

# CODE OF ETHICS of the Healthcare Technology Sector

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Edition

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## CODE OF ETHICS of the Healthcare Technology Sector

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## I. INTRODUCTION

Technological advances applied to health, new technologies for the diagnosis and treatment of diseases, and the development of healthcare technologies improving the health and well-being of patients would not have been possible without the necessary collaboration between healthcare professionals, health institutions, patient associations and the healthcare technology industry.

In order for the technological innovations backed by the business sector to have a positive impact on healthcare services, knowledge of clinical needs, of patients and professionals experience and welfare needs of the healthcare centres is a must.

A sector as innovative as healthcare technology, which is in constant evolution developing new solutions and generating new opportunities for clinical practice, represents a challenge for medical training, which has to be continually updated in order to apply in its clinical practice innovations and techniques developed by the advancement of science.

The development of a collaboration framework between healthcare professionals, patient associations, health institutions and the healthcare industry with the aim of implementing new solutions to improve patient health and ensure the education and training of healthcare providers in new technologies, should be done according with the highest ethical guarantees.

This is why in 2005, the Spanish Federation of Healthcare Technology Companies (Fenin) approved its Code of Good Practice (hereinafter CBP) whose mission and purpose was to ensure compliance with the highest ethical standards for the industry. Throughout these years, the CBP has undergone several modifications in order to adapt its provisions to new needs and harmonize its regulation with that of the other European States in our area.

In this process of improving ethical standards, the Healthcare Technology Sector should respond to social demands by applying maximum rigour and socially responsible behaviour in all areas of its activity in Spain, so that the decisions related to the use and procurement of healthcare technology are carried out in compliance with ethical principles that guarantee the quality of the National Health System for the benefit of patients.

The behaviour of the Healthcare Technology Sector, as a key agent of the Health System, should be exemplary and should not be limited to merely complying with the legislative provisions. This code demonstrates the commitment of the business sector to transparency and ethical behaviour through self-regulation that guarantees compliance with the highest ethical standards in its relations with healthcare professionals, patients and health institutions that may directly or indirectly purchase, recommend, use or promote the use of healthcare technology.

This new Code of Ethics for the Healthcare Technology Sector is an integral part of the regulations of the Spanish Federation of Healthcare Technology Companies (Fenin) and its associated companies, as well as of all entities that voluntarily decide to join, and reflects their commitment to respect and promote the principles established in the Code in its relations with healthcare professionals, patients and health institutions.

In order to maintain its effective compliance, the Code not only will be enforceable by those who have assumed the commitment to implement and apply it, but also by all its employees, delegates, distributors, sub-distributors, agents and representatives.

The latest update of the Code is motivated by the adaptation of the ethical framework of this sector to the new European standards, reflected in the Code of Ethical Business Practices of MedTech Europe, European employers' association of the sector, of which Fenin is member.

To this end, the Board of Directors and the General Meeting of Fenin, at their meeting on December 20, 2016, have agreed to approve this new Code of Ethics of the Healthcare Technology Sector, whose **main novelties include**:

- Establishing the **exclusive use of indirect sponsorship in educational events organized by third parties**, with the aim that the decision of which professionals benefit from medical training at said events is not decided by the Company.
- Providing **transparency** to the economic contributions destined by the industry to medical training in educational events organized by third parties.
- Reviewing and clarifying concepts, since experience in the implementation of the code has recommended updating and revising some notions and provisions.

## II. SCOPE

The Code is applicable to the relations of Companies in the Healthcare Technology Sector with Healthcare Professionals (hereinafter HCPs), patients and Health Organizations in Spain, regardless of the country in which they carry out their professional activity, as well as to relations of Companies with Spanish HCPs, patients and Health Organizations in activities abroad. In addition, this Code applies only to the principles set forth in Section 4, to the interactions of Companies with patient associations.

All Fenin associates, as well as all entities or institutions that voluntarily adhere to it, will be obliged to comply with the Code, being responsible for their employees and collaborators, sales representatives, distributors, sub-distributors, agents, vendors and other channels. In order to achieve this objective, in the contracts entered with them, they should add any clauses stating this commitment and provide training and information on its content.

Companies adhering to the Code shall respect at all times the obligations of their customers and suppliers with their own ethics and conduct codes.

The Code will be applicable both to the relations of Companies with HCPs who carry out their activity in the public and private sectors, as well as to relations with Health Organizations whether public, private or both.

The Companies that have affiliates, subsidiaries or parent companies in other countries will ensure compliance with the code with respect to their interactions with HCPs developing their activities in Spain.

## III. DEFINITIONS

**Companion:** Spouse or person with similar affective relationship, relative or guest of the HCP, or any other person who does not have a genuine professional interest in the information to be shared during the Event.

**Leisure and entertainment activities:** All those activities not directly related to the training or scientific activity of HCPs as well as any recreational activity.

Includes, without limitations, dance activities or activities where live music is the main attraction, tourist routes, theatrical functions, sporting events (skiing, golf or football matches...), visits to museums, monuments or historical buildings and other recreational activities. The reproduction of background music during an event will not be considered leisure and entertainment activities.

**Training Grants:** The provision of funds, products or services to health organizations, intended exclusively for the support and promotion of specific health training for HCPs, patients and/or the general public. This training needs to be clinical, scientific and/or healthcare in nature on topics of interest to the therapeutic areas in which the Company carries out its activity.

**Research Grants:** Any contribution, by or on behalf of a Company, of funding, products, equipment and/or services to any organization that carries out an investigation solely for the purpose of supporting 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, healthcare technologies and/or clinical techniques designed to improve patient outcomes.

**Grants for courses or training days:** Any financial cooperation carried out by or on behalf of a Company and established with Health Organizations intended exclusively to support the training of HCPs. They include training days for HCPs with a degree (fellowships) as well as those awarded to students of health professions (scholarships).

**Code:** The Code of Ethics of the Healthcare Technology Sector, as well as any document on the same (FAQ document, implementation guide...)

**Educational conferences organized by third parties:** Any independent educational or scientific activity, intended to promote scientific knowledge, medical advances and/or health management, consistent with relevant guidelines established by professional societies and patient associations. The organizer may have the accreditation provided for in the Code.

**Financial difficulties:** Any serious and unavoidable financial problems of Health Organizations caused by elements or circumstances beyond their control that affect their activity and that could jeopardize patient care.

Those derived in whole or part from poor management of the health organization are not considered Financial difficulties.

Financial difficulties must be objectively justified and documented.

**Charitable donations:** Any type of delivery with transmission of ownership and without consideration or intention to influence, of money, equipment, or products intended for the exclusive use for charitable or philanthropic purposes. The Company will not be able to determine the use that the organization receiving the donation will give to it. These donations may only be made to charitable and non-profit organizations.

**Business, Company or Associated Company:** Those legal entities that develop their activity in Spain and that are subject to the Code of Ethics including all the Companies associated to Fenin as well as those that, without being members, voluntary and formally adhere to the Code.

**Event:** A Company-organised event or an event organized by third parties.

**Educational Event:** Any training or informative session 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 the 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 thereof. The organizer may have the accreditation provided for in the Code.

**Events Organized by Third Parties for Training on Clinical Techniques and Procedures:** Training events organized by third parties without following guidelines or instructions of the Company intended primarily to train healthcare providers on the safe and effective conduct of one or more clinical procedures where training refers to:

- specific therapeutic, diagnostic and/or rehabilitation procedures on clinical methods and/or techniques (rather than the use of specific health products or technologies), and
- demonstrations and/or training for healthcare providers, where the majority of the training program is developed in a clinical setting, including practices in the operating theatre, animal practices, practices with human anatomical samples, simulators and other environments associated to the practical implementation of the procedure.

Any brief educational activity consisting of a healthcare providers moving to another institution to train others or to be trained (proctorship and preceptorship), will not be included within this definition.

**Company-Organised Events:** These are any Training Events in Healthcare Technologies and other meetings aimed at HCPs and/or Health Organizations organized, financed, managed and executed in whole or in part by or on behalf of the Company.

**Company-Organised Training Event in Clinical Procedures and/or Use of Healthcare Technologies:** Training session organized by a company whose objective is to provide healthcare providers with the education and specific training for:

- safe and effective use of healthcare technologies, therapies and/or related services,
- safe and effective operability of clinical procedures,
- related pathologies or medical and/or clinical conditions.

In all cases, the information and/or training should refer to the healthcare technologies, therapies and services related to the activity of the Company.

**Health Institution:** Any organization considered a health centre in accordance with the provisions of Spanish Royal Decree 1277/2003 of 10 October, which establishes the general bases on authorization of health centres, services and establishments, as well as any organization that, without being defined by virtue of said Royal Decree, is active in the healthcare industry, such as health services, scientific and/or professional societies, as well as patient associations.

**Samples:** Are reusable or disposable products (consumables, equipment, implants, etc.) supplied free of charge by or on behalf of a Company to Health Organizations or HCPs who have the qualification and facilities necessary to use them in order to allow healthcare providers and patients to familiarize themselves with these products on clinical use.

Not included under the definition of Samples are free products:

- for demonstration;
- for evaluation;
- corresponding to a charitable donation;
- those intended for clinical research and/or training grants;
- those supplied without additional cost as part of the overall purchase price in trade agreements, or as substitute products under a guarantee agreement.

**Notification to Employer:** The prior and written notification made to the manager of the health centre, regarding the collaboration of a Company and any HCP, which must be carried out in accordance with this Code.

Although it does not require express authorization, notification must be made in writing and prior to the activity and with enough time for the institution to oppose against it if deemed necessary.

It is not mandatory to include the detail of expenses incurred by the Company. The purpose of the notification is to inform the employer of the HCP of the relationship between the Company and the HCP.

**Professional Congress Organiser (PCO):** Legal person, whether profit-making or not, that manages events, congresses, conferences, seminars and similar events. They may have the accreditation provided for in the Code.

**Health Organization:** Any legal entity or body (regardless of its legal or organizational status) that is a health, medical or scientific association or organization, which has a direct or indirect influence on the prescription, recommendation, purchase, order, supply, dispensing, use, sale or (free or for valuable consideration) use of healthcare technologies and related services, including but not limited to hospitals, procurement organizations, clinics, laboratories, pharmacies, research institutions, trusts, universities or any educational institution or professional or scientific society (excluding associations and/or foundations of patients), through which one or more HCPs provide their services. They may be public, private or both.



**Panel of Experts:** A group of individuals with proven experience in a particular area (e.g. therapy, reimbursement, specialty, procurement process) jointly offering unbiased advice and guidance to a company within a defined scope. The experience of the group complements the internal knowledge of the Company. A panel of experts is normally used to support product development, or the development of new indications of a product, or to support the development of business strategies.

**Demonstration Products:** Any reusable or single use product supplied free of charge by or on behalf of a Company to Health Organizations or HCPs who have the qualification and facilities necessary to use them. Demonstration Products may only be provided during the time necessary for the purpose of demonstrating the safe and effective use and proper functionality of a product, and shall not be used for clinical use in patients. The following will not be considered as Demonstration Products:

- Samples;
- Products for evaluation;
- Products intended for clinical research and/or training grants;
- Products forming part of a charitable donation;
- the products supplied at no additional cost as part of the overall purchase price in trade agreements, or as substitute products under a guarantee agreement.

**Products for Evaluation:** Are those healthcare technologies provided free of charge by or on behalf of a Company to Health Organizations or HCPs who have the qualification and facilities necessary to use them for evaluation in order to obtain specific data and/or information from the Users for the period of time necessary under the conditions of use and intended purposes, according to the conditions of commercialization in Spain.

The following will not be considered Products for Evaluation:

- Demonstration Products;
- Samples;
- Products forming part of a charitable donation;
- Products intended for clinical research and / or training grants;
- the products supplied at no additional cost as part of the overall purchase price in trade agreements, or as substitute products under a guarantee agreement.

**Healthcare Professional (HCP):** Any individual (whether having a healthcare function, or being a public employee or representative of any public sector entity or employee or representative of any private sector entity, including, without limitation, Healthcare Providers, Research coordinators or purchasing personnel, or not) who in the course of their activities may directly or indirectly purchase, use, recommend, administer, supply, dispense, purchase or influence the purchase, acquisition, or prescription of healthcare technologies.

**Healthcare Provider:** Any person recognized as such in Law 44/2003, of November 21, on the organization of health professions, or any regulations that may replace it.

**Speaker:** Speaker, moderator or panel member, acting as presenter during an event. The authors of scientific communications, whether via abstract or poster, will not be considered as speakers.

**Sales, Business and/or Promotional Meetings:** Any type of event or meeting organized by the Company with the aim of promoting the sale of its healthcare technologies and/or related services, as well as those destined to promote the Company's brand(s), and includes meetings to discuss the characteristics of the product, the benefits of use and/or marketing conditions.

**Event Validation System:** It is either the Conference Vetting System as a centralized decision-making process that validates the compliance of Third Party Organized Educational Events with the MedTech Code of Ethical Business Practices that is independently managed by Medtech Europe (<http://www.ethicalmedtech.eu>), or, for those outside this scope and relating to events in Spain, the conference review system of the Fenin Ethics and Compliance Unit (<http://www.fenin.es>).

**Healthcare Technology:** For the purposes of its implementation in this Code, any product (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, telematic services, maintenance services, management services, and user training services.

## IV. PRINCIPLES OF THE CODE

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

**Principle of Advancement of Medical Technology:** The development, advancement and innovation of healthcare technology require the collaboration of Healthcare Providers, Health Institutions and industry. The advancement of healthcare technology will allow finding new solutions to the diseases of patients, bringing significant benefits to the National Health System.

**Principle of Safe and Effective Use of Sanitary Technology:** In order to avoid risks in the use of healthcare technology and to ensure maximum efficiency, it is necessary that the Companies provide patients, HCPs and Health Institutions with appropriate instruction, education, training, training, service, and technical assistance.

**Principle of Research and Education:** The support of the Companies for research and education, should serve to improve the clinical skills of Healthcare Providers and thus contribute to the patient's access to new technologies and health services in conditions of maximum safety.

**Principle of Image and Perception:** Companies should always and in any situation take into account the image and perception of the healthcare technology industry, which should be protected during interactions and relationships with professionals, patients and Health Organizations.

**Principle of Separation:** Relationships between industry and HCPs and Health Organizations should not under any circumstances compromise their autonomy and impartiality, generate advantages in the decisions and purchase procedures nor promote recommendations by the HCPs.

**Principle of Transparency:** Industry relations with patients, HCPs and Health Organizations must be transparent and comply with applicable laws, regulations and ethical codes.

**Principle of Honesty:** Trust, professionalism and rigour should govern relations between industry and the rest of the agents of the health system, and should act with loyalty and good faith, with the aim of improving the skills of Healthcare Providers and improving the health and safety of the patient.

**Principle of Equivalence:** The remuneration paid by the Companies to the HCPs for services rendered must be proportional and in line with the market value of the services provided.

**Principle of Documentation:** The interactions of the Companies with HCPs and Health Organizations must be documented by means of a written agreement establishing, among others, the purpose of the interaction, services to be performed, payment or reimbursement of expenses, as well as the remuneration to be paid. In any case, the activities must be documented. The Company shall keep the documents for a reasonable period of time in order to justify the necessity of the service performed, the nature thereof, as well as the reasonableness of the remuneration paid.

**Principle of Legality:** Industry relations with patients, HCPs and Health Organizations must, at all times, comply with current legislation.

## V. QUALITY OF PRODUCTS AND SERVICES

Companies must ensure that:

- Products are manufactured, marketed or used and services are rendered in full in compliance with the current legality and nationally and/or internationally recognized standards.
- Products placed on the market, which are not yet regulated by national or European legislation, have a technological and quality content that makes them valid and useful for the intended use and for which they have been manufactured.
- The technical characteristics of each product are those specified on the labels, and as described in illustrative brochures, promotional materials and the instructions for use accompanying the product, according to the current legislation.
- The services offered are designed to meet the needs of users in order to obtain a satisfactory result for them, through continuous improvement and always within the framework of compliance with current regulations and subject to the highest quality standards.

## VI. GENERAL CRITERIA AND REQUIREMENTS FOR EVENTS

The criteria and requirements included in this section will apply to Company-Organised Events (both educational and promotional) and Educational Events Organized by Third Parties, where the Companies give any type of direct or indirect support (Training Grants, support to HCPs to attend events and promotional activities).

Companies will not be authorised to directly give training grants to cover the attendance of healthcare professionals to educational events organized by third parties, with the exception of events organized by third parties for training in techniques and clinical procedures and healthcare professionals attending in order to participate, as part of a consulting agreement, as speakers at a symposium organized by the Company within the framework of an educational conference organized by a third party.

### 1. Event Program:

The program of the event must be directly related to the specialisation or medical or professional practice of the HCP who will attend the event, or must be sufficiently relevant to justify their attendance.

For educational events organized by third parties, although companies may propose to the organizer contents for the program and speakers when required by the organizers, the final decision regarding its contents will be the exclusive responsibility of the organizer.

The detailed program must be available in advance, present a clear schedule without excessive pauses between the sessions (the minimum duration of an event should be 6 hours for a full day and 3 hours for a half day, including reasonable breaks).

Likewise, the program should identify speakers of each session from the start.

Promotional materials of the event (brochures, websites...) will be consistent with the scientific or promotional nature, as the case may be.

Companies should not organize Company-Organised Events, or support, financially or otherwise, Events Organized by Third Parties that include social activities, sports or any other form of recreational activity.

In the educational events organized by third parties, the recreational activities must be outside the hours of the educational program and their cost should not be included in the registration to the event, to facilitate their enrolment and payment separately by the HCPs who wish to take part in them.

Leisure activities should not be the main attraction of the Event or interfere with the overall educational content of the program, and should be performed during times when they do not overlap with the educational sessions.

Not included in the aforementioned prohibition are the welcome cocktail, the working lunches and the official dinners that usually appear in the program of the Events, as long as they meet the requirements referred to in Section 4 below and do not incorporate additional elements (cultural, leisure or entertainment, etc.).

## **2. Location and Venue of the Event:**

In the organization or support of an event, the Companies must take into account the following in relation to the location and venue (hotel, conference centre, etc.):

- The location of the event and the venue should not become the main attraction of the event.
- Possible negative public perceptions of the place and venue for the Event. The perceived image of the place and the venue should not be ostentatious, oriented to holiday tourism or a location linked to recreational activities.
- The venue must have the necessary infrastructure (spaces, furniture and audio-visual equipment) appropriate to the program of the event.
- The places where the activities are held should be selected taking into account the ease of access and cost for the majority of the participants. Therefore, the location and venue of the event should be close to an airport or train station, with the appropriate connections depending on the point of origin of the attendees, and with ground transportation infrastructures suitable for travel to the venue of the Event. In this sense, the Companies will not be able to organize or sponsor Events that take place outside of Spain, unless it makes more sense from a logistical point of view due to:
  - a) The majority of the participants coming from abroad; or
  - b) A relevant knowledge source or resource that cannot be easily moved to Spain and which is the main subject of the Event is located abroad.
- The venue for the event should be in or near a city that is a recognized business and /or scientific location, suitable for organizing an event that allows the exchange of ideas and transfer of knowledge.

- Companies must take into account the time of the year during which the Event is held. The date should not be associated with the tourist season in the selected geographic location. In this way, the tourist season will be understood, for summer destinations, as being between June 1 and September 30, and winter destinations, as being between December 1 and March 31.

### 3. Companions:

The Companies may not, directly or indirectly, pay and/or facilitate meals, transportation, lodging or other services to the Companions of HCPs, 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 accommodation to the venue).

"Facilitating" means booking and/or arranging meals, transportation, accommodation or other related services for a Companion of a HCP, by the Company or on their behalf.

In order to promote scientific exchange, the presence of Companions at any time during the event, including scientific sessions and/or breakfasts, meals, dinners and refreshments, will not be acceptable, even if the HCP or Companion bears the expenses.

### 4. Hospitality:

The Code looks for a balance between professional and complimentary treatment of the HCP by the Companies with the desire to avoid any possible interpretation that said hospitality may be used by the Companies as a means to influence the HCPs to purchase, prescribe or recommend their healthcare technologies.

The Companies may take care of moderate expenses of hospitality to the HCPs in the context of the celebration of Events (including previous, subsequent and during the course of the Event). Hospitality should be subordinated in time and scope to the main purpose of the Event and should avoid situations that may imply an inappropriate image for the sector.

Consequently, the 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 any case excludes leisure and entertainment activities.

Accommodation is considered reasonable if the hotel has up to 4 stars and is not primarily intended for leisure (spas, golf clubs, resorts, casinos, boutiques ...). The use of 5-star or equivalent hotels will be allowed as long as it is possible to prove that there are security or availability reasons requiring it and that its main activity is not leisure. "Luxury" five star accommodations will not be allowed in any case. Accommodation and other forms of hospitality may not exceed the official duration of the Event. In this regard, provision should be made for the return of participants in the next transport available.



In Spain, a meal (lunch or dinner) that does not exceed the amount of EUR 60 including taxes will be considered moderate. For Events held outside Spain, the maximum established by law or by the national association of the country hosting the event will apply.

Meals held as part of Sales, Business and/or Promotional Meetings must be subordinate to their main purpose, and therefore their location should facilitate the discussion and exchange of productive and efficient information (and, where appropriate, Audiovisual and /or healthcare technology products presentation). In this case they may not include, even in part, Leisure Activities (musical shows, performances, artistic exhibitions, tastings, etc.). The Companies will only take care of the meals of the active participants in the sales, business and/or promotional Meetings.

Under no circumstances the Companies will be responsible for:

- meals unrelated to Events, such as Christmas meals and dinners, anniversaries, etc;
- those meals in which there are no representatives of the Company, and
- alcoholic beverages, excluding wine and/or beer during the meal.

## 5. Travels:

The Companies will only cover the trips actually made and coinciding with the start/end dates of the Event, except where this is not possible, and never exceeding the day before or after the Event, unless justified. The HCP who wish to extend their stay must personally cover any additional cost generated (additional accommodation and meals, additional transport costs, etc.).

Regarding travel of HCPs by plane, companies will only pay for economy or tourist class, unless the flight lasts more than 5 hours (including connection times) in which case the use of business class will be allowed. Under no circumstances shall first class be permitted. The Companies will cover the cost of access to Executive or Preferential VIP Lounges, if the airline ticket does not cover it, for connections or delays of more than three hours.

Regarding train journeys, they must be done in second class/"turista plus" (Spanish first class without meal service), except for trips of more than 2 hours, in which case the "Preferente" (Spanish first class with meal service) class can be used. The Club and Grand Class classes are not permitted.

## 6. Reimbursement of expenses:

The companies will be directly responsible for the payment of the necessary expenses incurred by HCPs participating in Events. Reimbursement in cash to the HCP of the referred expenses shall not be allowed under no circumstances. As an exception to the rule, in the absence of a valid alternative, minor expenses of the HCPs (taxis, mileage, short distance transportation, parking, etc.) may be reimbursed to the HCP upon justification thereof.

The payment of any leisure and entertainment activity are excluded as well as the travel and per diem expenses, that is, any expense covered or reimbursed by the Company should be justified independently.

### **7. Transparency:**

Whenever a Company is responsible for costs incurred by an HCP derived from attending a Company-Organised Event or Events Organized by Third Parties for training in clinical techniques and procedures, it shall make a prior written notification to the manager of the health centre indicating the scope and purpose of said financial assistance. Scope refers to the destination of the financial assistance (support for attending a training course) and purpose the specific purpose of the financial assistance (registration, accommodation and / or travel).

## VII. EDUCATIONAL EVENTS ORGANIZED BY THIRD PARTIES:

The Companies may offer financial support in cash or in kind (healthcare technologies, etc.) to hold educational Events organized by third parties in accordance with the rules of this Code. Such Events may be:

- educational conferences organized by third parties;
- events organized by third parties for training on clinical techniques and procedures.

### 1. Educational Conferences Organized by Third Parties:

The Companies may offer financial support in cash or in kind to hold educational Conferences organized by third parties provided that:

- there is compliance to section 6 of the Code (Criteria and General Requirements for Events); and
- approval by the Event Validation System is received.

Such support may be provided through grants and other financing such as the following:

#### a. Training Grants:

The Companies will be able to award Training Grants for holding educational Conferences organized by third parties, provided that the foregoing conditions are fulfilled. These grants may also be allocated to the assistance of HCPs to educational conferences organized by third parties, but the companies will not be able to give these grants directly to individual healthcare professionals. In these cases, the health organization or institution receiving the Training Grant will be solely responsible for the selection of the participants, and this should be expressly reflected in writing in the collaboration agreement. In this agreement, the Companies will be able to define the professional profile of the HCP that may benefit from the grant, but in a way that does not reveal their identity nor directly identify them.

The Companies may also directly cover the expenses of HCPs who will participate as Speakers at a symposium organized by the company within the framework of an Educational Conference organized by a third party as part of a consultation agreement with these HCPs, in which case the Companies will be able to cover the costs of travel, lodging or registration of said Speakers.

**b. Promotional Activities:**

Companies may contract advertising services and/or visual aids, such as advertising space, space for exhibition stands, etc. Companies must ensure that the general image projected by promotional activities at the Congress or educational conference organized by third parties is perceived in all cases within parameters of professionalism. Under no circumstances should they cause discredit or reduce confidence in the Healthcare Technology Sector.

**c. Satellite Workshops/Symposiums:**

Companies may contract satellite workshops/symposiums during educational conferences organized by third parties for presentations on subjects related to the general content of the educational conference organized by a third party. Companies may decide the content and the speakers of these workshops/symposiums.

For the speakers contracted only for workshops or satellite symposiums, the Companies will be able to cover the necessary expenses for their participation, including travel, accommodation for the workshop/symposiums days and, if necessary, registration for access to the venue of the conference, and must be included in the contract with the HCP.

Workshops and satellite symposiums shall not interfere with the program of the event under any circumstance.

**2. Events Organized by Third Parties for Training in Clinical Techniques and Procedures:**

The Companies will be able to financially support Events Organized by Third Parties for the training in clinical techniques and procedures either by means of training grants or by directly financing the HCP the costs related to their attendance at the event in question, as long as the following standards are met:

- The economic support must comply with the criteria included in Section 6 (Criteria and General Requirements for Events). In this case, the Companies will be able to directly pay for travel, accommodation, hospitality and the registration fee of the HCP.
- The Event organized by third parties for training in clinical techniques and procedures in question must be validated by the Event Validation System applicable in each case.
- In order to provide financial support for events organized by third parties for training in clinical techniques and procedures, Companies must observe the requirements applicable to conduct and attendance at such events in the country where the HCP exercises his profession, in addition with the requirements in the country where the event is held.

### **3. Seal of Adherence to the Code of Ethics of the Healthcare Technology Sector for Organizers of Educational Events:**

Any entity organizing educational events for HCPs may request the Seal of Adherence to the Code of Ethics of the Healthcare 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 website the list of entities that have the Seal of Adhesion to the Code of Ethics of the Sector of Sanitary Technology.

To obtain the Seal, an application by email should be submitted to [selloetico@fenin.es](mailto:selloetico@fenin.es) together with:

1. Signed statement by the legal representative of the entity in the format approved by Fenin, including:
  - Adherence to the Code of Ethics of the Sector, its principles and requirements, particularly regarding those aspects related to the organization of events:
    - Educational program and deadlines for the interested parties
    - Location
    - Venue
    - Hospitality
    - Entertainment and Leisure Activities
    - Companions
    - Event Validation System
    - Others
- Provide those persons linked to the implementation of the Code within the organization with knowledge and information about the Code of Ethics.
- Apply the maximum confidentiality to the information of the Companies, to which they may have access in the management of the event, refraining from sharing or disseminating such information between the Companies or with third parties.
- Have appropriate policies and procedures to ensure compliance with the principles and requirements of the Code of Ethics.
- Describe in advance the profile of the beneficiaries of the training grants and selection criteria, in case the grants are intended to cover the attendance expenses of the participants to the different training events. The selection process should be documented.
- To allocate the funds provided by the Companies for the training of HCPs in full to this purpose, applying to the selection of the beneficiaries training non-discrimination, opportunity and reasonable necessity criteria, guaranteeing the non-interference of the Company giving the grant.

- To publish, prior to the management of the events, the amount to be deducted from the training grants received, in the form of management expenses. This amount should not exceed 10%.
- To pay back any surplus amounts at the end of the event to the Companies that have given Training Grants. This reimbursement will be based on the percentage corresponding to the contribution of each Company.
- To submit themselves to the audit procedure established by Fenin, whose objective is to verify compliance with this declaration and the Code of Ethics.
- Identify an interlocutor for the purposes of compliance with the Code by the relevant entity.
- Have the necessary organizational and management capacity to comply with this declaration.
- To submit to the procedure of withdrawal of seal in case of non-compliance with the declaration or the Code of Ethics.

2. Powers of the signatory of the Declaration.

The seal may be withdrawn:

1. At the request of the interested party, by electronic mail of the legal representative of the entity, including its powers.
2. In case of non-compliance with the Code of Ethics and/or its declaration of adherence thereto, the following procedure shall be instigated and may be requested due to the results of the audit or to a complaint by a Company adhering to the Code, and brought to the attention of Fenin's Ethics and Compliance Unit.
3. The Ethics and Compliance Unit:
  - a) Shall verify that the application meets the foregoing requirements.
  - b) Once the request is considered valid, it will grant a deadline of 5 working days so that the reported entity can file allegations.
  - c) Will resolve the complaint within a maximum period of 10 working days from the receipt of the allegations or the expiration of the period to submit them.
  - d) Will communicate within two working days the resolution to the entity and it will publish it on the web of Fenin if the seal is to be withdrawn.

## VIII. COMPANY-ORGANISED EVENTS

### 1. General Principles:

Companies may invite HCPs to the following events:

- Company-Organised Events regarding training in healthcare technologies
- Sales, Business and/or Promotional Meetings:

Company-Organised Events must comply in any case with the requirements referred to in Section 6 (Criteria and General Requirements for Events).

Whenever there is a legitimate reason, Company-Organised Events may take place in part or whole in facilities used by the Company (manufacturing and/or distribution facilities, demo rooms, maintenance workshops, etc.) or in the facilities owned by a Health Organization, that may be the centre of reference of the Company.

### 2. Company-Organised Events Regarding Training in Healthcare Technologies:

Where relevant, in order to contribute to safe and effective use of existing healthcare technologies or with the aim of providing training on new uses or therapies, the Companies will provide training to HCPs needing it, whether or not they are clients of the Companies.

The Companies will ensure that the people who give training in the said events possess the necessary technical knowledge and experience.

### 3. Sales, Business and/or Promotional Meetings:

Where applicable, the Companies may organize business meetings aimed at the sale and/or promotion of their healthcare technologies, including, but not limited to, meetings to discuss the characteristics, advantages and uses of their healthcare technologies, the negotiation of the terms and conditions of their supply and/or the management of their business relationship.

In addition to the requirements under point 1 (general principles), they must comply with the following requirements:

- As a general rule, these meetings should take place at or near the HCP's workplace.
- It will not be acceptable for the Companies to cover the costs of travel and accommodation of the HCP, except when it is necessary for the demonstration of non-portable healthcare technologies, in which case the requirements of Section 6 (Criteria and General Requirements for Events) shall apply.



## IX. AGREEMENTS WITH CONSULTANTS

### 1. General Principles:

Companies may hire HCPs as consultants and advisors to provide consulting services and other services, including but not limited to research, participation in a Panel of Experts, presentations at Company-Organised Events, and product development meetings.

The Companies may pay the HCPs any remuneration corresponding to the services rendered, which must be reasonable and according to market value.

In any event, agreements with consultants must respect applicable Law and codes of ethics.

These principles shall apply to any consulting agreements between HCPs and Companies, including those in which the HCP declines to receive remuneration for the provision of their services.

Consultancy agreements shall not generate, implicate or imply any incentive for any current or potential future purchase, lease, recommendation, prescription, dispensing, use, supply or acquisition of products or services of the Company.

For the selection of consultants, the Companies must enable independent decision-making processes that allow them to identify, prevent and mitigate risks of bribery and the potential risks of corruption that arise in relation to the hiring of consultants.

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

### 2. Criteria Applicable to Consulting Agreements:

In addition to the principles of the previous point, consulting agreements must meet all the following criteria:

- Consulting arrangements should only be made where there is a legitimate need for the provision of services as identified in advance.
- The number of consultants should not be more than the number reasonably necessary to fulfil the identified need.

- The selection of consultants should be based on criteria directly related to the need identified by the Company, as well as the training and experience of the consultant to address the identified need. The impact on the business generated by a study already carried out by the consultant or the health institution in which the latter carries out his professional activity is not a relevant criterion.
- Agreements with consultants should be documented in a written agreement, signed by the parties before the start of the provision of services. This contract shall specify the nature of the services provided and the remuneration in payment thereof.
- The contracting of the consultant should not represent any incentive for the purchase, lease, recommendation, prescription, dispensing, use, supply or acquisition of products or services of the Company.
- The remuneration for services rendered must be reasonable and reflect the fair market value of the services.
- Companies must keep records of services and products associated with the work performed by the consultant as well as the use by the Company of such services and products.
- The location and other aspects related to hospitality provided to the consultant (travel, subsistence, hotels, etc.) must follow the provisions of Section 6 (Criteria and General Requirements for Events).

### **3. Remuneration of Consultants:**

The remuneration of the HCPs hired as consultants by the Companies shall be adjusted to the fair market value of the services rendered.

They should not offer incentives or rewards to the HCP in their professional practice for the acquisition, lease, recommendation, prescription, dispensing, use, supply or acquisition of the Company's technologies and/or services. Likewise, they may not have these effects in the Health Institutions or Organizations in which they carry out their activity.

Any payment made for consulting services must respect the Law and assume all taxes. Companies may pay reasonable expenses incurred by consultants in providing the services covered by the consulting contract, including reasonable travel expenses, meals and accommodation expenses incurred by consultants if they attend meetings with or on behalf of the Companies. The consulting agreement must be reflected in writing and shall detail what kind of expenses may be claimed by the consultant in relation to the provision of services and the basis for payment of the same by the Company.

#### **4. Transparency:**

The Companies shall ensure that they comply with any applicable laws, regulations and professional codes of conduct that require any publication, disclosure or approval in connection with the recruitment of HCPs in consulting agreements. The Company must have the necessary consents, approvals or notifications, including that of the health centre, the corresponding administration or its manager, as appropriate.

If there are no such national requirements, Companies must maintain adequate transparency by notifying the manager of the health institution, revealing the purpose and scope of the consulting agreement.

The Companies will also include the appropriate transparency obligations for the consultant to ensure whether the consultant has participated in an investigation in the scientific publication where the results of the research will be made public, as well as in any publication or presentation of the same.

#### **5. Panel of Experts:**

In addition to the requirements set out in the previous sections, the Panel of Experts shall comply with the following standards:

- The participation of HCPs should not be used for the promotion of Company products to professionals.
- The object of the Panel of Experts should be limited in the agreement to specific projects of determined duration before the beginning of the work, and it may not be extended indefinitely.
- The results of the work of the Panel of Experts should be documented in writing and a record of any working session shall be recorded, where the individual contribution of each member of the panel shall be registered.
- The number of Panel members should be reasonable and necessary for the fulfilment of their objectives.

## X. RESEARCH

### 1. Studies Promoted by the Company:

Whenever there is a legitimate business need, the Companies will be able to promote, carry out, manage and finance studies of a scientific nature to generate data, either before or after the commercial launch of a healthcare technology. In this context, a legitimate business need will be understood as the generation of data to satisfy, including but not limited to:

- Medical needs, including patient safety
- Research and development
- Scientific purposes, including generation and testing of performance indicators and comparison of objective scientific parameters
- Regulatory compliance, including the health product surveillance system, safety, reimbursement and economic analysis, including clinical data and cost-effectiveness analysis, and relevant data for the evaluation of healthcare technologies as well as the decision-making of reimbursement.

When a Company hires a HCP to provide advisory or consulting services, for instance, to conduct a study on behalf of the Company (i.e., acting as principal investigator), it must ensure that such advisor or consulting agreement complies fully with Section 9 (Agreements with Consultants).

According to the Documentation Principle, any agreement reached by a Company to provide services related to the investigation must be formalized by means of a written agreement that shall include, as part of its content:

- The research protocol;
- The work schedule, and
- It will establish the need to have all necessary consents, approvals and authorizations that must be obtained prior to the start of the study (ethical committees, etc.).

The Company must, in any case, have written prior approval of the study by the relevant Health Organization when:

- The main investigator, or any person involved in the development of the study, is an employee of the Health Organization;

- There is use of the Health Organization resources (including, but not limited to, material resources and/or personal and/or data); and/or
- The study is carried out in the facilities of the Health Organization.

Any remuneration paid by the Company must be proportionate to the services actually rendered by the HCP (taking into account the time spent, the work performed, complexity and responsibilities assumed) and for the purposes of the study, must correspond to market values, must be monetary and must be subject to any taxes and/or withholdings relevant in accordance with current legislation.

Companies must ensure that their research activities comply with all applicable national legal and regulatory provisions, with the codes of conduct applicable to researchers, as well as the applicable Best Clinical Practice standards, if any.

In accordance with the principles of the Code, Companies should also ensure appropriate transparency in clinical trials in relation to their research activities and results, including the disclosure of adequate information about clinical trials of the Companies (public records, specialized scientific magazines, etc.). To this end, the Companies shall disclose clearly their participation as promoters in the publication of the studies.

When the Companies hire intermediary third parties to carry out the research (Contract Research Organisations or CRO), they must ensure that the work performed by these third parties on behalf of the Company is carried out in accordance with all legal and ethical requirements applicable, according to the requirements of this Code.

Under no circumstances should these studies be undertaken as a procedure for the promotion of healthcare technology or for the purpose of influencing the purchase, leasing, recommendation, prescription, dispensing, use, supply request and/or acquisition of healthcare technology marketed by the Companies.

The contracting Company shall request the delivery by the healthcare professional of documentary support of the services developed, as well as the results generated, and it is recommended to keep the documents for a reasonable period of time in accordance with the prevailing legal provisions, and never less than five years.

## **2. Studies Promoted by a Company after the Commercial Launch:**

In case of a legitimate business need, the Companies may promote the performance of studies of evaluation of healthcare technologies by third parties after their commercial launch. To this end, Companies may provide Sanitary Technologies for evaluation under a written service contract, in order to obtain the evaluation by a user employed by a health organization or institution.

Healthcare technologies for evaluation may be provided free of charge as part of the evaluation carried out by the HCPs in the corresponding health organization or institution, all of which must be formalized by written agreement, including the applicable protocol and/or questionnaire to be completed by users.

The contracting Company shall request the delivery by the HCP, once the evaluation has been made, of documentary support of the services developed and the results generated.

The supply of products for evaluation and/or related services may not influence and/or tempt HCPs and/or Health Organizations or Institutions to purchase, lease, recommend, prescribe, dispense, administer, use, request the supply and/or acquisition of healthcare technology marketed by the Companies, or constitute an undue advantage for the HCP, the health organization or institution, and/or any person related to them.

All supplies of products for evaluation must always fully comply with applicable laws, regulations and professional and industry codes of conduct (including but not limited to this Code).

The Company shall always have written prior approval of the study by the relevant Health Organization or health institution when:

- The main investigator, or any person involved in the development of the study, is an employee of the same;
- There is use of its resources (including, but not limited to, material resources and/or personal and/or data);
- The study is carried out in the facilities of the Health Organization.

In case of payment of a remuneration for the evaluation, it shall be provided to the services actually provided by the HCP and the Health Organization or Institution according to the fair market value and for the purposes of the study, must be monetary and must be subject to the relevant taxes and/or withholdings in accordance with the current legislation.

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

HCPs and/or Health Organizations or Institutions, acting individually or as part of a group in which they are actively involved, are likely to make valuable contributions that may improve healthcare technology. In this way, they may develop rights, such as patents, in the framework of sanitary technology development or intellectual property or industrial license agreements.

The provisions of Sections 9 (Agreements with consultants) and 10 (Research) shall also apply to the said development agreements.

The contracting of advisory and/or consulting services should not constitute an undue advantage, induce and/or urge HCPs and/or Health Organizations or Institutions to purchase, lease, recommend, prescribe, dispense, use, request for supply and/or acquisition of healthcare technology of the Companies. To this end, no HCP subject to royalty payments may be a member of the evaluation or procurement committees of the healthcare technology developed.

Prior to the subscription of an agreement for remuneration for intellectual and/or industrial property rights (licenses, royalties, charges) by a Company with a HCP and/or Health Organizations or Institutions, the Company shall assess and identify the legitimate need for a HCP and/or Health Organization or Institution to provide research and development services.

The criteria used to select HCPs and/or Health Organizations or Institutions should be directly related to the identified need and the person responsible for their selection should have the experience and technical knowledge necessary to assess which HCPs and/or Health Organizations meet said criteria.

Likewise, an agreement for the remuneration of intellectual and/or industrial property rights between a Company and a HCP and/or Health Organization or Institution may only be proposed when it is expected that the HCP and/or Health Organization has carried out or is going to carry out a new, relevant and sufficiently important development related to the sanitary technology of such nature that the HCP and/or Health Organization or Institution shall be considered, under the applicable legislation, as holder, co-holder, author or co-author of the intellectual or industrial property rights developed.

The number of HCPs and/or Health Organizations hired by a Company in the context of the need for research and development should not exceed the number reasonably necessary to achieve the intended or proposed objective.

Agreements relating to the payment of duties by or on behalf of a Company to a HCP and/or Health Organization or Institution must be formalized by written agreement, clearly identifying the criteria that will serve as the basis for the calculation of remuneration, which in any case shall be monetary, adequate and reasonable in accordance with the applicable legislation. As an example, payments made in exchange for the ownership and/or use of intellectual or industrial property rights should not be conditioned by the HCP:

- Purchasing, placing orders, promoting or recommending healthcare technology marketed by the Company;
- Purchasing, placing orders, promoting or recommending the healthcare technology resulting from the development project;
- Marketing the healthcare technology resulting from the development project.

Companies, where legally possible, should exclude from the calculation of the remuneration to be paid to the HCP and/or Health Organization or Institution the number of units acquired, prescribed, used or requested by the HCP and/or by other professionals related to the HCP and/or by the health institution in which the HCP develops its professional activity.

The contracting Company shall request the delivery by the HCP of documentary support related to the services developed, as well as the results generated, and it is recommended to keep the documents for a reasonable period of time in accordance with the prevailing legal provisions, and in any case, no less than five years.

This notwithstanding the obligations that the Companies must fulfil in relation to the payment of the relevant rights or connected to any other aspect related to the ownership, license, exploitation, etc., of intellectual and industrial property rights, under the applicable local regulations.



## XII. HEALTHCARE TECHNOLOGIES FOR DEMONSTRATION AND SAMPLES

### 1. General Principles:

Companies may supply their own products as demonstration products (hereinafter demos) or free samples to Health Organizations and HCPs in order to evaluate and familiarize themselves with the safe, effective and adequate use and the functionalities of such products and determine whether they will use, request, purchase, prescribe or recommend them.

As an exception to the rule, Companies may also provide products of other companies in conjunction with their own products if they are necessary for the demonstration, evaluation and appropriate use of those of the Company itself.

The demos and/or samples should not serve to reward or subsidize the purchase, rental, recommendation, prescription or use of the Company's products to the Organizations or Health Institutions and/or HCPs.

The Companies will maintain at all times adequate records in relation to the provision of demos and samples to Health Organizations and HCPs, as well as their return in case of reusable products. The Companies shall keep a record, as well as stipulate in writing to the Health Organizations and/or Institutions and HCPs, the free nature of the demos and samples and any other conditions applicable on delivery.

### 2. Demonstration Products (Demos):

Companies may provide products to Health Organizations and/or HCPs, for example replicas or single use non-sterilized products, for the training and information of HCPs and patients.

The demos are not intended for clinical use in patients or for sale. The Companies shall keep a record, as well as disclose, preferably in writing, to the Organizations and/or Health Institutions and HCPs the free nature of the demos and samples and any other conditions applicable to their delivery on delivery.

### 3. Samples:

Companies may provide the Health Organizations and/or Institutions and/or HCPs at the very least the minimum number of samples necessary to familiarize themselves with the product (consumables, equipment, implants, etc.) and/or associated services, in order to acquire experience in its safe and effective use in the clinical environment and to determine if or when to use it, request it, buy it, prescribe it or recommend it in the future.

For samples of reusable products, the time required for the HCP to become familiar with the product will depend on its intended frequency of use; the time required for training; the number of HCPs who need to gain experience with the product, and similar considerations. The Companies will ensure, in any event, that they retain ownership of the samples of reusable products and that they have a process to withdraw them at the end of the period of familiarization.

The equipment will be treated equally and follow the same requirements as equipment for demos given to the Health Organizations.

## XIII. PREVENTION OF CONFLICTS OF INTEREST

Notwithstanding the applicable legislation on conflicts of interest and incompatibility regime for personnel at the service of the public sector, a conflict of interest shall be understood any decision and/or action promoted or in which the HCP intervenes, which, directly or indirectly, may cause a collision between their professional interests and their own personal interests and/or those of third parties, including but not limited to those of a Company. For these purposes, personal interests are considered:

- The person's own interests.
- Family interests, including those of the spouse or person with whom the subject maintains a similar relationship of affectivity and relatives within the fourth degree of consanguinity and second degree of affinity.
- The interests of persons with whom the subject has a pending litigation.
- The interests of people with whom the subject has a close friendship or open enmity.
- Those of legal persons or private entities where any of the above persons is exercising a senior post that implies management, advice or administration functions.

The Companies shall refrain from generating or participating in any relationship or interaction with HCPs that will give rise to this situation. This limitation will be applicable in the relationships or interactions with HCPs developing their activity in the public and/or private sector.

## XIV. CHARITABLE DONATIONS AND TRAINING AND RESEARCH GRANTS

### 1. General Principles:

Charitable Donations and Training and Research Grants (hereinafter referred to as Grants) will never be contingent to or generate incentives for the sale, hire, recommendation, prescription, use or supply, present, past or future, of the products or services of the Companies. Support for charitable and philanthropic programs should not be perceived as a price concession, reward or inducement to customers to purchase, rent, recommend, prescribe, use or supply the Company's products or services. Any organization receiving the Grants shall be legally qualified to receive them.

The Companies will not give Assistance to HCPs in a personal capacity or in response to requests or petitions from them unless they are and act as representatives of an organization qualified to receive them and making the request in writing on their behalf.

The payment, or delivery by any means of any other form of Grants, will always be made to the qualified organization requesting it. The Companies will not give Grants on behalf of HCPs.

The Grants will identify the Company as the supplier of the same.

The Companies will establish independent processes, separate from sales and marketing functions, and with solid decision mechanisms that have clear, consistent and transparent criteria for the review and approval of applications for Charitable Grants, Scholarship and Research Grants. These processes may be internal or outsourced, in accordance with their organizational structure, and shall include a documented prior assessment of the application as well as relevant information concerning the receiving organization, including, but not limited to, the nature of the terms and conditions to which the Grant is subject and may also include information about how such Grant was used on previous occasions and whether it was in accordance with the terms and conditions in which it was granted.

All Grants must be properly documented by the Company and must be granted only in response to a written request from the receiving organization or to a documented initiative from the Company that contains sufficient information to allow an objective assessment of that request, this is, at least, a detailed description of the scope and purpose of the program, activity or project to which the Grant will be dedicated, as well as a description of the purported recipient, its legal status and structure and, where applicable, a budget. No assistance will be granted until an agreement is signed by both parties documenting the terms under which it is granted.

## **2. Charitable donations:**

Companies may only make Donations to non-profit entities for charitable or philanthropic purposes that are genuinely involved in such activities. The Companies will not have any control over the final use of the funds or other type of support they provide to the entities, beyond the general restrictions necessary to ensure that such funds or other support are intended for genuine charitable purposes.

The Companies will not make Donations on behalf of or for the benefit of a HCP, even if they waive their payment for services rendered and request that payment should be done to a charity on their behalf. Neither will they pay the registration of HCPs to events of a charitable nature, such as charity runs. The Donations may take the form of payments at Events to raise funds, such as dinners or charity tournaments, and the Company may use these inscriptions, in whole or in part, for its own employees, or return those that have not been used to the Charitable entity so that it decides on its use, but they will not be able to register HCPs, nor to disclose their names to the charity in order that the entity itself may invite them.

The Companies will not make Donations in order to support the regular operation or the current or operational expenses of a Health Organization or Institution, either directly or indirectly through foundations or other entities linked to the Health Organization or Institution. Nevertheless, donations to non-profit hospitals in the case of demonstrable financial difficulties are acceptable in exceptional cases, provided that the donations are exclusively for the benefit of patients, and of limited value.

## **3. Training Grants:**

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

Applications for training included in public procurement processes, which must also be appropriately documented, will not be considered as a Grant.

The Companies shall document and make public all training grants in accordance with the following standards:

- During the first 6 months of the year, the Companies will disclose all grants given to Health Organizations or Institutions, either directly or through Professional Event Organizers (for example, technical secretariats).

- Organizations and/or Health Institutions should be identified by their name and tax identification number.
- Companies should disclose in aggregate the amounts paid in Euros, for each clearly 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 destined to courses or training days/ grants for public awareness campaigns
- Optionally the Companies may indicate its purpose.
- The Companies shall document the methodology used in the preparation of information, including a general summary and specific aspects such as handling VAT or other fiscal aspects. At Fenin's request, the Companies will facilitate this methodology.
- The information must be published on MedTech Europe's web-site (<http://www.ethicalmedtech.eu>) and will remain in the database at least 3 years from the date of publication.
- The first publication must be made in the first 6 months of 2018, with the data referring to the year 2017.

MODEL									
	Full name of the Health Organization	City (head office)	Country of main activity	Registered Office	VAT (single identifier)	Training Grants Including: 1 - Support for educational events organized by third parties 2 - Support for the participation of HCPs in educational events organized by third parties	Purpose (Optional)	Other Training Grants (including courses or training days and grants for public awareness campaigns).	Purpose (Optional)
Health Organization	Health Organization 1					Annual amount	Optional	Annual amount	Optional
	Health Organization 2					Annual amount	Optional	Annual amount	Optional
	etc.					Annual amount	Optional	Annual amount	Optional

The Companies may provide support for the following purposes, amongst others:

**a. Support of educational Events Organized by Third Parties:**

As a general rule, any educational event organized by third parties supported by means of a Grant should meet the criteria set out in Section 6 (General Criteria for Events).

**a.1. Support for the participation of HCPs in educational Events organized by Third Parties:**

When the purpose of the Grant is to support the attendance of the HCPs at Educational Events Organized by Third Parties, the receiving Health Organization or Institution shall be solely responsible for the selection of participants, which shall be expressly reflected in writing in the grant agreement.

**a.2. Support for educational Events Organized by Third Parties:**

The Health Organization or Institution organizing the event and beneficiary of the assistance will be solely responsible for:

- The content of the programs;
- The selection of the speaker; and
- Payment of the fees of the Speaker, if applicable.

The Companies will have no participation in determining the content of the educational program or in the selection of the Speakers, which will be reflected in the agreement that will be signed with the beneficiary entity. If expressly requested to do so, the Companies may recommend Speakers or make comments about the program.

This section does not apply to Events organized by a Professional Event Organizer that organizes an educational event independently of any health organization or institution, in which case, Companies may carry out commercial sponsorship agreements, which in any event must be documented.

**b. Scholarships and Fellowships:**

The Companies may provide support for scholarships or fellowships to support the medical education of HCPs.

Only Health Organizations that have HCPs in training programs may request or receive these grants. The Companies will not provide assistance requested by individual HCPs.

Likewise, the Companies will not have any implication in any way in the selection of the HCPs who will benefit from the grant, which will be reflected in the agreement that must be signed with the Health Organizations.

Travel costs or other associated costs incurred by the beneficiaries shall not be reimbursed or paid on their behalf by the Companies in any case. In case they pretend to assume them, they should be provided for and included in the grant given to Health Organizations.

**c. Grants for public awareness campaigns:**

The Companies may provide assistance to Health Organizations as well as to patient associations 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 Therapeutic areas in which the Companies are interested and/or involved.

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

**4. Research Grants:**

The Companies may provide research grants to support studies initiated by third parties clearly defined 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 quantities of product free of charge and limited to the duration of the investigation.

Any support provided by the Company (human, in-kind or monetary) may only be assigned or used for the specific study for which the Research Support has been granted, excluding the use of such support or resources in the ordinary activity of the institution benefiting from them.

The Companies that provide these grants must ensure that they do not influence the investigation. However, in order to ensure that the grant is given for a particular research project, they must be aware of the scope of the research and the purposes for which the grant is requested, and shall ensure that the written agreement with the receiving Health Organization or Institution includes the Company's rights to verify that the Grant will be applied only to the intended use of the agreement. This verification may include a request for documentation related to the study, such as a copy of the research protocol, a copy of the ethics committee's approval, or a copy of the study report at the conclusion or early termination of the investigation.

All applications for Research Grants must be received in writing and should, at least, detail the type, nature and objectives of the research, the milestones and budget, the approximate duration of the research and, where appropriate, the requirements for the approval of the ethics committee or other authorizations. The Companies may study an application prior to the approval of the ethics committee, but should not make a final decision before the investigation receives formal approval.

The research grant agreements shall include provisions relating to adverse event communications where appropriate, and shall require the disclosure by the receiving organization and the principal investigator of the grant received, and from which Company, in every oral submission or written results.



## XV. PUBLICITY AND PROMOTION

Any advertising and promotional activities shall comply with current legislation, considering when advertising and promotion should be made, under what conditions and to whom it may be directed based on the nature and use of the product.

The fact that any advertising and promotional activities have previously undergone the review of the Spanish Association for the Self-Regulation of Commercial Communication (AUTOCONTROL) will be considered evidence of good faith.

Any promotional material should incorporate the company logo or product brand, and in its absence would be considered an incentive.

## XVI. TRAINING MATERIALS AND GIFTS

As an exception to the rule, Companies may provide training materials and/or inexpensive gifts to HCPs as long as the following requirements are met:

- Comply with the provisions of the applicable regulations.
- Be of little value, considered inexpensive when its market price does not exceed EUR 10.
- That there are training materials and/or gifts directly related to the practice of the HCP, or that directly benefit the care or attention of patients, or having a genuine training function, for instance, the delivery of stationery (pens, notebooks, etc.) or data storage devices (pendrive, DVD, etc.) when they include scientific content, as well as for clinical practice.
- The delivery of food, alcoholic beverages and any other product for personal use of the HCP is forbidden.
- They should not be delivered in response to a request from the HCP.
- They may not be cash or equivalents.

In any event, the delivery of training materials and gifts may constitute a reward or incentive to HCPs for the purchase, lease, recommendation, prescription, use or administration of the products or services of the Company.

Notwithstanding the foregoing, Companies may from time to time deliver to Health Organizations training materials worth more than EUR 10 provided that such materials:

- Have a genuine training role for the HCPs who are part of the health organization or institution; and
- Benefit directly from the care or assistance of patients (e.g., scientific books or anatomical models).

These materials will not be delivered to the HCPs for their personal use, and should be directly related to the therapeutic areas in which the Company carries out its activity, and should not be part of the general operating expenses of the Health Organizations or Institutions. The Companies must keep a record of the delivery of said training materials to the Health Organizations or Institutions.

## **XVII. IMPLEMENTATION AND FOLLOW-UP**

In order to enforce the ethical provisions and commitments set forth in this Code, Fenin will have the necessary resources to ensure its implementation and compliance, establishing the procedures to be followed in each case.

The Deontological Committee, the Monitoring Committee of 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 composition, functions and procedures applied to these Committees are included in Section 19 of the Code.

## **XVIII. CONFIDENTIALITY OF DATA AND COMPETITION**

The Companies shall ensure that personal data, patient data and other confidential data are maintained and used in accordance with current legislation in this area.

The Companies shall respect free market competition by complying with the current regulations designed for its protection.

## **XIX. REGULATION OF THE CODE CONTROL BODIES, PROCEDURES AND INFRACTIONS AND SANCTIONS**

The Deontological Committee, the Ethics and Compliance Unit and the Ethics Code Monitoring Committee, 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 regime of infractions and sanctions that must be applied in case of breach of the Code.

### **1. Code control bodies**

#### **1.1. Deontological Committee of the Healthcare Technology Sector**

##### **1.1.1. Composition**

The Deontological Committee of the Healthcare Technology Sector will be appointed by Fenin's Board of Directors, and the term of office of three years will be renewable from the time of its appointment. Members who cease to hold office before the expiration of their term of office shall be replaced for the remainder of their term of office.

The Deontological Committee will be formed by:

- Three members, all professionals of recognized prestige in the field of health and/or ethics, who have no relationship with companies to avoid potential conflicts of interest.
- A Secretary, who will be the Legal Advisor of Fenin, with the right to speak but without voting rights.

##### **1.1.2. Operation**

In order for the Committee to be validly constituted, it should have the participation of the three members and the Secretary.

It shall be convened as often as necessary, after the Secretary has summoned, indicating the agenda, at least 48 hours in advance, except meetings due to emergency reasons, in which case the above period may not be fulfilled, the emergency being duly motivated.

Agreements 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 from any field and invite them to attend their meetings, but without the right to vote. Likewise, it may carry out as many actions as it deems necessary to verify the facts that are the subject of the complaint, and may request the collaboration of the Ethics and Compliance Unit, or third parties as it deems necessary.

The Committee may obtain copies or information of any document or evidence it deems relevant, including copies of communications sent to the competent health authorities, as well as copies of the internal manuals and procedures of the companies that establish the standards used by their employees in the performance of their work to interact with HCPs.

The Secretary will perform the following functions:

- Convening and coordinating the meetings, drawing up the agenda and preparing the minutes of the meetings.
- Communication with the parties involved in the activities of the Committee.
- Keeping records of complaints and enquiries received.
- Preparation of the activity reports of the Committee.
- Coordination and communication with the other bodies and forums of Fenin.
- Coordination and management of the procedures regulated in these Regulations.

The members and the Secretary of the Committee shall maintain the confidentiality of the information to which they have access to as well that regarding their deliberations and actions.

### **1.1.3. Tasks**

The Deontological Committee shall:

- Ensure implementation of the Code.
- Issue circulars, through the Secretary, on interpretations of the Code in order to facilitate compliance.
- Receive and process claims of possible non-compliance with the Code.
- Mediate between the parties involved in a claim, seeking the agreement on disputes in matters subject to the Code.
- Transfer to the Autocontrol Jury, via the Secretary, of the claims received, except when the Ethics Committee has achieved an agreement between the parties.

- Issue opinions of a technical or deontological nature on issues presented by Fenin in the scope of its actions, except for specific voluntary consultations on specific promotional or advertising material that should be prepared, as appropriate, to the Technical Office of Autocontrol, that will resolve them by issuing the corresponding prior consultation report or "Copy advice", in accordance with its Regulations.
- To resolve, on a confidential and non-binding basis, doubts and queries regarding the application of the Code that are voluntarily raised.
- Propose to the Monitoring Committee motivated amendments to the Code and/or the standards that develop it.

## **1.2. Ethics and Compliance Unit of the Healthcare Technology Sector**

### **1.2.1. Composition**

The 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 Fenin's organizational structure, which will enable the necessary budgets for this purpose.

### **1.2.2. Principles of action**

Propose to the Monitoring Committee motivated modifications of the Code and/or the standards that develop it.

- Confidentiality: The Unit will maintain the confidentiality of the information to which it has access as well as its actions.
- Equality: The Unit will act objectively and will treat all companies fairly in the same way.
- Truthfulness: All actions carried out by the Unit shall be considered true and faithful.
- Independence: The Unit will be independent of the interests of the parties and will enjoy autonomy to carry out its work.
- Diligence: The Unit will use the most appropriate means to guarantee maximum agility in the management of the procedures under its responsibility.

### **1.2.3. Tasks**

It is the responsibility of the Unit to carry out the following functions:

- Ensure implementation of the Code.
- Perform counselling, guidance and training in relation to the Code.
- Prepare proposals for the Monitoring Committee for amendment, improvement and updating of the Code.

- The prior review of non-international training events organized by third parties, according to the corresponding provisions of the Code.
  - The request to MedTech Europe for the evaluation of international training events organized by third parties, when required by any Company.
- The revision of the declarations to obtain the ethical seal and to grant it, for requesting entities that fulfil the requirements.
- The revision of the audit reports of the entities that have the ethical seal.
- The procedure of withdrawal of the ethical seal.
- The preparation of activity reports for Fenin's governing bodies, when required.
- The management of the procedure of prior review of educational events organized by third parties, and to appear on site to be able to obtain information during the celebration of the events.
- Issue warnings or make recommendations of a preventive nature to the Companies when there is a risk of infringement.
- To make claims to the Deontological Committee if from previous investigations it may be deduced the existence of an alleged breach of the Code.
- Issue clarifying notes on the specific matters within its competence.
- Issue certificates that allow accrediting the conformity of the Code with a specific activity. Specific promotional or advertising materials are excluded, which should, where appropriate, be voluntarily forwarded to the Autocontrol Technical Office for prior consultation report or "Copy advice".
- Carry out the investigation procedure necessary to gather evidence to determine if there may be possible breaches of the Code and to make a subsequent claim.
- Get the opinion and assistance of experts from any field. Likewise, it may carry out as many actions as it deems necessary to establish the facts investigated prior to the preparation of a claim.
- Collect copies or information of any document or evidence it deems relevant, including copies of communications sent to the competent health authorities, as well as copies of the internal manuals and procedures of the Companies that establish the standards used by their employees in the performance of their work to interact with HCPs.

### **1.3. Autocontrol Jury**

By agreement of its governing bodies, Fenin shall submit, under the terms specified by agreement, the control of compliance and interpretation of the Code to the Autocontrol Jury, which is governed by its own Rules of Procedure.

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



### **1.3.1. Tasks**

With regard to the application of the Code, the Autocontrol Jury will resolve claims brought against a Company in light of the ethical rules contained therein, elucidating, in each case, whether or not there has been an infringement of said Standards and their severity.

In addition to declaring the wrongness or unlawfulness of the commercial, advertising or promotional activity in dispute and requesting an injunction or modification or rectification, the decision of the Autocontrol Jury that determines the infringement of the claimed action will impose, when it corresponds, to a sanction to the Company reported in accordance with the list of infractions and penalties provided for in this section, weighted according to the specific circumstances 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 one of the parties), it may request the support of external experts of recognized solvency and necessary independence, in order to assist them in the questions raised by the Jury for the clarification of those issues of a technical or scientific nature relevant to the proper resolution of the matter.

The experts will 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.

Subject to the need for expert intervention in a particular matter, the Jury will propose a list of experts of recognized solvency and necessary independence, who will communicate to the parties to the conflict so that they can prepare, as the case may be, any objection to one or more of the experts included on that list. As a consequence of this process, the Autocontrol Jury will decide the appointment of the expert who will report the said matter. If deemed necessary or the parties request their nomination, the Autocontrol Jury may appoint up to three experts. In any case, the parties may freely, and at their own cost, provide the expert evidence they deem appropriate.

### **1.3.2. Notification and execution of the decisions of the Autocontrol Jury**

The resolutions issued by the Autocontrol Jury in application of the Code will be immediately communicated to the interested parties for compliance, as well as to Fenin for its due execution and, as the case may be, to proceed with the recovery of the pecuniary sanctions imposed by the Autocontrol Jury. Subsequently, the resolutions will be made public through their inclusion in the magazine, website or other means of Autocontrol, without prejudice to the measures of disclosure of the full text of the resolutions that Fenin agrees in each case.

### **1.3.3. Previous Consultation**

In order to ensure the adequacy of their advertising and promotional activities to the Code, the Companies may send to the Technical Office of Autocontrol, for their prior examination through the system of prior consultation or confidential copy and non-binding, all the publicity and promotional elements or materials of health products in those cases where there are doubts as to their suitability according to the provisions of the Code. The Technical Office will respond to these queries within three business days of the request.

The Requesting Companies will provide the Technical Office of Autocontrol all information related to the advertising being examined by the latter in order to perform 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 of the allegations and documents delivered by the advertiser, will decide the confirmation or revocation of its content. In the event of a claim against the advertising or promotional action under examination, the Section of the Autocontrol Jury that would have known of that review will refrain from participating in the procedure to be followed before the Autocontrol Jury.

The companies will not use for advertisement neither the content of the previous consultation or copy advice or the fact of it having been requested.

However, they may submit such prior consultations before the Courts of Justice, administrative authorities and the Jury of Autocontrol in case of litigation. The Autocontrol Jury shall presume the good faith and lack of intentionality of the Company that had carried out an advertising or promotional action based on a prior consultation or positive copy advice issued by Autocontrol, unless it had been contributed or known during the procedures of processing the claim, facts or relevant circumstances that had not been brought to the attention of the Technical Office at the request of prior consultation.

The processing of the prior consultations or "copy advice" of Autocontrol within the framework of this Agreement shall entail a fee that will be agreed by Fenin with Autocontrol.

#### **1.4. Monitoring Committee for the Code of Ethics**

##### **1.4.1. Composition**

The Monitoring Committee will be formed by:

- A member, entitled to speak and vote, corresponding to each Sector of Fenin
- A coordinator, who will be a member of Fenin's Board of Directors
- A Secretary, who will be the Legal Advisor of Fenin, with the right to speak but without voting rights.

The members of the Monitoring Committee will commit themselves to treat the topics discussed during their meetings with the utmost confidentiality, without at any time being able to share or use the information obtained through it for purposes other than those of the Committee.

The members of the Committee shall be appointed by the corresponding Boards of Directors of the Sectors, the terms of office shall be two years and shall be renewable.

The Sectorial Boards of Directors may replace their representative in the Monitoring Committee earlier than the aforementioned term of two years.

The coordinator of the Committee will act as its contact person before the governing bodies of Fenin, and will chair the meetings of the Monitoring Committee.

The Secretary will perform the following functions:

- Convening and coordination of meetings, preparation of agenda and minutes.
- Preparation and drafting of the Committee proposals for the modification, improvement and updating of the Code.
- Issue communications from the Committee to third parties

#### **1.4.2. Tasks**

It is the responsibility of the Monitoring Committee to carry out the following functions:

- Analyse the implementation of the Code and discuss and agree specific proposals aimed at better compliance and disclosure.
- Propose to the Board of Directors of Fenin any revisions to the Code that it deems necessary.

#### **1.4.3. Operation**

The Monitoring Committee will meet when the coordinator deems it necessary or at the request of five of its members.

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

### **1.5. Conflicts and Disciplinary Committee**

#### **1.5.1. Composition**

Its composition will be in agreement with the provisions of the Fenin Internal Statutes and Regulations.

#### **1.5.2. Tasks**

Regarding the application of the Code, the Conflicts and Disciplinary Committee will be responsible for ensuring the execution of the resolutions issued by the Autocontrol Jury, including the effective and prompt collection of economic sanctions imposed for any breach of the Code.

#### **1.5.3. Operation**

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

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

Communications between the Companies, the Conflicts and Disciplinary Committee and their collaborating bodies may be carried out by electronic mail or other electronic means of remote communication.

## **2. Procedures**

### **2.1. General Rules**

The deadlines indicated in days in the following procedures will be understood to refer to working days in the city of Madrid according to the official working calendar published in the Spanish Official State Gazette.

The calculation of these days will be carried out starting from the next one in which the notification of the action in question takes place.

The month of August and the days between December 15 and January 6, inclusive, will be excluded from the calculation of the terms.

In justified cases, the Secretary of the Committee may agree on an extension of the deadlines, which shall not exceed half the deadline established in the procedures.

Communications and notifications within the framework of the procedures will be carried out by electronic mail, and must be recorded by the interested party, as well as the date, identity and content of the notification, all these data being incorporated in the file.

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

### **2.2. Consultation Procedure**

The Companies may submit to the Ethics Committee consultations that will be confidential and non-binding on any issues related to the Code; with the exception of specific consultations on specific promotional or advertising material that should be prepared, as the case may be, to the Technical Office of Autocontrol, which will resolve them by issuing the corresponding prior consultation report or "copy advice" in accordance with its Regulations.

The consultations will be sent via e-mail to the Secretary of the Deontological Committee, who will keep them in his records.

The consultations shall contain at least the following information:

- Name of the company making the inquiry.
- Text of the query, expressed in a clear and simple way, specifying the provisions of the Code for revision.

In addition, the applicant may submit any documentation deemed appropriate for a better understanding and resolution of the consultation carried out.

The consultations shall be answered within a period not exceeding fifteen days after their receipt by the Secretary of the Committee.

The Deontological Committee may request from the Requesting Company the information and documentation it considers relevant and convenient. Likewise, when it deems it necessary, the Committee may request the collaboration of the Monitoring Committee before responding to the consultation.

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

The companies will not use for advertisement neither the content of the consultation or the fact of requesting it. However, they may submit such prior consultations before the Courts of Justice, administrative authorities and the Autocontrol Jury in case of litigation.

The Committee shall inform the other supervisory bodies about the consultation and the response given, keeping the confidentiality of the requesting Company.

### **2.3. Procedure for Requesting the Evaluation of Educational Events Organized by Third Parties**

The Companies must communicate to the Ethics and Compliance Unit any Educational Events organized by third parties whether they are going to give a Grant to a Health Organization or Institution or to a Professional Event Organizer with the purpose of sponsoring the attendance of HCPs to the Event.

This will not be necessary if the Event has already been analysed and reviewed by the Unit. The Companies will be able to consult the Events analysed in the Fenin website, which will include the list of revised Events and the evaluation of the Unit.

The communication to the Unit must be carried out at least 60 days before the event, and it should include:

- Name of the company.
- Name of the Event.
- Entities involved in the organization of the Event (scientific and professional societies, technical secretariat, etc.).
- Medical or health speciality to which it is addressed (cardiology, pulmonology, etc.) and to the regional scope of the event (national, autonomous community, etc.).
  - Approximate total number of participants in the Event.
- Dates of the Event.
- Location (city and location - congress centre, hotel, etc.).
- Event Program (educational and social, if any).

The Unit will facilitate a procedure for the submission of communications by electronic means to ensure the agility of the process, its effectiveness and the confidentiality of the data.

The Unit may request additional information from the companies and entities involved in the organization of the Event, and may propose corrective measures that allow the adaptation of the Event to the provisions of the Code.

The Unit may initiate the complaints procedure against Companies participating in an Event without complying with the corrective measures identified and/or in breach of the provisions of the Code.

The Unit shall publish its assessment of the Event on the Fenin website within five working days of receipt of all the information and clarifications requested.

The Companies will communicate through their legal representative to the Unit up to a maximum of two persons who will act as responsible for the communication of Events by each Company and which will act as contact persons to the Unit.

The Unit will keep a record of all the communications received and of their evaluations, which will be confidential, adhering to current legislation, among others, regarding the protection of personal data.

#### **2.4. Procedure for Investigating Breaches of the Code**

All Companies accept the obligation to collaborate in good faith and actively in any investigation procedure. The procedure will be initiated by the head of the Unit after a well-founded suspicion of an infringement of the Code.

To this aim, the Unit responsible shall open a research file that should have documentation regarding:

- The description of the facts that give rise to the opening of the file and the section of the Code that may have been infringed.
- All evidence gathered.
- All the measures undertaken
- The conclusions of the investigation.
- The completion of the procedure.

The procedure will end with the filing in case it is not possible to prove a violation of the code, or with a complaint to the Ethics Committee according to the procedure established for this purpose.

In the event that the Unit considers that there is sufficient evidence of a breach of the Code, it shall communicate the results of the investigation via e-mail to the affected company, allowing a period of 5 working days to submit any remarks and arguments and to provide any evidence it deems appropriate for its defence.

Once this deadline is concluded without any arguments or if they were not conclusive regarding the responsibility of the company in relation to the facts, the Unit will initiate the claims procedure.

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

- Make requests for information and request as much information and documentation as necessary.
- To participate in Events both own and organized by third parties.
- Contract the services of third parties in the event that the use of external resources is necessary to carry out the investigation. If it has an economic impact, it will be fully assumed by the investigated Company if it is finally resolved by agreeing that there has been an infraction of the Code (both in the mediation and resolution phases), regardless of the corresponding sanction.

### **2.5. Claims Procedure**

The procedure may be initiated by:

- Any company
- The Ethics and Compliance Unit

In order 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 his representative, who must prove their faculties.
- (ii) Name and address of the respondent.
- (iii) Detailed presentation of the facts constituting the alleged infringement of the Code, as well as specification of the section of the Code that is considered infringed.
- (iv) Documents and means of evidence on which the claim is based. In addition, the complainant may propose in his statement any other means of proof to prove the facts subject to a claim, which will be practised if the Deontological Committee deems it necessary.

Only complaints related to events that have been carried out in the last twelve months and which are not subject to administrative sanctioning or judicial proceedings will be processed.

If the complaint does not contain the required information, the Secretary of the Deontological Committee will immediately notify the claimant, requesting the information of the claimants within five days to complete the file.

Once said deadline has elapsed without the claimant providing the required information, the Secretary will agree to close the file, informing the claimant.

When the complaint is complete, the Secretary of the Committee shall, no later than three working days, transfer it to the subject of the claim, so that the latter may make such arguments as he deems appropriate within five days of receipt of the complaint.

Subsequently, the Secretary will send a copy of the file along with a summary note to the members of the Deontological Committee, in order to discuss the issue as soon as possible.

As soon as possible, the Secretary shall convene the parties to a mediation meeting before the Committee in order to reach an amicable settlement between the parties, solving and filing the complaint without having to transfer it to Autocontrol Jury.

In case the parties reach an agreement, 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:

- The acknowledgment of the infringement by the respondent.
- Corrective or amendment measures agreed to repair the damages and prevent it from recurring in the future.

The parties shall immediately comply with the agreement, and the Conflict and Discipline Committee shall verify its execution.

If the parties do not reach an agreement in the mediation phase, the Secretary will transfer the file to the Autocontrol Jury within a maximum of two days from the mediation meeting.

In the event that the Committee considers there are urgent reasons recommending a prompt resolution of the complaint, within five days of receipt of the complaint, the Committee shall forward it directly to the Autocontrol Jury without attempting mediation.

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

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The Companies undertake and commit to:

- Respect the principles and obligations of the Code and respond for its non-compliance.
- Comply and make their respective subsidiaries and affiliates of the Healthcare Technology Sector, distributors, agents or any collaborator comply with the Code in their operations in Spain.

Any breach of the Code will be classified as minor, serious and very serious, according to the following criteria:

- Scale of the infringement and, in particular, its potential risk to the health of patients.
- Impact on the health or scientific profession, or society in general, of the infringement.
- Recurrence of infringement.
- Damage to the image of the Healthcare Technology Sector

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



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

- a) Degree of intentionality.
- b) Non-compliance with previous warnings.
- c) Recurrence of infringement.
- d) Concurrence of several violations in the same event or promotional activity.
- e) Economic profit for the Company derived from the infringement.

In compliance with the criteria indicated above, the Jury will agree to impose the following financial penalties:

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

In the event of absence of the mandatory communication of Educational Events Organized by Third Parties, the penalty will be EUR 1,000 for each Event not communicated in good time and in an appropriate manner to the Unit.

In the case of presentations of several claims manifestly unfounded, the Jury may impose the pecuniary penalty that 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 violation, the Deontological Committee may propose to Fenin's Board of Directors to remove the Company from the Federation, in accordance with the procedure established in its Statutes and Internal Regime Regulations, not being able to be admitted at least one year after the removal, paying all the fees that would have been paid during the period of dismissal.

In cases in which the Jury considers the existence of an infringement and the Company concerned acted in good faith in accordance with a previous consultation carried out by the Jury according to the provisions of the Code, provided that there is a similarity between the facts and the terms of the Consultation, the Jury will resolve to urge the Company to stop this promotional behaviour, but it will not impose any further sanction.

Fenin will execute the sanctions imposed by the Jury and those agreed during the mediation phase. With the amount of financial penalties, a special fund will be set up in Fenin, which will be used to finance the cost of the program for monitoring and implementing the Code, as well as activities to promote compliance with the Code and training in this area.

The resolution adopted by the Autocontrol Jury will determine which party will bear the costs arisen from the processing of the claim as well as the rates accrued to Autocontrol and the costs of contracting services carried out during the investigation of the procedure, according to the following rules:

- If the claim is held or rejected in full, the Company whose claims are rejected shall bear the aforementioned expenses.
- If the claim is partially held or rejected, each party will bear its own expenses and those generated from the same (evidence presented and submissions made during the claim, etc).

## XX. ENTRY INTO FORCE AND REVISION

The Code will enter into force on January 1<sup>st</sup>, 2018.

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

