

## **CODE OF ETHICS**

### **CHAMBER OF MEDICAL DEVICES AND HEALTHCARE SUPPLIES NATIONAL ASSOCIATION OF COLOMBIAN BUSINESSMEN**

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## **I. INTRODUCTION**

The Chamber of Medical Devices and Healthcare Supplies of the National Association of Colombian Businessmen groups domestic and international firms, vendors (manufacturers and importers) of diagnostics products, biomedical equipment, supplies and healthcare industry products, these items being generically referred to at this time as Medical Devices, seeking to make a contribution to preserve market-specific stability and development through subject-matter research on industry-specific issues, together with the Medical Device and Healthcare Supply Industry, with the National, Departmental and Local Governments, overseer authorities and other domestic and international players within the system.

The nature of the usage and product life cycle of medical devices involves an interaction with individuals handling them, irrespective of whether or not they are healthcare professionals. Products marketed under the name “medical devices” include a range of assets enabling the diagnosis, prevention, oversight, treatment, therapeutic intervention or relief of a condition, disability or injury, as well as the modification of or support for an anatomical structure in a physiological process.

This document will compile guidelines that structure the interactions of the members of ANDI's Chamber of Medical Devices and Healthcare Supplies and their relationship with those individuals and legal entities that lease (rent), have usage lending activities connected with, use, repair and/or procure medical devices.

All the membership of the Chamber and its distribution chain undertake to subscribe to this Code of Ethics. Member-companies of the Association are to promote ethical business practices and an socially responsible industrial conduct.

## **2. PURPOSE**

This document seeks to establish ethical standards for ensuring a sound, effective and appropriate interaction amongst member-companies of ANDI's Chamber of Medical Devices and Healthcare Supplies and those individual or institutions that operate, distribute and/or use medical devices to the extent that medical decisions become focused on patient benefit, all of which being within the framework of Colombian Law.

## **3. DEFINITIONS**

### **Promotional Activity**

It's any activity leading to the disclosure and dissemination of any uses, indications and features of medical devices and healthcare supplies. Within the framework of the Code, such promotional activity also includes any advertising targeting parents or consumers, either directly or indirectly, provided this is permissible under current law.

### **Entertainment Activity**

**Entertainment** refers to the set of activities that enable human beings to use their time off for enjoyment, thus forgetting momentarily about their concerns.

### **Medical Device**

These are products in the diagnostics area, such as reagents, biomedical equipment and other supplies.

### **Healthcare Industry Institutions**

These are the Health- Care Service Provider Institutions (abbreviated "IPS's" in Colombia), Health-Promoting Entities [government contracted HMO-type organizations] (abbreviated "EPS's" in Colombia), Special Arrangement Healthcare Entities [government employee plan medical insurance offerors], local institutions and -- in general-- any institution that is responsible for or has any decision-making power over the procurement or use of medical devices and healthcare supplies.

### **Sponsorship**

It's the financial support to healthcare industry institutions for the conduct of an educational event. FOR PROFESSIONALS.

### **Educational Contribution**

Events organized by a third-party for providing educational or scientific knowledge or standards drafted for the promotion of scientific knowledge and effective health care may be sponsored by any member while also following such guidelines as provided for in its in-house policies.

### **Healthcare Professionals**

These are physician providers, dentists, optometrists, bacteriologists, nurses, nutritionists, physical therapists, respiratory therapists, speech/language pathologists, psychologists, audiologists and --in general-- those in any health-science field or specialty or any other person who practices a profession enabling him/her to prescribe, recommend, acquire, dispense or manage a product in terms of patients or customers.

#### **4. TRAINING IN AND EDUCATION ON PRODUCTS AND SERVICES**

Medical technology offeror companies are responsible for providing appropriate training in and education on their products and services, meaning there is an obligation to provide training in safe and effective use; these training programs may include hands-on sessions.

User training is to be conducted in appropriate educational friendly settings; at times, these training sessions may be held in venues where medical devices are in operation.

#### **5. EDUCATIONAL CONFERENCE SUPPORT**

Continuing education provided to healthcare professionals on the appropriate use of medical devices shall be for the purpose of complementing, updating and preserving the skills of the holders of any occupation, profession or specialty and improving services by strengthening healthcare industry talent.

It is preferable that support for events promoting the above-mentioned purposes be provided through the institution undergoing the training, so that it has control over the program, instructors, and educational methods and materials, as strictly devoted to educational activities, without deriving any benefit whatsoever from the products.

Financial assistance may be given to an organizer for funding any meals and snacks provided to attendees; these meals and snacks are to bear a relationship to the time and purpose of the conference, and they may not be away from the space assigned for medical or professional education in general.

Member companies may allow certain third parties to provide financial assistance to conferences:

1. If the meeting is mainly devoted to the promotion of scientific and targeted educational activities.
2. If the trainer institution or sponsor of the conference elects the healthcare professionals who are to attend. These requirements ensure content integrity and an independent selection of attendees.

Companies may also buy or rent spaces feasible for showing their products at these conferences.

Companies may cover the costs of training the individuals who will be operating any medical technologies being offered.

## **6. SALES AND PROMOTIONAL AND BUSINESS MEETINGS**

So long as domestic law governing these practices is not violated, promotional meetings may be held to have both healthcare professionals and professionals responsible for choosing or selecting medical technologies become familiar with the features, specifications, comparative advantages and prices of a given product. Should this meeting involve a tour of or visit to any production plant, corporate headquarters international event or demonstration of (non-portable) equipment whose carriage is difficult, a per-diem allowance (lodging, food and transportation) may be provided for their carriage.

Whenever meetings are held for discussing products, negotiations or terms of sales in venues other than the location of the Healthcare Professional (for instance, visits to manufacturing plants), the member may cover reasonable costs for lodging and transportation in accordance with both the in-house policies members have for this purpose and such guidelines as provided for in this Code.

In terms of these meetings for exchanging information, reasonable food expenses may be covered. Members shall not cover expenses of any guests and companions of Healthcare Professionals participating in said meetings.

Costs covered for attendees are to be strictly limited to those professionals who are relevant to the information that is going to be shared at said visit or meeting.

As a result, partner-members may not provide or pay for any food, per-diem allowances, lodging or other costs applicable to the spouses of guests of Healthcare Professionals or any other person who does not have a good-faith professional interest in the information to be shared at the meeting.

No incentive whatsoever may be offered to any healthcare professional as consideration for any use, promotion, sale, recommendation or indication of medical device and healthcare supply industry products.

## **7. CONSULTING AGREEMENTS**

Occasionally, healthcare professionals provide valuable information to medical technology developer companies. Therefore, contractual agreements for research, product development, presentations at training sessions and other services may be paid to such healthcare professionals who are suitable to perform this; these types of payments should be given legal form by way of a contractual agreement providing for the scope of same and giving legal form to such performance.

Professionals may be engaged for providing services which are consistent with their area of education or specialization; therefore, the individual who may be engaged can be compensated proportionally to the complexity and relevance of professional services, in addition to any reasonable expenses for transportation, lodging, and meals, all being limited to the time frame in which the professional is devoted to service provision. The per-diem allowance paid for transportation, food and lodging may only be extended to such days immediately prior and subsequent to the official agenda of the event or service, unless logistics and transportation issues substantiate otherwise.

Engaged professionals are to have full independence in giving their opinions and providing their analysis, reporting any conflict of interest, if any, to event organizers and participants, provided, however, that such information is part of the event's official agenda.

Standards provided for to perform these contractual agreements are as follows:

- Contractual agreements of this nature between healthcare professionals and companies are to be reduced to writing and describe every single service to be provided. Whenever there is a contractual agreement for clinical investigation, an investigational protocol is of the essence.
- Consulting agreements are to be entered into whenever there is a substantiating need therefor.
- Provisions on Payment of Royalties: Healthcare service companies may develop intellectual property in connection with a product, technological development or an intellectual property licensing agreement if they are active participants in such development.
- All contributions are to be documented in an appropriate manner

If there is any previously identified and legitimate request for any engaged services, it is not to be for the purpose of inducing service providers to buy the products from the members. Any work performed by said healthcare professionals is to be carried out in an appropriate location in accordance with the type of services being provided.

Selection of service-provider healthcare professionals is to be made exclusively on the basis of their experience and qualifications to cover a stated need. The number of healthcare professionals borne in mind for service engagement is to be substantiated in full on the basis of aspects including but not limited to the event's program, the number of participants, [and] the number of sessions.

Any compensation is to be determined based on the fair market value and in no manner whatsoever in connection with the volume or amount of any past, present or future business with said health-care professional.

Engaged services are to be documented in writing with an appropriate description of the service being provided; any consideration therefor is to be requested, authorized and stated prior to the provision of such service. Any payment is to be made to the order of the service provider, upon applying any local taxes and related legal requirements. Payments may not be made in cash.

Members may pay for or reimburse any reasonable and documented expenses for food, transportation and lodging incurred by healthcare professionals in connection with the provision of services. This is to be formally documented and authorized.

- Any professionals involved in developing a product or technology with their know-how may enter into intellectual property licensing agreements.
- If a healthcare professional provides any original, innovative or --in the belief of the company-- significant contribution, it is to be documented appropriately to give that person any credit as deserved.
- Any payment to a healthcare professional for his/her intellectual property contributions is to be based on factors for preservation of impartial decision-making and avoidance of undue influence.

Any person who observes this Code is to abide by the rules on competition; and any activities in conflict with the rules on competition and for unfair competition may not be conducted at any time.

## **8. ENTERTAINMENT ACTIVITY**

Any company interactions with healthcare professionals are to be strictly limited to the professional environment, and they are to be a conduit for the uneventful flow of any medical or scientific information for enabling improved patient services.

Payment may be provided for any reasonable costs of food, cocktail receptions and entertainment connected with a meeting's program. Nevertheless, said activities are to have their time and focus subjected to the training or educational objective of any meeting.

## **9. PRESENTS**

A Company may occasionally provide Healthcare Professionals with items that benefit patients or have an authentic educational role for Healthcare Professionals.

Companies may not offer cash or any equivalent thereof.

## **10. MEALS ASSOCIATED WITH INTERACTIONS WITH HEALTHCARE PROFESSIONALS**

Food is required whereas a company's relationship with healthcare professionals may necessitate spaces for submitting results, sharing scientific, medical or educational information and some workdays. These meals are to be moderate and occasional, and their cost may not give the appearance of undue influence.

Accordingly, time-sensitive meals may be provided, and the following requirements are to be met:

**Requirement 1. Purpose-Based.** They should not be part of an entertainment or recreational activity; they should only be offered as a result of scientific, educational or business informational exchanges.

**Requirement 2. Locations.** Based on stated purposes, these meals should be served in locations enabling scientific discussions in which professional information can be exchanged easily and dynamically.

**Requirement 3. Participants.** These meals may only take place whenever there are participants connected with the purpose of the meeting.

## **11. INFORMATION**

A company may assist in resolving clinical symptoms and improving healthcare services by providing those individuals who make decisions concerning the use of medical devices with exact and objective information to enable them to choose the given medical technology that conforms to the needs of specific clinical symptoms.

The following activities are permissible:

- ⊗ The clinical value of the company's medical technologies, services and procedures may be specified.
- ⊗ Exact information may be provided concerning the processes in which the products offered by the company are used, including that on a specific moment within the process and their effect on healthcare services.
- ⊗ Furnish information designed for providing technical or another type of support to assist in the appropriate and efficient use or installation of the company's Medical Technology.



- ⊗ Facilitate patient access through their ratio to healthcare professionals [and] assistance in patient coverage decision-making by those who choose or select and pay for medical technologies.
- ⊗ The company may provide information in connection with its medical technologies if it's exact and objective.
- ⊗ A company may not unduly interfere with or attempt to change any decision by a healthcare professional concerning the specific technology he/she elects as ideal for specific clinical symptoms.
- ⊗ A company may not obstruct clinical decisions for providing coverage, reimbursement and cost-effective healthcare support; for instance, it is not to offer any services at no charge that do away with operating costs or other expenses that may be incurred by any healthcare professional.
- ⊗ Companies are not to suggest or agree to arrangements for invoicing any services that are not medically necessary or become involved in any fraudulent practices for obtaining inappropriate payments.

## 12. SUPPORT AND CONTRIBUTION

A company may provide support for or assistance in research [and] educational activities and make charitable donations, but it may not use them for avoiding responsibility or as an unlawful incentive. Thus, in-house areas of companies are to be clear on the processes for these types of actions; basic criteria are to be:

- ⊗ Clear criteria for providing said support.
- ⊗ Implement procedures to have transparency in said support and avoid that these be used as unlawful incentives.
- ⊗ This support is to be strictly documented.

**Support for Research.** Such support may be provided for enabling research that results in valuable scientific and clinical information which may lead to developing improved treatments, improved diagnosis, [and] better healthcare services; such support is not to have any tie to the procurement of medical Technologies.

**Educational Contributions.** They may be provided to conference organizers or educational institutions to support the education of medical students, residents, [and] educational specialists (Fellowships.) They will not be given directly to any healthcare professional at any time.

**Charitable Donations.** Monetary donations or those of your products are welcome for the purpose of achieving better access to medical technologies by less fortunate populations. These donations are to be made to charitable organizations, and it is the company's responsibility to ensure and ascertain that such is the purpose of these companies.

Donations are part of the commitment of members to the community, and they reflect our identity as responsible corporate citizens. All donations are to be made as follows:

- There is to be a history of the submission of a formal application and an appropriate evaluation which guarantee that these are not made to gain any undue influence or for any inappropriate events or activities.
- Donations are to be made to private care institutions or other non-profit organizations authorized to receive said donations under applicable local law. Donations may not be made at any time to either individuals or on behalf of a healthcare professional.
- Donations are not to involve obtaining any marketing advantages or be contingent on any past, current or future sales. Members are to consider implementing procedures which ensure that donations are made and documented adequately.

### **13. SAMPLE AND EVALUATIONAL PRODUCTS**

A company may provide products at no cost to healthcare professionals under the following circumstances:

- ⊗ If products provided at no cost will be used in an evaluation or demonstration. In terms of demonstrations, the time, purpose and conditions of same shall be documented as provided by law as to samples which have no commercial value.
- ⊗ Single use products (either consumable or disposable) are to be used for evaluational purposes; the number of these products provided at no cost may not be in excess of the reasonable amount required for the evaluation. The results of the evaluation are to be shown.
- ⊗ Multiple use products, including software which is to be provided within a reasonable time frame to enable a correct evaluation.
- ⊗ Usually, products provided to healthcare professionals for demonstrations are non-sterilized single use products; thus they are used to educate, raise the awareness of or train healthcare professionals or their patients. For instance, samples used to have the patient become familiar with the types of devices that might be implanted in him; thus samples are not applicable to patients. With these types of products, companies should provide manuals, sample products, [and] a statement which specifies the nature of these products.