abimed
Associação Brasileira da Indústria de Alta Tecnologia de Produtos para Saúde

PRODUTO NEUTRO de CARBONO
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CODE OF CONDUCT | 2015

Adopted by the Associação Brasileira da Indústria de Alta Tecnologia de Produtos para Saúde

abimed

Acelerando a inovação no Brasil

Ethics has always been a priority for the Brazilian Association of High Technology Industry of Health Products (Abimed). Nine years have passed since the entity has launched its first Code of Conduct, establishing ethical behavior standards and relationship with its associates. It was the first Code in the segment and in Brazil. It was the first time an association proposed a set of principles to guide the activities of companies within the health field.

As of then, the Code has been reviewed and updated many times so that we come up with this current version, which is the result of thorough work carried out by the Ethics Committee of Abimed for two years. The Committee is also liable for the actions so that the Code is enforced by the associates and for the analysis and procedures in case of misconduct.

The document we launch now sets a new stage in the process of learning and improvement started in 2006 and that will continue forever – just like the changes in the country, the corporate world and the relationships thereof.

For us at Abimed the priority is to allow the Code to be a living instrument to guide the daily practice of associated companies, especially small and mid-size companies, which may not have a compliance department. The enforcement of the Anticorruption Act makes this tool even more important and necessary.

The Code of Conduct reinforces Abimed's commitment towards health, the society and the country. That is why only companies that respect and follow the Code and behave according to ethical and transparent principles can associate to and remain with the entity.

As a representative of the high technology industry, Abimed is in charge of contributing towards the establishing of a business environment that favors the development of innovation and its access by population. This is only possible if ethics is present and prevails in the entire health system.

Fabrício Campolina
President of the Administration Council

Carlos Alberto Goulart
CEO

Abimed's Ethics Committee launches the new version of its Code of Conduct, based on two strategic key elements: innovation and ethics, so as to meet and prepare for the highest corporate integrity standards that guide its actions.

In addition to carrying out the biannual reviews as provided in our statute, the purpose of reviewing the Code is the alignment with the current situation of major changes in the Brazilian regulatory scenario, considering the fact that the legislation that holds legal entities liable for actions against public administration became effective in 2014.

Globally, we also see an increasing trend towards anti-corruption, which led to initiatives such as the establishment of the UN Global Compact and the OECD convention (Organization for Economic Cooperation and Development).

As part of the review of the Code of Conduct, many aspects were taken into account, in special the importance of the relationships between the industry of health products and the healthcare professionals. This relationship is extremely important to ensure the proper and safe use of health products and for the development of new techniques and procedures that will ensure the patients' well-being and health.

On account of that, continuous medical education was given special attention during the review, which tried to ensure the establishment and the preservation of transparent relationships between the healthcare professionals and the industry of health products.

The innovative nature of this version of the Code can also be seen in the incorporation of other aspects that are essential to the supply chain of health products, in special the recommendations that the companies follow compliance standards regarding third parties and intermediaries, which play a significant role in the marketing and operation of these products.

This way, Abimed reinforces its commitment towards transparency and ethical and honest conduct of its associates in the relationships with healthcare professionals, government agencies and third parties not only by this document, but

Denis Jacob
President of the Ethics Committee

I. Preamble

The Associação Brasileira da Indústria de Alta Tecnologia de Produtos para a Saúde ("ABIMED") is an organization that brings together advanced technology companies ("Companies") in the areas of manufacturing, importing, exporting, and distributing Advanced Medical Technology and hospital products. ABIMED works to improve the Brazilian medical/hospital services through the importation of equipment and quality materials at competitive prices compatible with available Advanced Medical Technology. ABIMED promotes progressive simplification of importation processes and systems and the reduction of technical barriers that do not fundamentally guarantee the safety and efficacy of products and services, which will favor expanding access of Health Technologies to Brazil. ABIMED is a dynamic, influential partner to the government of Brazil, private authorities, and related associations. ABIMED's mission is to be a reference in the promotion of a favorable environment to business competition on a local and global scale.

Goal & Scope of the Code of Conduct

The objective of the ABIMED Code of Conduct is to establish the minimum standards of ethical conduct that will govern the actions of the ABIMED member companies. The principles within this Code of Conduct are designed to limit Company activities to comply with legal orders and observe technical, moral and ethical standards recognized by national and international societies.

Interactions with Health Care Professionals

The scope of beneficial interactions between Health Care Professionals and Companies is broad and includes interactions intended to:

- *Promote the Advancement of Advanced Medical Technologies.* Developing and improving cutting edge Advanced Medical Technologies are collaborative processes between Companies and Health Care Professionals. Innovation and creativity are essential to the development and evolution of Advanced Medical Technologies, which often occur outside a Company's laboratory.

- *Enhance the Safe and Effective Use of Advanced Medical Technologies.* The safe and effective use of sophisticated electronic, in vitro diagnostic, surgical, or other Advanced Medical Technologies often requires Companies to provide Health Care Professionals appropriate instruction, education, training, service and technical support. Regulators often require this type of training as a condition of product approval.

- *Encourage Research and Education.* Companies' support of bona fide medical research, education, and enhancement of professional skills improves patient safety and increases access to Advanced Medical Technologies.

- *Foster Charitable Donations and Giving.* Companies make monetary and Advanced Medical Technology donations for charitable purposes, such as supporting indigent care, as well as patient and public education. This increases access to – as well as the quality of – care and treatment in patient populations that may not otherwise be reached.

Interactions with Third Party Sales and Marketing Intermediaries

To ensure and improve ongoing patient and clinician access to innovative, reliable and effective medical technologies, it is often necessary for Companies to engage third party intermediaries to assist in the marketing, sale and/or distribution of the Companies' products or services. The form of, and terminology used by Companies to describe relationships with these third party sales and marketing intermediaries varies, but may include distributors, wholesalers, distribution or sales agents, marketing agents, brokers, commercial agents under commission regime and independent sales representatives ("Third Party").

- It is essential that Companies' interactions with Third Party, as well as Third Party behavior on a Company's behalf (including Third Party interactions with Health Care Professionals and governmental officials) are conducted pursuant to all applicable legal and ethical principles. ABIMED encourages Companies to adopt a Third Party Management Compliance Program banning all forms of bribery by any person or entity acting on a Company's behalf including Third Party, and communicating this Code 0f Conduct.

II. Purpose of the Code of Conduct

ABIMED recognizes that Health Care Professionals' first duty is to act in the best interests of patients. Companies can serve the interests of patients through beneficial collaborations with Health Care Professionals. To ensure that these collaborative relationships meet high ethical standards, they must be conducted with appropriate transparency and in compliance with applicable laws, regulations and government guidance.

ABIMED recognizes the obligation to facilitate ethical interactions between Companies and Health Care Professionals in order to ensure that medical decisions are based on the best interests of the patient. The ethical principles that govern these interactions are the subject of this Code of Conduct.

The purpose of this Code of Conduct is to establish a minimum set of standards that will govern the ethical interactions between Companies that develop, manufacture, sell, market, or distribute Advanced Medical Technologies, Government Officials, and Health Care Professionals in Brazil.

To ensure that the relationships between Companies, Government Officials, and Health Care Professionals meet the highest ethical standards, all interactions should be conducted in accordance with the following principles:

• Integrity: Acting honestly, truthfully and fairly with all parties.

• Independence: Health Care Professionals' and Government Officials' interactions with Companies' should not be used to improperly influence or skew the Health Care Professionals' medical decision making from the best interests of the patient by undue or improper advantages.

• Appropriateness: Arrangements with Health Care Professionals and/or Government Officials shall conform to the proper commercial standards by being accurate, fair and corrupt-purpose-free.

• Development: Relationships with Health Care Professionals and/or Government Officials are destined to thrust medical technology and innovation, and to take care and improve patient's life quality.

• Transparency: Interactions between Companies and Health Care Professionals and/or Government Officials shall have a clear purpose and scope, shall always comply with domestic and local laws, regulations or professional codes of conduct, and shall avoid any improper actual or potential conflicts of interest.

The safe and effective use of Advanced Medical Technologies, and the continuing advancement of Advanced Medical Technologies, requires collaborative interactions between Companies, Government Officials and Healthcare Professionals. However, when interactions are not conducted in accordance with appropriate ethical standards, they pose a risk of inappropriately influencing the decision-making process of Health Care Professionals. Even appropriate interactions may undermine the public's confidence if they appear to be intended as an inappropriate inducement.

Collaborative interactions between Companies, Government Officials and Health Care Professionals should preserve independent decision-making by Health Care Professionals and public confidence in the integrity of patient care, treatment and product selection. Companies and Health Care Professionals should not interact in any way that could improperly influence a Health Care Professional's purchasing or medical decision-making or appear to do so.

The above guidelines and principles apply to all interactions between Companies, Health Care Professionals, and Government Officials. They supplement, and are subject to, the laws of each country, province or region in which a Company conducts business and Companies are responsible for knowing and complying with those laws. The additional principles set forth below are intended to supplement, not to limit, the general provisions above.

III. Definitions

Advanced Medical Technologies

Advanced Medical Technologies are often highly dependent upon "hands on" Health Care Professional interaction from beginning to end—unlike drugs and biologics, which act on the human body by pharmacological, immunological or metabolic means. For example, implantable Medical Technologies are often placed in the human body to replace or strengthen a body part. Surgical Medical Technologies often serve as extensions of a physician's hands. In other circumstances, Medical Technologies are noninvasive reagents, instrumentation and/or software to aid in the diagnosis, monitoring and treatment decisions made by Health Care Professionals. Some Medical Technologies work synergistically with other technologies, or are paired with other products that deploy devices in the safest and most effective manner. Many Advanced Medical Technologies require technical support during and after deployment.

Health Care Professionals

Health Care Professionals are those individuals or entities involved in the provision of health care services and/or items to patients, which purchase, lease, recommend, use, arrange for the purchase or lease of, or prescribe companies' "Advanced Medical Technologies" in Brazil.

Government Officials

Government Officials are:

- Health Care Professionals employed by or acting on behalf of a health care entity owned or controlled by a government body of Brazil or any other country, such as a public hospital or a state university;

- Any employee, manager, director, office holder, or official of a Brazilian or foreign government-controlled entity (e.g., government-owned hospitals, healthcare centers, pharmacies or university hospitals; or any business owned or controlled by any national, provincial or local government);

- Any person who is a member of the military or holds a legislative, administrative, or judicial position of any national, provincial or local government of Brazil or any other country;

- Any employee, office holder, candidate, or elected or appointed official of a political party of Brazil or any other country;

- Any employee or official of a public international organization such as the World Bank, the International Monetary Fund, the United Nations, the International Committee of the Red Cross, the Inter-American Development Bank, or the European Union;

- Any individual who, even if transitorily or without remuneration, holds a public post, employment or function in a government agency, or who works for companies that have been contracted to render services or to execute activities that are typical of the public administration.

IV. Code of Conduct Compliance

The ABIMED Code of Conduct is mandatory for all companies that are members or affiliates of ABIMED. All Companies that are members of ABIMED are required to adopt this Code of Conduct and policies and procedures that foster compliance with the Code with respect to their interactions with Health Care Professionals related to Advanced Medical Technologies.

Companies of ABIMED are required to submit to ABIMED a certification within 12 months of the adoption of this Code that the Company has adopted the Code. The certification will be required to be submitted to ABIMED every two years; as long as there are no Company leadership changes within a Companies Brazil operation. This certification must be signed by a legal representative of the Company in Brazil and/or the person in-charge of the Company´s compliance department in Brazil.

Companies that are ABIMED members must supply contact information for the Company's Compliance Department or an anonymous hotline (when available) to facilitate reporting of possible violations of the Code.

Companies are encouraged to follow the nine elements of a compliance program, appropriately tailored for each Company, namely:

1. commitment from senior management and a clearly articulated policy against corruption;

2. implementing written policies and procedures;

3. designating a compliance officer and/or compliance committee, with necessary oversight, autonomy and resources;

4. conducting effective training and education;

5. developing effective lines of communication (including an anonymous reporting function);

6. conducting risk assessments and internal monitoring and auditing;

7. enforcing standards through well-publicized disciplinary guidelines;

8. responding promptly to detected problems and undertaking corrective action and/or disciplinary sanctions;

9. conducting appropriate third-party due diligence on third parties and in the context of mergers and acquisitions.

Note:

All Companies have an independent obligation to ensure that their interactions with Health Care Professionals comply with all applicable laws and regulations within the jurisdictions that they operate. Applicable laws or regulations may provide more specificity than this Code, and Companies should seek counsel to address any additional questions. This Code of Conduct is intended to facilitate ethical behavior, and is not intended to be, nor should it be, construed as legal advice. The Code is not intended to define or create legal rights, standards or obligations. Any interpretation of the provisions of this Code, as well as Companies' interactions with Health Care Professionals and Government Officials not specifically addressed in this Code, should be made in light of the following principle: Companies shall encourage ethical business practices and socially responsible industry conduct and shall not engage in any unlawful inducement.

V. Company-Conducted Product Training and Education

Companies have a responsibility to make training and education on their products and Advanced Medical Technologies available to Health Care Professionals. Companies may also provide education to Health Care Professionals on topics concerning or associated with the use of their Advanced Medical Technologies.

- "Training" means training on the safe and effective use of Advanced Medical Technologies.
- "Education" means communicating information directly concerning or associated with the use of Companies' Advanced Medical Technologies, e.g., information about disease states and the benefits of Advanced Medical Technologies to certain patient populations.

Training and Education programs include, but are not limited to, "hands on" training sessions, workshops, lectures and presentations, and grand rounds. Companies should adhere to the following principles when conducting training and education programs concerning Advanced Medical Technologies for Health Care Professionals:

- Programs and events should be conducted in settings that are conducive to the effective transmission of information. These may include clinical, educational, conference, or other settings, such as hotels or other commercially available meeting facilities. In some cases, it may be appropriate for a Company representative to provide training and education at the Health Care Professional's location.

- Programs providing "hands on" training on Advanced Medical Technologies should be held at training facilities, medical institutions, laboratories, or other appropriate facilities. The training staff used by the Company should have the proper qualifications and expertise to conduct such training. Training staff may include qualified field sales employees who have the technical expertise necessary to perform the training.

- Companies may provide Health Care Professional attendees with modest meals and refreshments in connection with these programs. Any such meals and refreshments should be modest in value and subordinate in time and focus to the training and/or educational purpose of the meeting.

- Where there are objective reasons to support the need for out-of-town travel to efficiently deliver Training and Education on Advanced Medical Technologies, Companies may pay for reasonable travel and modest lodging costs of the attending Health Care Professionals. It is not appropriate for Companies to pay for the meals, refreshments, travel, or other expenses for guests of Health Care Professionals or for any other person who does not have a bona fide professional interest in the information being shared at the meeting. To the extent possible, Companies should make travel bookings directly on behalf of the Health Care Professionals. If direct travel booking is not possible, then reimbursement shall only be made for actual and appropriate costs incurred, and upon submission of original receipts or other adequate proof of payment. Reimbursements shall be made by electronic bank transfer. Payment must not be by cash.

Training and education on off label use or on uncleared devices must not occur. In the event it is necessary to import or use such products for other purposes, such as market research or testing, the regulatory legislation must be observed and, if necessary, health authorities must be consulted.

VI. Supporting Third-Party Educational Conferences

Bona fide independent, educational, scientific, and policymaking conferences promote scientific knowledge, medical advancement and the delivery of effective health care. These typically include conferences sponsored by national, regional, or specialty medical associations and conferences sponsored by accredited continuing medical education providers. Companies should ensure that support for third-party educational conferences preserves the independence of medical education and should not be used as a means of inappropriate inducement. Companies may support these conferences in various ways:

- *Conference Grants.* Companies may provide a grant to the conference sponsor to reduce conference costs. They may also provide grants to a training institution or the conference sponsor to allow attendance by medical students, residents, fellows, and others who are Health Care Professionals in training. Companies may provide grants when: (1) the gathering is primarily dedicated to promoting objective scientific and educational activities and discourse; and (2) the training institution or the conference sponsor selects the attending Health Care Professionals who are in training.

Companies may provide support for attendance of events by medical students, residents, fellows, and others who are Health Care Professionals in training through conference grants to the training institution. Such grants should be paid only for a genuine, independent educational function and may only be used to reimburse the legitimate expenses for bona fide educational activities.

All grant arrangements and sponsorships should be appropriately documented and should not be provided as an unlawful inducement. The conference sponsor should independently control and be responsible for the selection of program content, faculty, educational methods, and materials.

Seeking harmonization with international practices of conduct and interaction with Health Care Professionals, it is recommended that Companies avoid the direct financial support of Health Care Professionals to attend third-party educational conferences (subscriptions, hotel, meals, flights and etc.). As of January 1st, 2018 this type of educational support will no longer be permitted.[1]

If a Company does elect to provide financial support to cover the cost of conference attendance by individual Health Care Professionals to attend third-party educational conferences, then the Company should: (a) adopt objective criteria for selecting Health Care Professionals to be receive sponsorships that do not take into account the volume or value of purchases made by, or anticipated from, the recipient; (b) ensure that a Company's sales personnel do not control or unduly influence the decision to sponsor a particular individual Health Care Professional; (c) implement appropriate procedures to ensure that such sponsorships are not used as an unlawful inducement; and (d) ensure that all sponsorships are appropriately documented. Financial support for travel expenses should satisfy all other principles set forth in Section VI.

- Conference Meals and Refreshments. Companies may provide funding to the conference sponsor to support the provision of meals and refreshments to conference attendees. Companies may also provide meals and refreshments for Health Care Professional attendees if such meals and refreshments are provided: (1) to all Health Care Professional attendees (with the limited exception noted below), and (2) in a manner that is consistent with applicable standards established by the conference sponsor and the body accrediting the educational activity.

  Meals and refreshments may be provided to fewer than all Health Care Professional attendees if the Company providing such meals and refreshments satisfies all other principles related to meals set forth in Section X. Any meals and refreshments should be modest in value, subordinate in time and focus to the purpose of the conference, and clearly separate from the continuing medical education portion of the conference.

- Faculty Expenses. Companies may make grants to conference sponsors for reasonable honoraria, travel, lodging, and modest meals for Health Care Professionals who are bona fide conference faculty members.

- Advertisements and Demonstration. Companies may purchase advertisements and lease booth space for Company displays at conferences. This support should not be conditioned on the past or future purchases of Company products by the institution.

VII. Sales, Promotional, and Other Business Meetings

Companies may conduct sales, promotional and business meetings with Health Care Professionals to discuss, among other things, Advanced Medical Technology features, sales terms, or contracts. Often, these meetings occur close to the Health Care Professional's place of business; however, such meetings may occur at another appropriate location that is conducive to the effective exchange of information.

1. The gradual implementation of the new indirect sponsorship model to support medical education is fundamental to ensure that the medical training process is not impaired, therefore, avoiding potential risks to patients, besides enabling the elaboration of an adequate control framework to the new model. The phased approach is also aligned with international practices, such as the Eucomed (European Confederation of Medical Devices Associations) Code of Conduct.

It is appropriate to pay for reasonable travel costs of attendees when necessary (e.g., for plant tours or demonstrations of non-portable equipment) and/or to provide occasional modest meals and refreshments in connection with such meetings. It is not appropriate to compensate a Health Care Professional with a payment or any other transfer of value for the Health Care Professionals time spent while attending or participating in any educational training and/or sales, promotional, or other business meeting conducted by the Company in which no service is provided by the Health Care Professional (services are regulated by Section VIII of this Code). To the extent possible, which is strongly encouraged, Companies should make travel bookings directly on behalf of the Health Care Professionals. If direct travel booking is not possible, then reimbursement shall only be made for actual and appropriate costs incurred, and upon submission of original receipts or other adequate proof of payment. Reimbursements shall be made by electronic bank transfer. Payment must not be by cash.

However, it is not appropriate to pay for meals, refreshments, travel, or lodging of guests of Health Care Professionals or any other person who does not have a bona fide professional interest in the information being shared at the meeting. See Section X for additional principles related to the provision of meals associated with Health Care Professional business interactions.

VIII. Consulting Arrangements with Health Care Professionals

Companies engage Health Care Professionals to provide a wide-range of valuable, bona fide consulting services through various types of arrangements, such as contracts for research, product development, development and/or transfer of intellectual property, marketing, participation on advisory boards, presentations at Company-sponsored training and other services. Companies may pay consultants fair market value compensation for performing these types of services, provided that they are intended to fulfill a legitimate business need and do not constitute an unlawful inducement. An unlawful inducement means a remunerative arrangement intended to unlawfully influence a Healthcare Professionals medical decision-and product selection.

Companies should comply with the following standards in connection with consulting arrangements with Health Care Professionals:

- Consulting agreements should be in writing and clearly describe all services to be provided. When a Company contracts with a consultant to conduct clinical research services, there should also be a written research protocol. Additionally, the Health Care Professional's employer must be notified of the consulting agreement being entered into.

- Consulting arrangements should be entered into only where a legitimate need for the services is identified in advance and documented.

- Selection of a consultant should be made on the basis of the consultant's qualifications and expertise to meet the defined need.

- Compensation paid to a consultant should be consistent with fair market value in an arm's length transaction for the services provided and should not be based on the volume or value of the consultant's past, present or anticipated business. Compensation paid to a consultant may only be made after the services have been performed. Compensation shall be made by electronic bank transfer or check. Payment must not be made in cash.

- A Company may pay for documented, reasonable and actual expenses incurred by a consultant that are necessary to carry out the consulting arrangement, such as costs for travel, modest meals, and lodging. . To the extent possible, which is strongly encouraged, Companies should make travel bookings directly on behalf of the Health Care Professionals. If direct travel booking is not possible, then reimbursement shall only be made for actual and appropriate costs incurred, and upon submission of original receipts or other adequate proof of payment. Reimbursements shall be made by electronic bank transfer. Payment must not be by cash.
- The venue and circumstances for Company meetings with consultants should be appropriate to the subject matter of the consultation. These meetings should be conducted in clinical, educational, conference, or other settings, including hotel or other commercially available meeting facilities, conducive to the effective exchange of information.
- Company-sponsored meals and refreshments provided in conjunction with a consultant meeting should be modest in value and subordinate in time and focus to the primary purpose of the meeting. Companies should not provide recreation or entertainment in conjunction with these meetings.
- A Company's sales personnel may provide input about the suitability of a proposed consultant, but sales personnel should not control or unduly influence the decision to engage a particular Health Care Professional as a consultant. Companies should consider implementing appropriate procedures to monitor compliance with this section.
- Companies are responsible for maintaining proof of performance of the services provided by the consultants, such as the results of clinical studies and reports of activities performed.

Provisions on Payment of Royalties

Arrangements involving the payment of royalties to a Health Care Professional should meet the contractual standards set forth above. Health Care Professionals, acting individually or as part of a group in which they are an active participant, often make valuable contributions that improve products or Advanced Medical Technologies. They may develop intellectual property, for example, patents, trade secrets, or know-how, under a product or technology development or intellectual property licensing agreement.

A Company should enter into a royalty arrangement with a Health Care Professional only where the Health Care Professional is expected to make or has made a novel, significant, or innovative contribution to, for example, the development of a product, technology, process, or method. A significant contribution by an individual or group, if it is the basis for compensation, should be appropriately documented.

The calculation of royalties payable to a Health Care Professional in exchange for Intellectual Property should be based on factors that preserve the objectivity of medical decision-making and avoid the potential for improper influence. For example, royalties paid in exchange for Intellectual Property should not be conditioned on: (1) a requirement that the Health Care Professional purchase, order or recommend any product or medical technology of the Company or any product or technology produced as a result of the development project; or (2) a requirement to market the product or medical technology upon commercialization. (Companies may, however, elect to enter into separate consulting agreements with Health Care Professionals for marketing services if such services meet the requirements set forth in this Section VIII above.) Companies are strongly encouraged to consider whether it is appropriate and practicable to exclude from the calculation of royalties the number of units purchased, used, or ordered by the Health Care Professional and/or members of the Health Care Professional's practice.

IX. Prohibition on Entertainment and Recreation

Company interactions with Health Care Professionals should be professional in nature and should facilitate the exchange of medical or scientific information that will benefit patient care. To ensure the appropriate focus on an educational and/or informational exchange and to avoid the appearance of impropriety, a Company should not provide or pay for any entertainment or recreational event or activity for any non-employee Health Care Professional. Such activities include, for example, theater, sporting events, leisure, adult entertainment or vacation trips.

Such entertainment or recreational events, activities, or items should not be provided, regardless of: (1) their value; (2) whether the Company engages the Health Care Professional as a speaker or consultant; or (3) whether the entertainment or recreation is secondary to an educational purpose.

X. Modest Meals Associated with Heath Care Professional Business Interactions

A Company's business interactions with Health Care Professionals may involve the presentation of scientific, educational, or business information. Such exchanges may be productive and efficient when conducted in conjunction with meals. Accordingly, modest meals may be provided as an occasional business courtesy consistent with the limitations in this section.

Purpose. The meal should be incidental to the bona fide presentation of scientific, educational, or business information and provided in a manner conducive to the presentation of such information. The meal should not be part of an entertainment or recreational event.

Setting and Location. Meals should be in a setting that is conducive to bona fide scientific, educational, or business discussions. Meals may occur at the Health Care Professional's place of business. However, in some cases the place of business may be a patient care setting that is not available for, or conducive to, such scientific, educational, or business discussions. In other cases, it may be impractical or inappropriate to provide meals at the Health Care Professional's place of business, for example, (1) where the Advanced Medical Technology cannot easily be transported to the Health Care Professional's location, (2) when it is necessary to discuss confidential product development or improvement information, or (3) where a private space cannot be obtained on-site.

Participants. A Company may only provide a meal to Health Care Professionals who actually attend the meeting. A Company may not provide a meal for an entire office staff where everyone does not attend the meeting. A Company also may not provide a meal where its representative is not present. A Company may not pay for meals for guests of Health Care Professionals or for any other person who does not have a bona fide professional interest in the information being shared at the meeting.

XI. Educational Items: Gifts

Occasionally, a Company may provide items to Health Care Professionals that benefit patients or serve a genuine educational function for Health Care Professionals, if: (1) appropriately tailored to an educational event or product training; (2) the item is of minimal value; and (3) related to the Health Care Professional's work or for the benefit of patients. Other than medical textbooks or anatomical models used for educational purposes, any such items should have a value of less than BRL$100.

Non-educational branded items should be limited to pens and notepads. A Company may not provide items that are capable of use by the Health Care Professional (or his or her family members, office staff or friends) for non-educational or non-patient-related purposes, for example, a tablet or MP3 player.

Companies may not provide Health Care Professionals with gifts of personal nature, including, but not limited to, cookies, candies, wine, flowers, chocolates, gift baskets, or holiday gifts. Companies are never permitted to provide Health Care Professionals with cash or cash equivalents.

XII. Provision of Coverage, Reimbursement and Health Economics Information

As Advanced Medical Technologies have become increasingly complex, so have payer coverage and reimbursement policies. Patient access to necessary Advanced Medical Technology may be dependent on Health Care Professionals and/or patients having timely and complete coverage, reimbursement, and health economic information. Consequently, a Company may provide such information regarding its Advanced Medical Technologies if it is accurate and objective. A Company also may collaborate with Health Care Professionals, patients and organizations representing their interests, to achieve government and commercial payer coverage decisions, guidelines, policies, and adequate reimbursement levels that allow patients to access its Advanced Medical Technologies. Permissible activities involving the provision of coverage, reimbursement and health economic information may include, but are not limited to:

- Identifying the clinical value of the Company's Advanced Medical Technologies and the services and procedures in which they are used when providing coverage, reimbursement and health economics information and materials to Health Care Professionals, professional organizations, patient organizations, and payer;
- Collaborating with Health Care Professionals, their professional organizations, and patient groups to conduct joint advocacy on coverage, reimbursement and health economics issues; supporting Health Care Professionals and their professional organizations in developing materials and otherwise providing direct or indirect input into coverage and reimbursement policies;
- Promoting accurate payer claims by providing accurate and objective information and materials to Health Care Professionals regarding the Company's Advanced Medical Technologies, including identifying coverage, codes and billing options that may apply to those Advanced Medical Technologies or the services and procedures in which they are used;
- Providing accurate and objective information about the economically efficient use of the Company's Advanced Medical Technologies, including where and how they can be used within the continuum of care;
- Providing information related to the Company's Advanced Medical Technologies regarding available reimbursement revenues and associated costs;
- Providing information relating to changes in coverage or reimbursement amounts, methodologies and policies and the effects of such changes in order to facilitate a Health Care Professional's decision to buy or use the Company's Advanced Medical Technologies;

- Providing accurate and objective information designed to offer technical or other support intended to aid in the appropriate and efficient use or installation of the Company's Advanced Medical Technologies.

- Facilitating patient access to the Company's Advanced Medical Technologies by providing Health Care Professionals with assistance in obtaining patient coverage decisions frompayer. This assistance may include providing information and/or training on payer policies and procedures for obtaining prior authorization, and providing sample letters and information on medical necessity and appeals of denied claims. In addition, at the request of a Health Care Professional to facilitate patient access to the Company's Advanced Medical Technology, and subject to appropriate privacy safeguards, the Company may assist the patient by facilitating the preparation and submission of requests for coverage determinations, prior authorizations, pre-certifications and appeals of denied claims, relating to a Company's own Advanced Medical Technology; however such assistance should not be provided as an unlawful inducement.

A Company may not interfere with a Health Care Professional's independent clinical decision-making or provide coverage, reimbursement and health economics support as an unlawful inducement. For example, a Company should not provide free services that eliminate an overhead or other expense that a Health Care Professional would otherwise of business prudence or necessity have incurred as part of its business operations if doing so would amount to an unlawful inducement. Further, a Company should not suggest mechanisms for billing for services that are not medically necessary, or for engaging in fraudulent practices to achieve inappropriate payment.

XIII. Research and Educational Grants and Charitable Donations

A Company may provide research and educational grants and charitable donations. A Company may not provide such grants or donations as an unlawful inducement. Therefore, a Company should: (a) adopt objective criteria for providing such grants and donations that do not take into account the volume or value of purchases made by, or anticipated from, the recipient; (b) implement appropriate procedures to ensure that such grants and donations are not used as an unlawful inducement; and (c) ensure that all such grants and donations are appropriately documented.

A Company's sales personnel may provide input about the appropriateness of a proposed grant or charitable donation recipient or program, but sales personnel should not control or unduly influence the decision of whether a particular medical or healthcare institution will receive a grant or donation or the amount of such grant or donation. Companies are encouraged to implement procedures to monitor compliance with this section.

Companies are strictly prohibited from offering or attempting to offer any cash, assets, property, services, or use of facilities for political contributions to any Government Official.

a. Research Grants

Research provides valuable scientific and clinical information, improves clinical care, leads to promising new treatments, promotes improved delivery of healthcare, and overall benefits patients.

A Company may provide research grants to support independent medical research with scientific merit. Such activities should have well-defined objectives and milestones and may not be linked directly or indirectly to the purchase of Advanced Medical Technologies. Company-initiated or directed research involving a Company's Advanced Medical Technologies (such as clinical study agreements) is addressed separately in Section VIII.

b. Educational Grants

Educational grants may be provided for legitimate purposes, including, but not limited to:

- *Advancement of Medical Education.* A Company may make grants to support the genuine medical education of medical students, residents, and fellows participating in fellowship programs that are charitable or have an academic affiliation, or other medical personnel. (For additional considerations regarding educational grants, see Section VI.)

- *Public Education.* A Company may make grants to support education of patients or the public about important health care topics.

c. Charitable Donations

A Company may make monetary or Advanced Medical Technology donations for charitable purposes, such as supporting indigent care, patient or public education, or the sponsorship of events where the proceeds are intended for charitable purposes. Donations should be motivated by bona fide charitable purposes and should be made only to bona fide charitable organizations. In rare instances, donations may be made to individuals engaged in genuine charitable activities for the support of a bona fide charitable mission. Donations must never have the purpose of benefiting a specific individual.

Companies should exercise due diligence to ensure the bona fide nature of the charitable organization or charitable mission. Donations should be made only in response to written requests and should be evaluated against objective criteria adopted by the Company. Donations should be appropriately documented and should be made in compliance with all applicable laws and regulations.

XIV. Evaluation and Demonstration Products

Providing products to Health Care Professionals at no charge for evaluation or demonstration purposes can benefit patients in many ways. These benefits include improving patient care, facilitating the safe and effective use of products, improving patient awareness, and educating Health Care Professionals regarding the use of products.

Under certain circumstances (as described below), a Company may provide reasonable quantities of products to Health Care Professionals at no charge for evaluation and demonstration purposes. This section is limited to providing evaluation and demonstration products only and is not intended to address any other arrangement.

Company products that may be provided to Health Care Professionals for evaluation include single use (e.g., consumable or disposable products) and multiple use products (sometimes referred to as "capital equipment"). These products may be provided at no charge to allow Health Care Professionals to assess the appropriate use and functionality of the product and determine whether and when to use, order, purchase, or recommend the product in the future. Company products provided for evaluation are typically expected to be used in patient care.

Single Use/Consumables/Disposables. The number of single use products provided at no charge should not exceed the amount reasonably necessary under the circumstances to allow an adequate evaluation of the products.

Multiple Use/Capital. Multiple use products provided without transfer of title for evaluation purposes should be furnished only for a period of time that is reasonable under the circumstances to allow an adequate evaluation. The terms of an evaluation of such multiple use products should be set in advance in writing. Companies should retain title to such multiple use products during the evaluation period and should have a process in place for promptly removing such multiple use products from the Health Care Professional's location at the conclusion of the evaluation period unless the Health Care Professional purchases or leases the products.

Demonstration. Demonstration products are typically unsterilized single use products or mock-ups of such products that are used for Health Care Professional and patient awareness, education, and training. For example, a Health Care Professional may use a demonstration product to show a patient the type of device that will be implanted in the patient. Demonstration products typically are not intended to be used in patient care. Demonstration products also are typically identified as not intended for patient use by use of such designations as "Sample," "Not for Human Use," or other suitable designation on the product, the product packaging, and/or documentation that accompanies the product.

A Company should provide Health Care Professionals with documentation and disclosure regarding the no-charge status of evaluation and demonstration products.

Public Entities. In case the Health Care Professional works to or is related to Public Entities, the offer of products without charge must be assessed on a case by case basis, mainly to check if a public tender is feasible and possible in that specific circumstance.

XV. Request for Proposals and Tenders

In the context of public tenders, Companies may not provide items, grants, or donations that are not clearly defined within the RFP document.

XVI. Third Party Relationships

Companies are encouraged to adopt a Third Party Management Compliance Program in addition to an overall compliance program, applicable to all relevant personnel, including a Company's senior leadership. Taking into account a variety of risk-based factors, as well as local applicable laws; such programs may include the following elements:

a. Written Policy/Procedure. Adopt a compliance policy banning all forms of bribery by any person or entity acting on the Company's behalf including Third Party. Such policies may include more detailed implementing policies for common risk areas (for example, travel, gifts, hospitality, entertainment, grants or donations, research, capital equipment).

b. Risk Assessment. Evaluate the risk profile for proposed and utilized Third Party arrangements, including, for example, assessing:

1. Risk in country/geography through information such as, but not limited to, the Transparency International "Corruption Index" as well as specific risk profiles of planned or utilized Third Party;

2. Information concerning local market legal requirements;

3. Information from the Third Party for potentially unusual arrangements (unusually high commissions, high degree of interaction with government officials, marketing budgets, off shore payment accounts, etc.);

4. Information available from public sources or employees for potential issues associated with the Third Party. The Risk Assessment can inform the application of other elements of this section.

c. Diligence Program. Establish a risk-based pre-engagement and renewal due diligence program to identify, prevent, and mitigate risks relating to the market in which the Third Party is engaged to operate, as well as any specific activities the Third Party deploys on behalf of the Company.

d. Written Contract. Encourage contract terms that require adequate controls and implementation of the Company's anti-corruption policy, such as the following:

1. Compliance with Applicable Laws, Principles and Company Policies;

2. Right to conduct independent audits, including where possible access to relevant books and records;

3. Rights for early termination for failure to comply with applicable laws or Company policies;

4. Diligence rights upon renewal.

e. Training and Education. Establish initial and regular training and education for Third Party and relevant Company personnel who manage Third Party relationships on applicable laws, Company policies, and the Code. Where practical, training should be done in local language.

f. Monitor/Audit. Consider (and exercise reasonable efforts in) risk-based, routine monitoring, auditing, and other assessment of Third Party relationships for compliance with applicable laws, Company policies, and the Code, as well as relevant contract terms; and regular certification of Third Party personnel on compliance with applicable laws, Company policies, the Code, and relevant contract terms.

g. Appropriate Corrective Action. Reserve and undertake necessary and appropriate corrective measures, consistent with applicable local laws if a Third Party fails to comply with applicable laws, company policies, the Code, or relevant contract terms or engages in other impermissible conduct.

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Associação Brasileira da Indústria de Alta Tecnologia de Produtos para Saúde

Alameda dos Maracatins, 508 – 3º andar
Ed. New Century Place - Indianópolis
São Paulo – SP | CEP 04089-001

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