Research grant agreements shall include provisions for adverse event reporting where appropriate and shall require disclosure, in all oral or written presentations of results, by the recipient organization and principal investigator of the grant received and by which company.

4. Collaborative research:

When necessary and when permitted by local laws and regulations, companies may collaborate with other non-industry partners to develop and/or conduct scientific research for a legitimate purpose. Therefore, scientific research shall be understood to have a legitimate purpose when it is intended to improve patient care or is carried out for the benefit of patients.

Thus, it must be ensured that the benefits of collaborative research do not go to individual health professionals. In case of benefits due to the participation of a healthcare organization in a collaborative research project, these should go to the healthcare organization or similar entity. In no case shall a collaborative research project incentivize or reward the healthcare professional or other relevant decision-makers, for the acquisition, leasing, recommendation, prescription, dispensing, use, supply, or procurement of the company's technologies and/or services.

In this sense, the research project must respond to a legitimate interest and meet all the necessary approval requirements (ethics committees, good practice guidelines, protocols, etc.)

Collaborative research may be conducted before, during, or following regulatory approval of a drug, medical technology, therapy, or service.
Each collaborator should actively contribute significant complementary skills, experience, and/or resources to the research, such as study objectives and design, methodology, protocol development, study conduct, statistical analysis plan, study report, and publication. Before engaging in research collaborations, companies should consider key aspects such as the review and approval or authorization process; due diligence processes; budget and contracting; what interactions are permitted during the execution of the research, as well as other relevant considerations.

A collaborative research project must be clearly defined to justify its consideration as collaborative and not as a company-initiated study or as a study initiated by a third party (for which research grants may be awarded).

Under the principle of documentation, any agreement to conduct collaborative research should be formalized in a written agreement transparently detailing roles and responsibilities and following the study protocol. In this regard, companies shall ensure that the pooling of the skills, experience, and/or resources of all research collaborators is clearly expressed in the collaborative research agreement and that all activities undertaken by companies within such research are fulfilled in accordance with applicable legislation, regulation, codes of conduct, and good practice guidelines.

05. Organization and promotion of studies through prizes and contests:

5.1. Awards or contests organized by the company:

- The organization of competitions must be linked to works on the therapeutic area related to the company's activity and their purpose must be to improve the knowledge of the product or therapy. In no case may they constitute an incentive to use, recommend, administer, supply, dispense, purchase, or influence the purchase, acquisition, or prescription of the products of the company organizing these prizes or contests.

- In any case, the rules of the contest or prize must be made public, as well as the members of the jury, it must be open to all professionals in the therapeutic area, regardless of whether they are users/buyers of the company's products or not, and the name of the winning professional must be made public in the same way in which the contest or prize was published.

- Awards must not consist of cash payments in favor of health professionals or healthcare organizations and must be scientific or related to the therapeutic area of the company's activity.

- Publishing the study/work, collaborating with the awarded professional or organization for the development of a new phase of the study or a new study, or the possibility of obtaining complementary training, under the provisions of the Code, is in accordance with the ethical standards of the sector. In these cases, if a service provision relationship is established between the professional and the organizing company, it must be documented in the corresponding contract and the Employer Notification provided for in this Code must be made.

- Under no circumstances shall companies organize prizes, contests, or raffles that serve to give health professionals or healthcare organizations gifts unrelated to the professional activity (tablets, computers, trips, etc.). In any case, gifts must comply with the provisions of the Code.

5.2. Sponsorship of prizes or contests organized by third parties:

- Companies may sponsor awards organized by third parties, linked to the study of products or therapies in the field of the company's activity and their purpose must be to improve the knowledge of the product or therapy. For example, prizes may be sponsored for the best oral communication or the best poster at a congress organized by a scientific society.

- In any case, the company will not participate in the organization or evaluation of the prize or contest, and independence will be guaranteed in the bases and designation of the winner.

- In no case may they constitute an incentive to use, recommend, administer, supply, dispense, purchase, or influence the purchase, acquisition, or prescription of the products of the company organizing these prizes or contests.

5.3. Sponsorship of charitable prizes, contests, or raffles:

- As an exception, companies may sponsor or grant funds for prizes or contests organized for charitable purposes or to raise funds as a result of a public awareness campaign or a solidarity campaign.

- In no case may they constitute an incentive to use, recommend, administer, supply, dispense, purchase, or influence the purchase, acquisition, or prescription of the products of the company organizing these prizes or contests.

12

REMUNERATION FOR INTELLECTUAL AND/OR INDUSTRIAL PROPERTY RIGHTS (ROYALTIES)

REMUNERATION FOR INTELLECTUAL AND/OR INDUSTRIAL PROPERTY RIGHTS (ROYALTIES)

Healthcare professionals and/or healthcare organizations, acting individually or as part of a group in which they actively participate, are likely to make valuable contributions that improve medical technology. In this sense, they can develop, within the framework of medical technology development, agreements or intellectual or industrial property license agreements rights such as patents.

The provisions of Chapters IX Service Provision Agreements and XI Research shall also apply to such development agreements.

The contracting of advisory, consulting, or any other type of services must not constitute an undue advantage, induce, and/or urge healthcare professionals and/or healthcare organizations to purchase, lease, recommend, prescribe, dispense, use, request for supply, and/or purchase medical technology from companies. To this effect, no healthcare professional subject to payment of royalties may be a member of the evaluation or purchase committees of the developed medical technology.

Before a company signs a remuneration agreement for intellectual and/or industrial property rights (royalties) with a healthcare professional and/or healthcare organization, the company shall assess and identify the legitimate need for a healthcare professional and/or healthcare organization to provide the research and development services.
The criteria used to select health professionals and/or healthcare organizations should be directly related to the identified need, and the person responsible for their selection should have the experience and technical knowledge necessary to evaluate which health professionals and/or healthcare organizations meet those criteria.

In addition, an intellectual and/or industrial property rights remuneration agreement between a company and a healthcare professional and/or healthcare organization may only be proposed when it is expected that the healthcare professional and/or healthcare organization has made or will make a novel, relevant, and significant development related to the medical technology of such a nature that the healthcare professional and/or healthcare organization is deemed, under applicable law, to be the owner, co-owner, author or co-author of the intellectual or industrial property rights developed.

The number of healthcare professionals and/or healthcare organizations engaged by a company in the context of the same research and development project should not exceed a reasonable number to achieve the intended or proposed objective.

Agreements relating to the payment of fees by or on behalf of a company to a healthcare professional and/or healthcare organization must be formalized by written agreement. It must clearly state the criteria based on which the remuneration is calculated, which in all cases must be monetary, adequate, and reasonable under applicable law. By way of example, payments made in exchange for the ownership and/or use of intellectual or industrial property rights should not be conditional on the healthcare professional's:

- purchase, order, promotion, or recommendation of medical technology marketed by the company;
- purchase, order, promotion, or recommendation of medical technology resulting from the outcome of the project; and
- commercialization of medical technology resulting from the project.

To the extent permitted by law, companies must exclude from the calculation of the healthcare professional and/or healthcare organization's remuneration, the number of units purchased, prescribed, used, or requested by the healthcare professional and/or by other professionals related to the healthcare professional and/or by the healthcare organization in which the healthcare professional practices.

The contracting company must request that health professionals and/or healthcare organizations provide documentary evidence of the services provided and the results obtained, and it is recommended that they be kept for a reasonable period, according to current legislation, but not less than five years.

This is without prejudice to the obligations that companies may have under applicable local regulations regarding the payment of royalties, or any other aspect related to the ownership, licensing, exploitation, etc. of intellectual and industrial property rights.

13

DEMONSTRATION MEDICAL TECHNOLOGIES AND SAMPLES

DEMONSTRATION MEDICAL TECHNOLOGIES AND SAMPLES

1. GENERAL PRINCIPLES:

Any delivery to a healthcare professional or organization of a medical device or product must be transparent and documented in such a way that it cannot be understood as a disguised sale, donation, inducement to purchase or use, recommendation, distribution, or supply. It can neither influence the purchase, acquisition, or prescription of medical technologies.

Companies may provide, free of charge, their products as demonstration products (hereinafter demos), samples or, products under commercial evaluation to healthcare organizations and healthcare professionals so they can evaluate and become familiar with the safe, effective, and appropriate use and functionalities of such products. The end goal is to determine whether to use, order, purchase, prescribe, or recommend them on a case-by-case basis.

Exceptionally, companies may also provide products of other companies together with their own if those are necessary for the demonstration, evaluation, or proper use of the company's products.

Demos, samples, and/or products under commercial evaluation should not be used to reward or provide bonuses for the purchase, rental, recommendation, prescription, or use of the company's products to healthcare organizations and/or healthcare professionals.

Companies shall always maintain adequate records regarding the provision of demos and samples to healthcare organizations and healthcare professionals, as well as their return in the case of reusable products. Companies shall note in their records and disclose in writing to health care organizations and health care professionals, no later than the time of provision, the free nature of demonstrations and samples and any other conditions applicable to their provision.

Companies shall guarantee that the delivered product or equipment is operable, as well as that it meets the legal and administrative requirements necessary for its use (for example, having the CE marking when necessary), and in any case, the company shall provide adequate training for the safe and effective use of the equipment or product.

When necessary, the company shall provide free of charge the consumables to be used in the demonstration.

2. DEMONSTRATION PRODUCTS (DEMOS):

Companies may provide demos as defined in this Code, to healthcare organizations and/or healthcare professionals. For example, replicas or non-sterile single-use products for the training and information of healthcare professionals and patients.

Demos are not intended for clinical use in patients or sale. Companies shall record, as well as disclose, preferably in writing, to healthcare organizations and health professionals, no later than the time of supply, the free nature of demos, their prohibition in human use, and any other conditions applicable to their provision.

The delivery of demos by companies must be recorded, guaranteeing their traceability.

In this sense, the delivery of these products must be documented by at least collecting:

- The organization and/or professional receiving the product.
- The nature of the delivery and the prohibition of its use in patients.
- That the company retains ownership of the product delivered free of charge, the duration of this delivery, and how to regain possession when appropriate.
- That the organization or healthcare professional receiving the product cannot lend or rent it to a third party.
- The maximum term of permanence of demos. This period shall be adjusted to the time required according to the type of demo and shall not exceed one month.
- Establish the necessary mechanisms to allow product traceability.
- To record the free consumables provided by the company, establishing the maximum limit following the purpose of the delivery and the expected time of delivery.

DEMONSTRATION MEDICAL TECHNOLOGIES AND SAMPLES

3. SAMPLES:

3.1 Companies may provide healthcare organizations and/or healthcare professionals with no more than the minimum number of samples necessary to become familiar with the product (consumables, equipment, implantable devices, etc.) and/or related services, to gain experience in its safe and effective use in clinical settings and to determine whether or when to use, order, purchase, prescribe, or recommend it in the future.

Deliveries of samples of medical devices to healthcare organizations and healthcare professionals must be labeled in such a way that the recipient cannot doubt as to the non-marketable status of the products delivered. Additionally, or when possible, the products should be identified with the expression "non-marketable samples". Samples of medical devices should be sent, where appropriate, with specifications for use by healthcare professionals.

Samples that are delivered to healthcare organizations must comply with their internal rules.

Companies shall keep a record of all products delivered, guaranteeing their traceability.

3.2. Products for commercial evaluation or reusable product samples.

In the case of reusable equipment or products, companies can supply them long enough to allow healthcare professionals to become familiar with the product. The time will depend on the anticipated frequency of use; the duration needed for training; the number of healthcare professionals who need to gain experience with the product and similar considerations. Companies shall ensure, in any case, that they retain ownership of the products for commercial evaluation or samples of reusable products and that they have a process in place to withdraw them at the end of the familiarization period.

Products for commercial evaluation or samples of reusable products provided to healthcare organizations and/or healthcare professionals will be delivered with appropriate training provided by the company for the safe and effective use of the equipment or product by healthcare professionals.

Companies must record the delivery of products for commercial evaluation or samples of reusable products, guaranteeing their traceability.

In this sense, the delivery of these products must be documented by at least collecting:

- The organization and/or professional receiving the product.
- The nature of delivery and its use in patients.
- That the company retains ownership of the product delivered free of charge, the duration of this delivery, and how to regain possession when appropriate.
- That the organization or healthcare professional receiving the product cannot lend or rent it to a third party.
- The maximum period of permanence of the same. This period shall be adjusted to the time required according to the type of the same and shall not exceed six months.
- That the necessary mechanisms to allow product traceability are in place.
- That the possible responsibilities for incorrect use of the equipment or product by those who must make use of them are stipulated.

14

PREVENTION OF CONFLICTS OF INTEREST

PREVENTION OF CONFLICTS OF INTEREST

Without prejudice to the applicable legislation on conflicts of interest and incompatibilities for public sector personnel, a conflict of interest shall be understood as any decision and/or promoted action, or actions in which healthcare professionals are involved that, directly or indirectly, may lead to a collision between their professional interests and their personal interests and/or those of third parties, including, but not limited to, those of a company. For these purposes, personal interests are considered:

- Self-interest.
- Family interests, including those of their partner and relatives within the fourth degree of consanguinity and second degree of affinity.
- The interests of persons with pending litigation.
- The interests of persons with an intimate friendship or manifest enmity.
- Those of legal entities or private entities where any of the aforementioned persons are holding a senior position involving management, advisory or administrative functions.

Companies shall refrain from generating or participating in any relationship or interaction with healthcare professionals that give rise to such a situation. This limitation shall apply to relationships or interactions with health professionals working in the public and/or private sectors.

To prevent and/or detect the presence of possible conflicts of interest, companies shall notify through the Employer Notification the center(s) where the health professional with whom they collaborate in the framework of any service agreement works or provides services.

Likewise, the corresponding Employer Notification must be made in those cases in which, according to the Code, companies assume the travel or lodging expenses of any health professional.

15

CHARITABLE DONATIONS AND EDUCATIONAL GRANTS

CHARITABLE DONATIONS AND EDUCATIONAL GRANTS

1.GENERAL PRINCIPLES:

Companies collaborating with entities that can be qualified as healthcare organizations or patient organizations must always be reimbursement-based so that the contribution is entirely destined for the purpose of the collaboration.

Apart from commercial or sponsorship agreements, companies may grant educational or research grants in accordance with the provisions of the Code.

Exceptionally, donations may be made to charitable entities such as non-governmental organizations (NGOs).

Charitable donations and educational and research grants (grants) shall never be contingent upon or create any inducement for the sale, rental, recommendation, prescription, use, or supply, now, in the past, or the future, of the company's products or services. Support for charitable and philanthropic programs should not be perceived as a price concession, a reward, or an inducement to customers to purchase, rent, recommend, prescribe, use, or supply the company's products or services.

If grants are awarded to the same recipient on more than one occasion within 12 months, companies must consider the possible risks of perception that may arise. In this sense, they shall establish the internal controls they deem appropriate to mitigate these risks.

Any organization receiving grants must be legally qualified to receive them.

Companies will not aid healthcare professionals in their personal capacity, or in response to requests or applications from healthcare professionals unless they are and act as representatives of an organization qualified to receive such assistance and make the request in writing on behalf of the organization.

Payment, or provision by any means of other forms of grants, shall always be made to the qualified applicant organization. Companies will not assist in favor of health professionals.

Grants will identify the company as the provider.

Companies shall establish independent processes, separate from sales and commercial functions and with robust decision-making mechanisms with clear, consistent, and transparent criteria, for the review and approval of grant applications. These processes may be led, for example, by the medical, legal, financial, or compliance departments of a company.

In any case, these processes may be internal or outsourced, in accordance with the organizational structure, and shall include a documented prior assessment of the application, as well as relevant information regarding the recipient organization, including, but not limited to, the nature of the recipient entity, scope of its activity, and terms and conditions to which the assistance is subject. It may also include information about how this assistance was used on previous occasions and whether it was used in accordance with the terms and conditions under which it was granted.

All grants shall be properly documented by the company and shall be awarded only in response to a written request by the recipient organization or a documented initiative by the company that contains sufficient information to permit an objective evaluation of the request, i.e., at a minimum, a detailed description of the scope and purpose of the program, activity, or project to be supported as well as a description of the suggested recipient, its legal status and structure and, if applicable, a budget.

No grant will be made until an agreement is signed by both parties documenting the terms under which the grant is made.

2. CHARITABLE DONATIONS:

Companies may only make donations to non-profit entities with charitable or philanthropic purposes and that are genuinely involved in such activities (NGOs). Companies shall have no control over the end use of any funds or other support they provide to the entities, beyond the general restrictions necessary to ensure that such funds or other support are used for genuinely charitable purposes.

Companies will not make donations on behalf of or in favor of a healthcare professional, even if the healthcare professional waives payment for services rendered and requests that payment be made on his or her behalf to a charity.

They will also not pay for the registration of health professionals to charity events, such as charity races. Donations may take the form of payments at fundraising events or initiatives, such as charity dinners or tournaments, and the company may use these registrations, in whole or in part, for its employees, or return unused registrations to the charity for the charity to decide on their use but may not register healthcare professionals or indicate their names to the charity for the charity to invite them.

CHARITABLE DONATIONS AND EDUCATIONAL GRANTS

Companies shall not make donations to support the regular functioning or ordinary or operating expenses of a healthcare organization or patient organization, either directly or indirectly through foundations or other entities linked to the healthcare organization or patient organization. However, donations to non-profit hospitals in case of demonstrable financial hardship are acceptable in exceptional cases, provided that the donations are solely for the benefit of the patient, and of limited value.

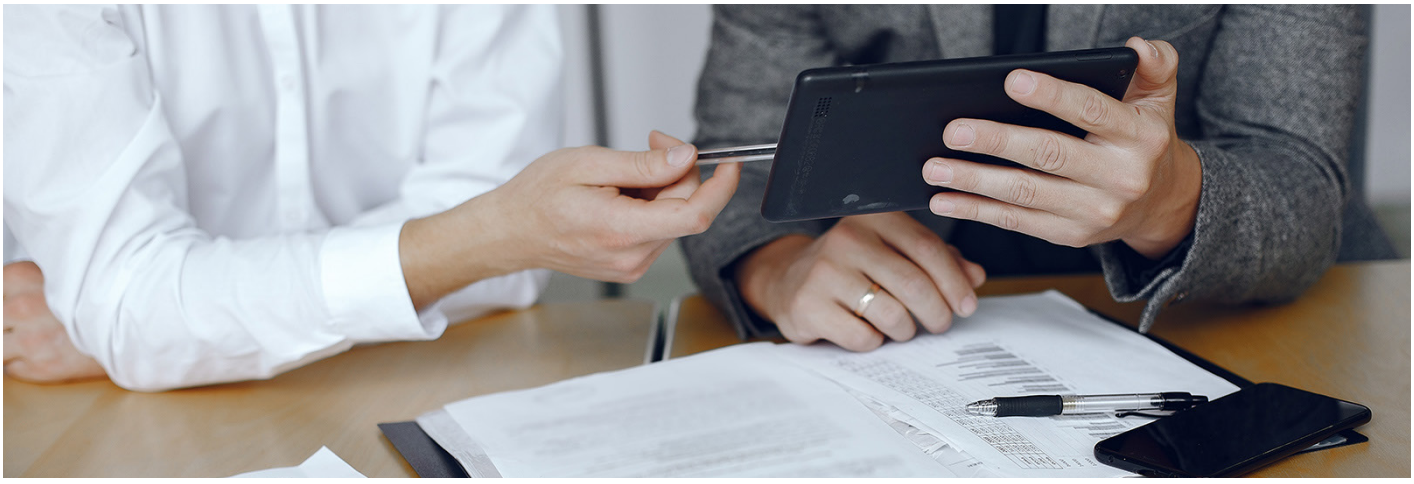
3. EDUCATIONAL GRANTS:

Companies may provide educational grants, specifying the purpose and destination of the grants in the agreement to be signed with the recipient organization. Companies shall also ensure that the agreement includes the possibility of verifying that the educational grant has been used for the intended purpose.

Training requests included in public procurement processes, which must also be properly documented, will not be considered educational grants. In any case, training grants included in these processes must comply with the principles of this Code and be consistent with the public procurement legislation in force.

Companies shall document and make public all educational grants under the following rules:

- During the first six months of the year, the companies will make public all grants awarded to healthcare organizations.
- Healthcare organizations should be identified by their name and tax identification number.
- Companies must disclose in aggregate the amounts paid in euros, for each identifiable recipient, separately and according to the following categories.
  - a. support of educational events organized by third parties and
  - b. other training grants including those for training courses or stays/grants for public awareness campaigns.
- Optionally, companies may indicate the purpose of the same.
- Companies shall document the methodology used in the preparation of the information including a general summary and specific aspects such as VAT treatment or other tax aspects. At Fenin's request, companies will provide this methodology.
- The information must be published on the MedTech Europe web platform (http://www.ethicalmedtech.eu) and will remain there for at least three years from the date of publication.



CHARITABLE DONATIONS AND EDUCATIONAL GRANTS

MODEL

	Name of the healthcare organization	City (headquarters)	Main country of activity	Registered Office	VAT ID (unique identifier)	Educational grants Including: 1 Support for educational events organized by third parties 2 - Support for the participation of health professionals at educational events organized by third parties	Object (Optional)	Other educational Grants (including courses or training stays, and aids for public awareness campaigns).	Object (Optional)
Health organizations	Healthcare organization 1					Annual amount	Optional	Annual amount	Optional
	Healthcare organization 2					Annual amount	Optional	Annual amount	Optional
	etc.					Annual amount	Optional	Annual amount	Optional

Companies may provide educational grants, among others, for the following purposes:

a. Support of educational events organized by third parties:

As a general principle, any educational event organized by a third party and supported through a educational grant must meet the criteria set forth in Chapter VI General Criteria for Events and, where applicable, be approved by the conference vetting system.

a.1. Support for the participation of health professionals in educational events organized by third parties:

When a educational grant is provided to support the attendance of health professionals at educational events organized by third parties, the recipient healthcare organization shall be solely responsible for the selection of participants, which shall be expressly reflected in writing in the educational grant agreement.

Educational grants to support the attendance of health professionals to educational events organized by third parties may cover registration, travel, accommodation, and meals. Companies should consider the possible notification and/or transparency obligations linked to such hospitality.

In the context of assistance for the attendance of health professionals at educational events organized by third parties, in no case will the reimbursement of expenses, including minor expenses such as cabs or meals, be reimbursed.

a.2. Support for educational events organized by third parties:

The healthcare organization or patient organization organizing the event and beneficiary of the grant will be solely responsible for:

- the content of the programs
- the selection of speakers and
- the payment of speaker fees, if applicable.

Companies will not participate in choosing the content of the educational program nor the selection of speakers, which will be reflected in the agreement to be signed with the beneficiary entity. If expressly requested to do so, companies may recommend speakers or offer feedback on the program.

This section does not apply to events organized by a professional conference organizer that organizes an educational event independently of healthcare organizations, in which case companies may enter into commercial sponsorship agreements, which in any case must be documented.

b. Training courses or stays:

Companies may provide grants for training courses or stays to support the medical education of health professionals.

Only healthcare organizations with health professionals in training may apply for or receive these grants. Companies will not provide the assistance requested by individual health professionals.

Likewise, companies will not be involved whatsoever in the selection of health professionals who will benefit from grants, which will be reflected in the agreement to be signed with the healthcare organizations.

Travel or other associated costs that may be incurred by the beneficiaries will in no case be reimbursed or paid on their behalf by companies. In case the intention is to cover them, they should be foreseen and included in the aid granted to the healthcare organizations.

c. Grants for public awareness campaigns:

Companies may assist healthcare organizations, as well as patient organizations for the legitimate purpose of providing information, awareness, and/or education to patients, caregivers, or the general public on relevant health issues or diseases in the therapeutic areas in which the companies are interested and/or involved.

Public awareness campaigns should not promote the use of or stimulate public demand for a particular therapy, service, or healthcare organization.

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ADVERTISING AND PROMOTION

ADVERTISING AND PROMOTION

All advertising and promotional activities must comply with current legislation, that dictates when it is suitable to implement advertising and promotional activities, and under what conditions and to whom it may be directed according to the nature and use of the product.

It shall be considered proof of good faith that advertising and promotional activities have been previously submitted to the review of the association for the self-regulation of commercial communication (AUTOCONTROL).

The promotional material must incorporate the company's logo or product brand, otherwise, it would be considered an incentive.

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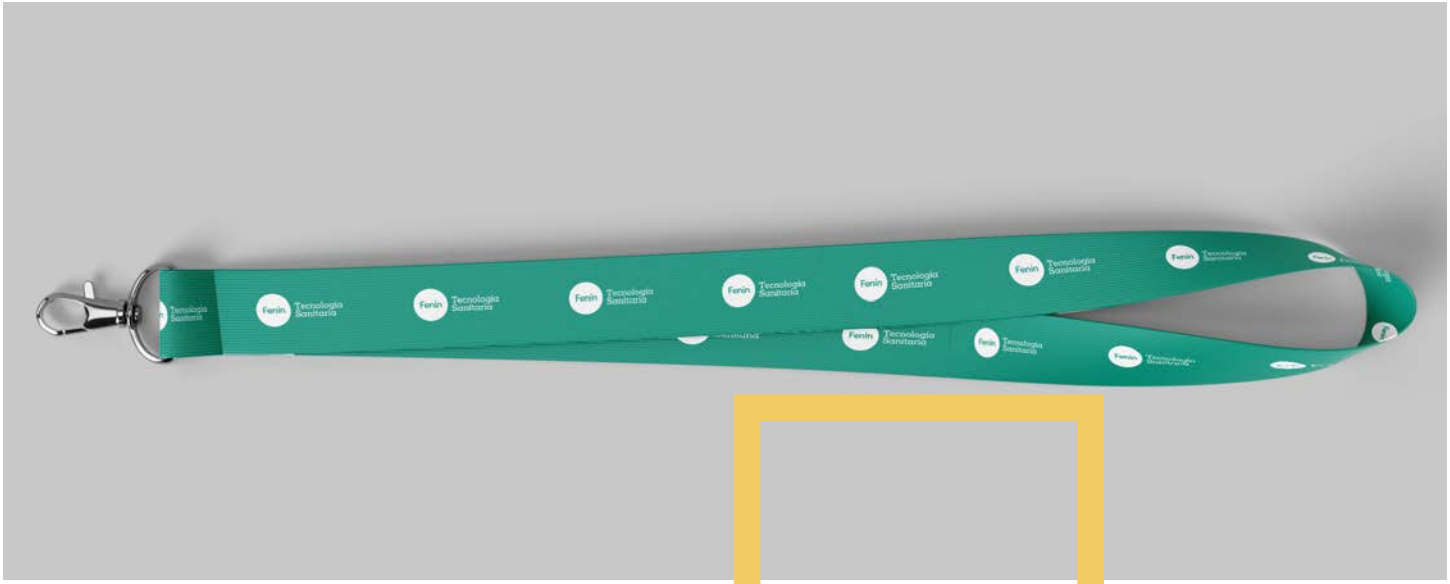
TRAINING MATERIALS AND PROMOTIONAL ITEMS



TRAINING MATERIALS AND PROMOTIONAL ITEMS

In general, giving gifts to healthcare organizations and professionals is not permitted. Exceptionally, companies may deliver training materials and/or promotional items of low value to healthcare professionals provided that the following requirements are met:

- They comply with the provisions of the applicable regulations.
- They are low value, which means that their market price does not exceed 12 euros.
- They are training materials and/or promotional products directly related to the practice of the healthcare professional, or that directly benefit the care or attention of patients, or that have a genuine training function. By way of example, the delivery of stationery (pens, notebooks, etc.), and data storage devices (pen drives, DVDs, etc.) is permitted when they include scientific content, as well as products for professional use in clinical practice.

  Materials that lack a direct relationship with the professional activity (clinical or assistance), such as caps, key rings, bag hangers, external batteries, or similar, may not be delivered.
- The delivery of food, alcoholic beverages, and any other product that is intended for the personal use of the health professional is prohibited.
- They should not be provided in response to a healthcare professional's request.
- They may not consist of cash or cash equivalents.

In no event shall the delivery of training materials and promotional items constitute a reward or inducement to healthcare professionals for the purchase, lease, recommendation, prescription, use, or administration of the company's products or services.

Notwithstanding the foregoing, companies may from time to time provide healthcare organizations with training materials of a value greater than 12 euros provided that such materials:

- have a genuine training function for health professionals who are part of the healthcare organization; and
- directly benefit patient care or attention (e.g., scientific books or anatomical models).

These materials will not be given to health professionals for their personal use and must be directly related to the therapeutic areas in which the company carries out its activity and must not be part of the general operating expenses of the healthcare organizations. In such cases, companies shall keep records of the delivery of such training materials.

Training materials and/or promotional items may not be offered to celebrate special personal events (e.g., birthdays, births, weddings, etc.).

Companies may also provide training materials and/or promotional items to patients under the provisions of the legislation on advertising.

These materials should be for informational purposes and should not advertise products that cannot legally be promoted to patients.

In any case, the value of these materials and/or articles may not exceed the amount of 12 euros.

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INTERACTIONS WITH PATIENT ASSOCIATIONS

INTERACTIONS WITH PATIENT ASSOCIATIONS

1. GENERAL PRINCIPLES

The healthcare environment has evolved to better respond to patients' needs and health-related decisions. By considering the knowledge, experience, and opinions of patients, the medical technology industry has designed and developed more innovative and personalized diagnostics, technologies, services, and solutions. As a consequence, patient well-being has become a critical issue for the medical technology industry.

Patient's quality of life can be significantly improved by providing timely, accurate, transparent, and meaningful information on disease prevention, diagnosis, management, treatment, products, and services. The work to improve patient health and create more sustainable healthcare systems generates an exchange of information that advances the common goals of patients, the medical technology industry, the research environment, and healthcare systems in general.

Companies recognize the expertise and commitment of patient organizations, and therefore the value of dialogue at the local and global levels. Patient organizations accompany patients and their families and often help them to cope with the complex healthcare environment. They are, therefore, an essential part of the life cycle of medical technologies.

Patient organizations and the medical technology industry share the goal of improving knowledge, prevention, diagnosis, management, and treatment of diseases. It is therefore advisable that these two groups develop appropriate guidelines in their interactions that lead to mutual trust and recognition of shared responsibilities.

Both parties have a responsibility to ensure that their interactions are ethical and transparent, that they respect the independence of patient organizations, and that they have the primary purpose of improving the needs of patients and/or their caregivers.

Collaboration between the medical technology industry and patient organizations is essential to raise awareness, disseminate information, and amplify the voice of patients.

Manufacturers, importers, or distributors of medical technologies can support patient organizations financially or by contributing their knowledge and experience to achieve the objectives described above. In any case, the financial contributions must be reimbursement-based, and in no case shall they be destined to support ordinary activity.

Any form of support granted by companies to patient organizations can never be commercially motivated, nor be perceived as such.

The provisions of this Code refer exclusively to interactions with patient organizations, so interactions between companies in the medical technology sector should preferably be through patient organizations, and not with individual patients.

The Code is not intended to influence in any way the relationship between patients and healthcare professionals and other caregivers, which is governed by the deontological principles of each profession, and by the trust between the healthcare professional and the patient. In no case is it intended to replace any applicable state or regional law or regulation.

2. PRINCIPLES THAT SHOULD GOVERN INTERACTIONS BETWEEN THE MEDICAL TECHNOLOGY INDUSTRY AND PATIENT ORGANIZATIONS

All interactions between companies and patient organizations should be based on the principles enshrined in the medical technology sector Code of Ethics, i.e., the principles of advancement of medical technology, safe and effective use of medical technology, research and education, image and perception, separation, transparency, honesty, equivalence, documentation, and legality.

Companies should pay special attention to the following aspects:

a. Transparency

Transparent collaboration allows for independent external scrutiny. Therefore, all agreements between a company and a patient organization must be documented in writing in such a way that the legitimate need, the objective, and the result of the support provided by Fenin's member companies and adherents to the Code of Ethics are recorded.

Such collaborations must comply with the law and any other applicable regulations, including transparency and reporting standards. In addition, both parties are encouraged to share their respective existing guidelines on these types of interactions, disclosing any potential conflicts of interest that may exist.

INTERACTIONS WITH PATIENT ASSOCIATIONS

Both parties shall be transparent as to the source of funding of the patient organizations' campaigns, training, educational, informational, or other activities supported by medical technology companies (e.g., on the respective websites, relevant campaign materials, annual reports, etc.).

b. Independence

The independence of patient organizations in all aspects of decision-making, policy development, and external communications is essential.

Since financial diversity is preferable, companies may not be a source of financing for the ordinary activities of patient organizations, but collaborations must correspond to specific activities or initiatives.

Relationships with patient organizations should never have a commercial purpose or seek to encourage, propose, or solicit the promotion or endorsement of a specific product or service, or influence the contents of messages, materials, events, campaigns, and any activity developed, organized, or promoted, by a patients' organization.

c. Integrity and trust

Any communication arising from a collaboration between a patient organization and the medical technology industry should be neutral in tone, clear, accurate, balanced, and fair. In any interaction, stakeholders bring their perspectives, skills, and experience to the table. These interactions must be based on mutual trust.

All collaborations must have a legitimate need, including an identified benefit for patients, and must never be used to induce or encourage the use of the company's products or services, or to seek improper information.

The advancement of public health through improved disease awareness, prevention, diagnosis, management, and treatment for the benefit of patients should prevail in supporting a patient organization.

d. Equivalence

Any support for activities or initiatives developed by a patient organization must be commensurate with the intended purpose and must have a fair market value.

e. Documentation

Company interactions with patient organizations should be documented by a written agreement that states, among others:

- the benefit of collaboration for patients
- the purpose of the interaction
- the content of the collaboration and direct or indirect contributions to be made
- and transparency commitments from both parties regarding the communication of funding sources

All documentation must be kept by the company long enough to justify the reasonableness and legitimate interest of the collaboration.

f. Legitimate Interest

Likewise, the principle of legitimate interest must also be present in interactions with patient organizations, which means that any collaboration must be related to the company's area of activity and the purpose of the collaboration must be to achieve better results for patients and/or improve access to healthcare for patients, without prejudice to activities related to the company's corporate social responsibility.

By way of example and without limitation, interactions with a legitimate interest would be those related to the exchange of experiences with patient organizations on education and awareness of diseases, as well as related activities aimed at promoting research and development and innovation (R+D+I).

INTERACTIONS WITH PATIENT ASSOCIATIONS

3. HOSPITALITY AND PARTICIPATION IN EVENTS WITH PATIENT ORGANIZATIONS

The criteria established in the Code regarding hospitality (Chapter VI) apply to interactions with patient organizations and their members.

Companies in the medical technology sector that participate in educational and/or informative events organized by patient organizations shall ensure that these are compatible with the provisions of Chapter IV of the Code when the nature of the event permits it.

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IMPLEMENTATION AND MONITORING

IMPLEMENTATION AND MONITORING

To enforce the provisions and ethical commitments outlined in this Code, Fenin will have the necessary bodies to ensure its application and compliance, establishing the procedures to be followed in each case.

The Deontological Committee, the Monitoring Committee for the Code of Ethics, and the Ethics and Compliance Unit are the bodies entrusted with the implementation, control, monitoring, and development of this Code and all the implementing regulations.

The participation of all companies in the debates related to the content and application of the Code will be encouraged through the creation of a forum open to all the member companies.

The composition, functions, and procedures applicable to these committees are set forth in Chapter XXI of the Code.

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DATA CONFIDENTIALITY AND COMPETENCE

DATA CONFIDENTIALITY AND COMPETENCE

Regulatory developments have determined that the consent of patients is no longer the sole or main criterion governing the processing of personal data, but that other legal interests must be considered, such as the protection of contracts, compliance with additional legal obligations, or the public interest in the field of public health or for scientific research purposes. Fenin and member companies maintain their commitment to legal compliance in this field and undertake to comply with the legal duties, including those of information, and to have adequate mechanisms for the preservation and treatment of data, as well as those that allow the affected parties to exercise their privacy rights (such as, among others, access, opposition, cancellation, or rectification).

Both Fenin and member companies firmly believe in the virtues of effective competition as a mechanism to dynamize markets and promote innovation, while recognizing that cooperation between the different agents that make up the medical technology industry is an essential tool for its evolution and growth, both at healthcare and business levels. Responsible business activity necessarily includes respect for the rules of competition and, therefore, Fenin and member companies observe in their conduct the general principles that oblige the companies to act independently of each other, since Fenin is a meeting point for the growth of the sector, not for the development of individual interests. Similarly, the companies do not engage in discussions on sensitive issues that may condition their competitive behavior.

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REGULATION OF THE CODE CONTROL BODIES, PROCEDURES, INFRACTIONS, AND SANCTIONS

REGULATION OF THE CODE CONTROL BODIES, PROCEDURES, INFRACTIONS, AND SANCTIONS

The Deontological Committee, the Ethics and Compliance Unit, and the Monitoring Committee for the Code of Ethics, in cooperation with the Jury of the Association for the Self-Regulation of Commercial Communication (Autocontrol), are the bodies responsible for the effective implementation of the Code.

The purpose of this Regulation is to establish the composition, functions, and procedures to be followed by these bodies, as well as to establish the system of infractions and sanctions to be applied in the event of non-compliance with the Code.

01.
Code control bodies

02.
Procedures

03.
Application of the Code, Infractions, and Penalties Regime

1. Code control bodies

1.1. Deontological Committee of the medical technology sector

- 1.1.1. Composition

  The Deontological Committee of the medical technology sector will be appointed by the Board of Directors of Fenin, and its term of office will be three years, renewable from the date of its appointment. Members who cease to hold office before the expiration of their term of office shall be replaced for the unexpired term.

  The Deontological Committee shall be formed by:

  - Three members, all professionals of recognized prestige in the field of health and/or ethics, who are not related to the companies to avoid possible conflicts of interest.
  - A secretary, who will be the head of the Legal Department of Fenin, will have the right to speak but not to vote.

- 1.1.2. Operation

  For the Committee to be validly constituted, it must have the participation of the three members and the secretary.

  It shall meet as often as necessary, with prior notice from the secretary who must send the agenda at least 48 hours in advance, unless it must meet for justified emergency reasons in which case the aforementioned term may not be met.

  Resolutions shall be adopted by a majority of its members.

  Minutes shall be taken of the meetings, which shall be signed by the members of the Committee and by the secretary.

  The Committee may seek the opinion and assistance of experts in any field and invite them to attend the meetings but without the right to vote. Likewise, it may carry out any actions it deems necessary to verify the facts that are the object of the complaint and may request the collaboration of the Ethics and Compliance Unit, or third parties as it deems necessary.

  The Committee may request copies or information of any documents or evidence it deems relevant, including copies of communications sent to the competent health authorities, as well as copies of the companies' internal manuals and procedures that establish the standards used by their employees in the performance of their interactions with health professionals.

  The secretary shall perform the following duties:

  - Convene and coordinate meetings, prepare the agenda and edit the meeting minutes.
  - Communicate with the parties involved in the Committee's activities.
  - Keep a record of complaints and inquiries received.
  - Prepare the Committee's activity reports.
  - Coordinate and communicate with the rest of Fenin's bodies and forums.
  - Coordinate and manage the procedures regulated in these Regulations.

REGULATION OF THE CODE CONTROL BODIES, PROCEDURES, INFRACTIONS, AND SANCTIONS

- 1.1.3. Functions

  The Deontological Committee will be in charge of:

  - Ensuring the application of the Code.
  - Issuing circulars, through the secretary and the Ethics and Compliance Unit, on interpretations of the Code to facilitate compliance.
  - Receiving and processing claims about possible breaches of the Code.
  - Mediating between the parties involved in a claim by seeking the conciliation of disputes in matters subject to the Code.
  - Transferring to the Autocontrol Jury, through the secretary, the claims received, except when the Deontological Committee has achieved conciliation between the parties.
  - Issuing technical or deontological opinions on matters requested by Fenin within the scope of its activities, except for specific voluntary consultations on specific promotional or advertising materials, which shall be submitted, where appropriate, to the Technical Office of Autocontrol, which shall resolve them by issuing the corresponding report of prior consultation or copy advice, in accordance with its Regulations.
  - Resolving in a confidential and non-binding manner, any doubts and queries on the application of the Code that are voluntarily submitted to it.
  - Proposing to the Follow-up Committee motivated modifications to the Code and/or the rules that develop it.

1.2. Medical technology sector Ethics and Compliance Unit

- 1.2.1. Composition

  This Unit reports to the General Secretariat of Fenin, with full independence from the governing bodies of the Federation.

  It will have the human and material resources necessary for the development of its functions, forming part of the organic structure of Fenin, which will be the one to allocate the necessary budgets for this purpose.

- 1.2.2. Principles of action

  The Unit's activities shall be governed by the following principles of action:

  - **Confidentiality:** The Unit shall maintain the confidentiality of the information to which it has access as well as its actions.
  - **Equality:** The Unit will act objectively and give equal treatment to all companies.
  - **Truthfulness:** All actions carried out by the Unit shall be presumed to be true.
  - **Independence:** The Unit shall be independent of party interests and shall enjoy autonomy to carry out its work.
  - **Diligence:** The Unit will use the most appropriate means to ensure maximum agility in managing the procedures under its responsibility.

- 1.2.3. Functions

  The Unit is responsible for carrying out the following functions:

  - Ensuring the application of the Code.
  - Performing advisory, guidance, and training tasks in relation to the Code.
  - Formulating proposals to the Monitoring Committee to modify, improve, and update the Code.
  - Prior reviewing of non-international educational events organized by third parties, in accordance with the relevant provisions of the Code.
  - Requesting to MedTech Europe the evaluation of international educational events organized by third parties, when asked by a company.
  - Reviewing applications for the Ethical Seal and awarding the Seal to organizations that apply and meet the requirements.
  - Reviewing the audit reports of entities that have the Ethical Seal.
  - Withdrawing the Ethical Seal.

- Preparing activity reports for Fenin's governing bodies when required.
- Managing the procedure for prior review of educational events organized by third parties and appearing on site to obtain information during the celebration of such events.
- Issuing preventive warnings or recommendations to companies when there is a risk of infringement.
- Formulating claims before the Deontological Committee if its previous investigations may lead to the existence of a presumed violation of the Code.
- Formulating consultations on the establishment of interpretative criteria to the Deontological Committee.
- Issuing explanatory notes on specific matters within its competence.
- Issuing certificates that allow accrediting the conformity of the Code of a specific activity. Specific promotional or advertising materials are excepted, which must be voluntarily submitted to the Technical Office of Autocontrol for prior consultation report or copy advice.
- Conducting the necessary investigation procedure to gather evidence to determine whether there may be possible breaches of the Code and formulating the subsequent complaint.
- Seeking the opinion and assistance of experts in any field. It may also carry out any actions it deems necessary to ascertain the facts under investigation as prior diligence to the formulation of a claim.
- Obtaining copies or information of any documents or evidence it deems relevant, including copies of communications sent to the competent health authorities, as well as copies of the companies' internal manuals and procedures that establish the rules used by their employees in the performance of interactions with health professionals.

1.3. Autocontrol Jury

Under the terms specified in the agreement, the governing bodies of Fenin agree to submit the control of the compliance and interpretation of the Code to the Autocontrol Jury, which is governed by its Regulations.

Fenin has established a collaboration agreement with Autocontrol that stipulates in detail the powers and operation of this body.

1.3.1. Functions

Regarding the application of the Code, the Autocontrol Jury will resolve the complaints presented to it against a company in the light of the ethical rules contained therein, clarifying, in each case, whether there has been a violation of said rules and its seriousness.

In addition to declaring the incorrectness or unlawfulness of the commercial, advertising, or promotional activity that is the object of controversy and urging the definitive cessation, modification, or rectification, the resolution of the Autocontrol Jury that determines the infringement of the claimed action shall impose, where appropriate, a sanction on the reported company according to the list of infringements and sanctions provided in this chapter, weighted according to the specific circumstances that may arise in each case.

In cases of a special technical or scientific complexity, and if the Autocontrol Jury deems it convenient or necessary (either ex officio or at the request of any of the parties), it may request the support of solvent, independent external experts, to assist it in the questions that the Jury raises for the clarification of those extremes of a technical or scientific nature relevant to the proper resolution of the matter.

The experts shall be subject to the same conditions of forbearance and grounds of objection that affect the members of the Autocontrol Jury in accordance with the provisions of its Regulations.

Once the need for expert intervention in a given case has been observed, the Jury shall propose a list of solvent and independent experts which shall be forwarded to the parties in conflict so that they may formulate, as the case may be, any objection to one or more of those included in said list. As a result of this process, the Autocontrol Jury will decide on the appointment of the expert who will report on the aforementioned matter. If deemed necessary or if the parties request their appointment, the Autocontrol Jury may appoint up to three experts. In any case, the parties may freely provide, at their own expense, such expert evidence as they deem appropriate.

- 1.3.2. Notification and execution of the resolutions of the Autocontrol Jury

Resolutions issued by the Autocontrol Jury after applying the Code will be immediately communicated to the interested parties for their compliance, as well as to Fenin for their due execution and, if applicable, to proceed to the collection of the pecuniary sanctions imposed by the Autocontrol Jury. Subsequently, the resolutions will be made public through their insertion in the magazine, web page, or other means of Autocontrol, without prejudice to the measures of dissemination of the full text of the resolutions that Fenin may agree to in each case.

- 1.3.3. Prior consultation

To ensure the compliance of their advertising and promotional activities with the Code, companies may send to Autocontrol's Technical Office, for prior examination through the confidential and non-binding copy advice system, all advertising and promotional pieces or materials for medical devices in those cases in which there are doubts as to their compliance with the provisions of the Code. The Technical Office will respond to these queries within three working days of their request.

The applicant companies shall provide the Technical Office of Autocontrol with all the information related to the advertisement under examination required by the latter for the performance of the prior consultation or copy advice.

In case of disagreement with the content of the prior consultation issued by the Technical Office of Autocontrol, the advertiser may voluntarily request its review by the Autocontrol Jury, which, in accordance with its Regulations and in view of the prior consultation issued by the Technical Office and the allegations and documents provided by the advertiser, shall decide on the confirmation or revocation of its content. The section of the Autocontrol Jury that would have heard such review shall abstain from participating in the procedure that would be followed before the Autocontrol Jury in the event of a complaint against the advertising or promotional action under review.

Companies shall not make any advertising use of the content of the prior consultation or copy advice or of the fact that it has been requested.

However, they may submit such prior consultations to the courts of justice, administrative authorities, and the Autocontrol Jury in the event of disputes. The Autocontrol Jury shall presume the good faith and lack of intentionality of the company that has carried out an advertising or promotional action based on a prior consultation or positive copy advice issued by Autocontrol, unless relevant facts or circumstances that were not brought to the attention of the Technical Office when the prior consultation was requested have been provided, or have become known during the procedure for processing the claim.

The processing of the previous consultations or copy advice of Autocontrol within the framework of this Agreement will entail a fee to be agreed upon between Fenin and Autocontrol.

1.4. Monitoring Committee for the Code of Ethics

- 1.4.1. Composition

The Monitoring Committee shall be formed by:

- one member, with voice and vote, corresponding to each sector of Fenin;
- a coordinator, who will be a member of the Board of Directors of Fenin, will have voice but no vote, except in the case of a tie in which case he/she will have the casting vote; and
- a secretary, who will be the head of the Ethics and Compliance Unit of Fenin, will have the right to speak but not to vote.

The members of the Monitoring Committee shall commit themselves to treating the issues addressed during its meetings with the utmost confidentiality, and at no time may they share or use the information obtained through it for unrelated purposes.

The members of the Committee shall be appointed by the corresponding Boards of Directors of the sectors, and their term of office shall be renewed every two years.

The sector Boards may change their representative on the Monitoring Committee without waiting two years.

The head of the Ethics and Compliance Unit, as well as the coordinator of the Committee, will act as interlocutors before the governing bodies of Fenin and will chair the meetings of the Monitoring Committee.

The secretary shall perform the following duties:

- Convening and coordinating meetings and editing the agenda and minutes.
- Preparing and drafting the Committee's proposals to modify, improve, and update the Code.
- Carry out the Committee's communications with third parties.

- 1.4.2. Functions

The Monitoring Committee is responsible for the following functions:

- Analyzing the implementation of the Code and discussing and agreeing on specific proposals aimed at better compliance with and dissemination of the Code.
- Proposing to Fenin's Board of Directors the revisions of the Code that it considers necessary.

- 1.4.3. Operation

The Monitoring Committee shall meet whenever the secretary or the coordinator deems it necessary or at the request of five of its members.

Resolutions shall be adopted by a simple majority of the members present.

1.5. Conflicts and Disciplinary Committee

- 1.5.1. Composition

Its composition shall be in accordance with the provisions of Fenin's Bylaws and Internal Regulations.

- 1.5.2. Functions

Regarding the application of the Code, the Conflicts and Disciplinary Committee shall be responsible for ensuring the enforcement of the resolutions issued by the Autocontrol Jury, including the effective and prompt collection of financial penalties imposed for non-compliance with the Code.

- 1.5.3. Operation

The Conflicts and Disciplinary Committee shall meet to enforce and execute the sanctioning resolutions of the Autocontrol Jury.

It shall be convened by its chair, at the request of any of the governing bodies of Fenin or half plus one of its members.

Communications between the companies, the Conflicts and Discipline Committee, and its collaborating bodies may be made by e-mail or other electronic means of remote communication.

2. Procedures

2.1. General rules

The deadlines indicated by days in the following procedures shall be understood to refer to working days in the city of Madrid in accordance with the official working calendar published in the BOE (Official State Gazette).

The computation shall be carried out from the following date on which the notification of the act in question takes place.

The month of August and the days between December 15 and January 6, both inclusive, shall be excluded from the computation of deadlines.

When there are justified causes, the secretary of the Committee may agree to an extension of the deadline, which in no case shall exceed half of the time established in the procedures.

Communications and notifications within the framework of the procedures will be carried out by e-mail, and there must be a record of receipt by the interested party, as well as the date, identity, and content of the notified act, and all this information will be included in the file.

In any case, the procedure before the Autocontrol Jury and the request for prior consultations with its Technical Office shall be governed by the rules set forth in its Regulations.

REGULATION OF THE CODE CONTROL BODIES, PROCEDURES, INFRACTIONS, AND SANCTIONS

2.2. Consultation procedure

Companies may submit confidential and non-binding queries to the Ethics Committee on any matters related to the Code, except for queries on specific promotional or advertising materials, which shall be submitted to the Technical Office of Autocontrol, which shall resolve them by issuing the corresponding prior consultation report or copy advice under its Regulations.

Queries shall be sent by e-mail to the secretary of the Ethics Committee, who shall keep a record of them.

The inquiries must contain at least the following data:

- Name of the company inquirying.
- Text of the consultation, expressed clearly and simply, specifying the provisions of the Code to which it refers.

Likewise, the applicant may provide any documentation deemed necessary for a better understanding and resolution of the consultation made.

Consultations shall be answered by the secretary of the Committee within a period not to exceed 15 days from their receipt.

The Ethics Committee may request from the company requesting the consultation as much documentation and evidence as it deems relevant and appropriate. Likewise, when deemed necessary, the Committee may request the collaboration of the Ethics and Compliance Unit and/or the Monitoring Committee before responding to the consultation.

The response of the Deontological Committee to the applicant will be by e-mail and will be confidential and non-binding neither for the applicant company nor for the Autocontrol Jury.

Companies shall not use the content of the consultation or the fact that it has been requested for advertising purposes. However, they may submit such prior consultations to the courts of justice, administrative authorities, and the Autocontrol Jury in the event of disputes.

The Committee will inform the other control bodies of the consultation and the response given, safeguarding the confidentiality of the company that made the consultation.

2.3. Procedure for requesting evaluation of educational events organized by third parties

Companies must notify the Ethics and Compliance Unit of educational events organized by third parties whether they are going to give a grant to a healthcare organization or a professional conference organizer to sponsor the attendance of health professionals at the event.

The notification to the Unit must be made at least 60 days before the celebration of the event and will be made online through the conference vetting system provided for in the Code and enabled by Fenin. Once the event has been validated through the conference vetting system, no further communication to the Ethics and Compliance Unit will be necessary.

The Unit may request additional information from the companies and entities involved in the organization of the event and may propose corrective measures to bring the event into compliance with the provisions of the Code.

The Unit may initiate complaint proceedings against companies that participate in an event without complying with the identified corrective measures and/or that fail to comply with the provisions of the Code.

2.4. Procedure for investigating violations of the Code

All companies accept the obligation to cooperate in good faith and actively in any investigation procedure.

The procedure shall be initiated by the head of the Unit upon reasonable suspicion that there may have been a violation of the Code.

Fenin may set up a whistle-blowing channel to facilitate the communication to the Ethics and Compliance Unit of those actions that may imply a breach of the Code.

To do so, an investigation file must be opened and documented:

- The description of the facts that gave rise to the opening of the file and the section of the Code that could potentially have been violated.
- All evidence collected.
- All the steps taken.
- Research findings.
- Completion of the procedure.

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The procedure shall end with the closing of the case if a breach of the code is not proven, or by filing a complaint with the Deontological Committee following the procedure established for this purpose.

If the Unit considers that there is sufficient evidence of a breach of the Code, it will communicate by e-mail to the company the results of the investigation, granting it a period of five working days to make comments and allegations and provide as much evidence as it deems appropriate for its defense before initiating the claims procedure.

Once this period has elapsed without any allegations being made, or if such allegations are not conclusive as to the company's responsibility in the facts, the Unit shall initiate the claims procedure.

Within the framework of the investigation procedure, among other actions, the Unit may:

- Request all information and documentation it deems necessary.
- Attend company events as well as those organized by third parties.
- Contract the services of third parties if the use of external resources is necessary to carry out the investigation. If there is an economic impact, this will be borne in full by the investigated company if it is finally resolved by agreeing that there has been a violation of the Code (both in the mediation and resolution phase), apart from the corresponding sanction.

2.5. Claims procedure

The procedure may be initiated by:

- Any company.
- The Ethics and Compliance Unit.

To initiate the procedure, an email should be sent addressed to the secretary of the Deontological Committee, which must contain:

(i) Name and address of the claimant and, if applicable, the details of the representative, who must prove power of attorney.

(ii) Name and address of the respondent.

(iii) Detailed statement of the facts constituting the alleged violation of the Code, as well as the specific section of the Code considered to have been violated.

(iv) Documents and evidence supporting the claim. In addition, the claimant may propose in his or her written statement any other means of proof to substantiate the facts that are the object of the claim, which shall be taken if the Deontological Committee deems it necessary.

Only complaints that deal with events that have taken place in the last 12 months and that are not the subject of administrative sanctioning proceedings or legal proceedings will be processed.

If the written complaint does not contain the required data, the secretary of the Deontological Committee shall immediately inform the complainant, requesting the provision of such data within five days to complete the file.

Once the aforementioned period has elapsed without the claimant providing the required data, the secretary shall agree to close the file and notify the claimant.

When the claim is complete, the secretary of the Committee shall, within three working days at the latest, forward it to the claimant, so that the latter may make such allegations as he/she deems appropriate within five days following receipt of the claim.

Subsequently, the secretary shall send a copy of the file together with a summary note to the members of the Ethics Committee, so that the matter may be discussed swiftly.

As soon as possible, the secretary shall summon the parties to a mediation meeting before the Committee to reach an amicable agreement between the parties, solving and filing the complaint without having to transfer it to Autocontrol Jury.

If there is an agreement between the parties, the secretary shall draw up minutes to be signed by the parties and by the members of the Committee and the secretary, which shall include:

- Acknowledgment of the infringement by the respondent.
- The corrective or rectifying measures agreed to repair the damage caused and prevent its recurrence in the future.

The parties shall immediately comply with the agreement reached, and the Conflicts and Disciplinary Committee shall be responsible for verifying its execution.

If an agreement is not reached in the mediation phase, the secretary shall transfer the file to the Autocontrol Jury within two days of the mediation meeting.

If the Committee appreciates reasons of urgency that recommend a prompt resolution of the complaint, within five days of receipt of the complaint, it may refer it directly to the Autocontrol Jury without attempting mediation.

3. Application of the Code, Infractions, and Penalties Regime

Companies undertake and commit to:

- Respect the principles of the Code and their obligations and accept the consequences of their non-compliance.
- Comply and enforce compliance of their respective subsidiaries and related companies in the medical technology sector, distributors, agents, or any collaborator with the Code when they carry out their activities in Spain, under the provisions of Chapter II of this Code.

Violations of the Code shall be classified as minor, serious, and very serious, according to the following criteria:

- Scale of the infringement and, in particular, its potential risk to patients' health.
- Impact on the health or scientific profession, or society in general of the infraction.
- Recurrence.
- Damage to the image of the medical technology sector.

Once the infraction has been classified as minor, serious, or very serious according to the above criteria, there may be aggravating factors that will be taken into account by the Jury when imposing the corresponding sanctions.

The accumulation of aggravating factors may change the initial rating from "minor" to "serious" or from "serious" to "very serious". These aggravating factors are as follows:

- a.Degree of intentionality.
- b.Failure to comply with previous warnings.
- c.Recurrence.

  d.Concurrence of several infringements in the same event or promotional activity.
- e.Economic profit for the company derived from the infringement.

Based on the above criteria, the Jury will decide on the imposition of the following financial penalties:

Minor infractions: EUR 3,000 to EUR 10,000.
Serious infractions: EUR 10,000 to EUR 30,000.
Very serious infractions: EUR 30,000 to EUR 100,000.

In the case of the absence of the mandatory communication of educational events organized by third parties, the penalty shall be 1,000 euros for each event not communicated in due time and form to the Unit.

In the event of repeated manifestly unfounded claims, the Jury may impose the financial penalty it deems appropriate, in proportion to the facts denounced.

In view of the resolution of the Autocontrol Jury, when there are circumstances of special severity in the infraction, the Deontological Committee may propose to the Board of Directors of Fenin the removal of the company from the Federation, following the procedure established in its Bylaws and Internal Regulations. The company may not rejoin the Federation until at least one year has elapsed since its withdrawal, and it shall pay all the fees that it would have paid during the period of dismissal.

In the cases in which the Jury appreciates the existence of an infringement and the company concerned acted in good faith following a prior consultation carried out by the Jury according to the provisions of the Code, provided that there is identity between the facts and the terms of the consultation, the Jury shall resolve by urging the company to cease such promotional conduct but shall not impose further sanctions.

REGULATION OF THE CODE CONTROL BODIES, PROCEDURES, INFRACTIONS, AND SANCTIONS

Fenin will execute the sanctions imposed by the Jury and those agreed upon in the mediation phase. With the amount of the pecuniary sanctions, a special fund will be constituted in Fenin that will be used to finance the cost of the control and application program of the Code, as well as activities to promote compliance with the Code and training in this area.

The resolution adopted by the Autocontrol Jury shall determine which party shall bear the expenses arising from the processing of the claim, as well as the fees accrued to Autocontrol and the costs of hiring services carried out during the investigation of the procedure, under the following rules:

- If the claim is upheld or rejected in its entirety, the company that has all of its claims rejected must assume the aforementioned costs in their entirety.

- In the event of a partial dismissal or rejection, each party shall bear its costs and those generated at its initiative (evidence or experts' reports, etc.).

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ENTRY INTO FORCE AND REVIEW

ENTRY INTO FORCE AND REVIEW

This revised version of the Code will enter into force on January 1, 2023.

It will be periodically reviewed to ensure its adequate application and response to the challenges and needs posed by legislation and society and must be approved by Fenin's Board of Directors and ratified by Fenin's General Assembly.

Approved at Fenin's General Assembly on December 20, 2022.


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