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abimed

Associação Brasileira da Indústria de Alta
Tecnologia de Produtos para Saúde

PREFACE

In line with the goal of keeping up with the latest developments in ethics, encouraging and enforcing global market best practices and pursuant to the civil society growing aspirations, the **Brazilian Association of High Technology Industrial Healthcare Products (ABIMED)** presents the fifth version of its **Code of Conduct**.

The present version, prepared by the **ABIMED Ethics Committee** with thorough dedication and broad support from its **Compliance Work Group**, pursued dialog with various actors in the health sector, exchanging information, reaching common understandings and seeking adherence throughout the health segment chain.

A well-structured Code of Conduct encourages debate over Ethics and Compliance among all its associate members, helping them to cope with daily challenges. By doing so, ABIMED significantly contributes to reduce conflicts of interests and conformity risks in general faced by these companies.

With this new version, ABIMED strengthens its commitment towards the promotion of a fair business environment, which favors not only a wider access of the population to a fair health system but the national socio-economic development as well.



Fabrício Campolina
Chairman of the Executive Board



Carlos Goulart
CEO

It is with great pride that we celebrate the end of the biennial (2016/2017) of the Ethics Committee with the launching of the **5th version** of the **ABIMED Code of Conduct**.

The preparation of this Code coincided with crises in the health sector, which also affected so many other sectors in Brazil. ABIMED members, however, well represented by members of the Executive Board, Ethics Committee, and Compliance Work Group, had peace of mind to use this experience in a constructive way, transforming in-depth reflections in the Code of Conduct that we consider to be the most comprehensive of this sector.

Despite the fact that industry associations are often remembered for representing company interests before government bodies and the society in general, ABIMED has always acknowledged and championed the integrity of the healthcare chain as one of its core missions. That is why ABIMED still firmly champions this cause, ten years after launching the first Code of Conduct of the Brazilian health sector.

Therefore, as individuals and then as managers, as users and then agents of the health system, we sincerely thank each of the member companies and each single executive who have devoted part of their time to build a Code of Conduct in line with the current challenges faced by high technology industrial healthcare products in Brazil. We hope that the present Code helps us remind ourselves every day that we share much more than a common activity – we share a mission.



Felipe Kietzmann

President of the Ethics Committee



André Figueiredo

Vice-president of the Ethics Committee

ACKNOWLEDGEMENT

We would like to acknowledge the dedication of all members of ABIMED Compliance Work Group, particularly its coordinators, **Anna Melloni**, **Gabriela Pellegrino**, **Karin Ullmann**, and **Renata Puga**, as well as ABIMED Governmental and Institutional Relations analyst, **Davi Uemoto**. They managed to lead a respectful and high level debate over the ethical challenges faced by this sector, ensuring that Member Companies played an key role in the updating the present Code of Conduct.

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OBJECTIVE

The objective of this Code of Conduct is to establish a basic set of standards of conduct to guide activities carried out by the Member Companies.

The present Code of Conduct aims to promote proper behavior on the part of Member Companies and is by no means a legal guidance. It should be stressed that laws, norms, and regulations applicable to Member Companies might offer additional constraints on the issues mentioned here.

FUNDAMENTAL PRINCIPLES

ABIMED is committed to promoting the ethical behavior of its Member Companies, always keeping patients' best interest in mind. To this end, the following Fundamental Principles must guide all actions and norms of this Code of Conduct:

- **Integrity:** work with integrity, pursuant to laws, norms, regulations, and the highest ethical principles in all activities;
- **Progress:** promote the continuous improvement of high technology healthcare products and of medical knowledge, as well as safe and efficient access and use of these products;
- **Transparency:** ensure that relations with health professionals and government officials have a clear and defined purpose, in order to avoid interest conflicts; and
- **Autonomy:** ensure the autonomy of health professionals and government officials, refraining from influencing them in exchange of personal advantages, and operate in conformity with applicable laws, norms, and regulations.

ACCOUNTABILITIES

ABIMED Code of Conduct is **mandatory** for all its Member Companies, whether in their **divisions and/or related to health equipment, devices, and products in general**, regardless of any formality.

Member Companies are accountable for adopting processes that ensure that all their associates, managers, employees, or service providers in general, including third parties, follow the present Code of Conduct provisions.

Member Companies are responsible for knowing and complying with all laws, regulations, governmental guidance, and other self-regulation norms applicable to their activities. The rules and principles of this Code of Conduct serve for ancillary purposes and do not limit any other obligation of the Member Companies.

DEFINITIONS

In the scope of this Code of Conduct, the words below have the following meaning:

- **ABIMED:** Brazilian Association of High Technology Industrial Healthcare Products
- **Sample:** consumable, disposable or non-durable health product, offered free of charge to a health professional and/or organization, so it can be tested by health professionals and/or their patients.
- **Patient Association:** legal entity created to educate, treat, and/or represent the general interests of patients who suffer from a given pathology.
- **Member Company:** an ABIMED Member Company, able to represent a subsector and activities related to facilities, devices, and medical materials.
- **Hospitality:** actions or minor items offered during a legitimate interaction in form of a small courtesy towards a health professional; it shall not involve any value nor be deemed excessive considering a legitimate interaction with a Member Company.
For example, items such as water, tea, coffee and snacks during events, as well as ambient music during events' pauses or meals, are considered hospitality.
- **Entertainment:** actions or items offered to entertain a health professional, involving value, disconnected with or considered above the line of a legitimate interaction with a Member Company.
For example, items like music performances as major attraction (in contrast with ambient music during meals, for instance), art performances, sport events, tours, etc. are considered entertainment.
- **Payment Source:** the ultimate party in charge of paying or funding a healthcare product, such as patients, cooperative societies, complementary health insurance plans, aid agencies, and/or public institutions.

- **Medical-Purpose Item:** professional-use item that contributes to teach health professionals and/or their patients about medical conditions, therapies, and/or healthcare products.

For example, medical-purpose items include scientific posters, scientific books, and anatomic models of healthcare products or human anatomy parts.

- **Proper Location:** a proper location for an interaction between the Member Company and a health professional in the form of a promotional or non-promotional meeting; the place must favor the parties' exchange of information and professional relation.

For example, tourist destinations — unless duly justified as necessary — and places of entertainment such as clubs, casinos, stadiums, theaters, cruise ships, etc., are not considered to be a proper location.

- **Government Official:** any private individual that holds a position, office, or public function that is directly or indirectly linked to a public administration body.

For the purpose of this Code of Conduct, representatives of foreign public administration bodies in Brazil will be considered government officials.

- **Health Organization:** legal entity created to represent healthcare professionals, or in any way connected to the healthcare product chain, performing activities such as purchase, assessment, recommendation, compounding or handling, and/or application of healthcare products. It includes, without limitation, hospitals, clinics, labs, pharmacies, universities or other health education and research institutions, professional or industry societies (except for patient societies).

- **Patient:** private individual that has used, uses, or may need to use any healthcare product.

- **Demonstration Product:** durable healthcare product, including devices, freely offered for undetermined periods to a healthcare professional or organization, in order to allow healthcare professionals and/or their patients to try them.
- **Healthcare Product:** medical equipment, device, and/or material, duly registered, produced, imported, promoted, and/or traded by a Member Company.
- **Healthcare professional:** any private individual, whose professional activity is connected to the healthcare product chain, including activities like purchase, assessment, recommendation, compounding or handling, and/or application of healthcare products. It includes, without limitation, physicians/medical doctors, nurses, pharmacists, physical therapists, scientists, researchers, healthcare technicians, attendants, public and private hospitals' employees and buyers, medical clinics and healthcare products POS (points of sale).

Member Companies' employees in the regular performance of their functions are excluded from this category for the purpose of the present Code of Conduct.

- **Product Health Inspection Certificate:** registration at ANVISA (Brazilian Health Regulatory Agency), duly authorization to promote and trade healthcare products, including their features, risks and approved uses.
- **Subsidy:** financial support in form of healthcare products and/or other resources by a member company to a health organization in a non-promotional nature, with educational, research and/or medical treatment support purposes.

Educational Subsidies include the funding of scholarships and medical residencies. Research Subsidies include funding clinical trials and the publication of scientific papers. Medical treatment support subsidies include funding and donation of healthcare products to awareness, diagnosis, and treatment campaigns.

- **Unauthorized Use of Product (Off Label):** use of a healthcare product that has not formally obtained a health inspection certificate, regardless of the fact that there might be evidence supporting its efficacy or safety
- **Fair Market Value:** fairly and properly determined market price range charged for a given service or provision in general.
The Fair Market Value may be measured by sector, nature, and/or location, based on historical data of legitimate sales and/or independent market research.
- **Undue Advantage:** each and every disreputable benefit in favor of a Member Company, generally arising from unlawful or unethical acts, particularly, without limitation, acts that imply trade advantages such as purchase, assessment, recommendation, compounding/handling and/or application of healthcare products, which were not grounded in independent technical decision.



Compliance Program and Interaction with Third Parties

1.1 Compliance Program

It is highly recommended that Member Companies ensure the following elements of a Compliance Program, properly adapted to their particularities:

- commitment at the top management level;
- implementation of formal politics and procedures;
- accomplishment of a consistent training plan;
- due diligence in relation to third parties and also in the scope of mergers and takeovers;
- appointment of a Compliance official and/or a Compliance Committee with proper technical training, autonomy & necessary resources; and
- implementation of risk assessments, monitoring, and audit activities, as well as maintenance of a reporting channel and independent investigation process, undertaking preventive and/or corrective actions whenever necessary.

1.2 Interaction with Third Parties

It is particularly highly recommendable that Member Companies maintain a **robust program for managing third parties and subcontractors**, such as, without limitation, those who take part in promotional and/or commercial activities linked to healthcare products, including retailers, wholesalers, marketing agents, and independent sales representatives.

Third party management program should include a due diligence process, anti-corruption training and other relevant norms; establishment of formal relations among parties through written agreements, and other applicable documents, monitoring of activities, moreover when they represent the company before public administration bodies, healthcare professionals, and/or patient organizations.



About ABIMED

2.1. ABIMED Social Goals

ABIMED works to improve medical and hospital services through high technology and quality medical equipment, devices, and materials in Brazil. ABIMED works to reduce bureaucracy related to production and import processes, as well as of any other obstacles hindering products' safety and efficacy. ABIMED is a dynamic and influential partner of the Brazilian government, public and private authorities, and of related associations in the health sector.

ABIMED mission is to represent the interest of its members, continuously contributing to the creation and maintenance of public policies that ensure a favorable environment for innovation and competitiveness in the healthcare product industry, both in the local and global markets.

2.2. Member Companies Participation

As they are become part of ABIMED, Member Companies commit themselves — including their partners, managers, associates, and/or collaborators in general — to contribute actively and legitimately to the accomplishment of ABIMED social goals, according to the item above.

Member Companies agree to keep updated record data at ABIMED, including the contacts of professionals who are accountable for issues discussed within the association scope, therefore ensuring their representativeness.

2.3. Disciplinary Proceedings

A Member Company that becomes aware of another Member Company past or present acts in contradiction with the present Code of Conduct must report it to the ABIMED Ethics Committee (www.abimed.org.br/denuncia) or send a letter to the association's address. Complainants or whistleblowers have the right to anonymity.

According to its internal regulation, the ABIMED Ethics Committee will judge possible violations of the Code of Conduct by Member Companies once it becomes aware of such wrongdoings.

The Ethics Committee may also deal with possible actions of Member Companies that may not constitute a direct violation of its Code of Conduct if its technical assessment deems such practice as inconsistent with ABIMED ethical standards.



Competition and interaction with the Public Power

3.1 Free Competition and Economic Order

Member Companies should trade with **loyalty** and **autonomy**, refraining from any acts that may endanger free competition and economic order.

Member Companies are allowed to discuss public nature issues and common interest questions within the healthcare sector's scope, such as, without limitation, economic regulation, scientific development, public and private payment policies, and industry trends in general.

By no means may Member Companies disclose, directly or indirectly, confidential or sensitive information among themselves. ABIMED, on its turn, must see to it that such situation does not happen within the organization's scope.

While interacting, Member Companies must observe the following:

- Member Companies should not reveal any relevant trade information among themselves, such as current or future prices, including discounts, credits and promotions; business models and strategies; nor statistics in general, such as market share, stockpiles, list of clients, manufacturers, retailers, and other third parties;
- the implementation of surveys among Member Companies and another healthcare sector firms for purposes like benchmarking might happen if the institute responsible for collecting, processing, and publicizing data is neutral and respects confidentiality of information as well as the usage of historical data, generally with more than one year assessment;

- all ABIMED meetings must have a legitimate agenda, announced with reasonable previous notice and a final record, made available to all participants; an ABIMED official trained in Competitive Compliance must be present at all meetings, including those organized outside the association;
- once it becomes aware of the infringement of any of the rules above, the ABIMED or Member Company representative must formally notify ABIMED Ethics Committee, notwithstanding other measures he/she may find necessary, such as communicating the problem to his/her own company and/or to the competent public authorities.

3.2 Access to Healthcare Products

Member Companies shall strive to provide access to healthcare products to patients and healthcare professionals throughout the Brazilian territory.

Member Companies shall avoid price variations among healthcare products buyers if such variations do not arise from legitimate negotiations and other objective criteria, such as purchase volume, payment deadline, and related costs.

3.3 Healthcare Products Payment Coverage

It is allowed for Member Companies to act jointly with public bodies representatives, health departments, professionals, or organizations, in legitimate advocacy of their trade interests, offering elements for decision making regarding the payment coverage of healthcare products by the patients and/or other payment instances, inclusion in coverage list, and payment value for cooperative societies/unions, complementary healthcare providers, charity entities, and/or by the Brazilian Health System.

Therefore, Member Companies may provide studies and technical information about medical conditions, therapies, and/or healthcare products, as well as economic data to support decision making for the safe and efficient use of available technologies.

Promotional or non-promotional information over healthcare products should be trustworthy, balanced and consistent with available technical studies. Under no circumstances should a promotional information, whether oral or written, be directed to healthcare professionals in disagreement with the Product's health inspection certificate.

3.4 Financial Discount

In the regular course of their activities, it is possible that Member Companies offer financial discounts to healthcare products buyers.

Only transparent discounts, arising from legitimate trade reasons, such as payment deadline anticipation by the buyer, therefore justifying an additional discount, are allowed. Additionally, it is recommended that discounts be occasional.

Whenever applicable, occasional financial discounts can equate fees charged by the buyer, deducting part of the due value for the purchase of healthcare products. Such fees will only be allowed when referring to legitimate services, provided for under agreements, and effectively performed by the buyer to the Member Company.

3.5 Public Procurement

Member Companies must strictly follow public notice specifications to sell healthcare products to public bodies and other entities subject to the Brazilian Bidding Law.

Member Companies have the right to offer samples and/or demonstration products to buyers, so that healthcare professionals and/or their patients can test their respective products, provided the rules on [item 7.1](#) are observed.

A Member Company representative, especially one who works in the sales or commercial department, is forbidden to help drafting the public notice and/or intervening in any other stage of the bidding process, unduly affecting the bid process.

Notwithstanding, if a buyer's representative asks for support, Member Companies might offer strictly and objective technical information, in writing and always referring to public and/or official data. In case of a specific request, Member Companies might offer technical details on a healthcare product, when possible limited to the information available on the Product's health inspection certificate.



Interaction with Healthcare Professionals

4.1. Interaction with Healthcare Professionals

4.1.1. Objectives of the Interaction with Healthcare Professionals

Member Companies must ensure that all their relations with healthcare professionals and organizations are proper, according to the applicable laws, norms, and regulations, as well to the Fundamental Principles and further rules of the present Code of Conduct.

Member Companies may interact with healthcare professionals for promotional and nonpromotional purposes. Non-promotional interactions must be aligned with one or more of the following purposes:

- encourage research and education in the healthcare sector: the legitimate support of companies towards research and education initiatives developed by healthcare professionals is a relevant contribution to the health sector as a whole;
- promoting development of healthcare products: innovation and improvement of high technology healthcare products often require a collaboration process between companies and healthcare professionals;
- improving safe and efficient use of healthcare products: high technology healthcare products often demand that companies promote training programs, services, and technical support for healthcare professionals, ensuring safe and efficient use;
- improving the access of underserved populations to medicine products, information, and services: companies play a relevant social role and may work together with healthcare professionals and/or organizations to donate products to provide assistance, educate patients, and render other charitable services in favor of underserved populations, contributing to the public healthcare system.

4.1.2. Promotional Interactions with Healthcare Professionals

Member Companies may interact with healthcare professionals to perform promotional activities, such as presentation, promotion, contract negotiation, list of orders, and after-sales in relation with their healthcare products. Such interactions may be performed in consulting rooms and professional addresses of healthcare professionals or in other proper locations for professional interactions.

Promotional information on healthcare products must be truthful, balanced, and consistent with available technical studies. Under no circumstance might promotional information, whether oral or written, be directed to healthcare professionals in disagreement with the Product's health inspection certificate.

Member Companies may pay or reimburse healthcare professionals involved in such interactions for reasonable expenses, such as accommodation, meals, and transport, considering the limits indicated in [Chapter VI](#). However, compensating healthcare professionals for the time they spend in promotional events is forbidden. Healthcare professional contracts will be discussed in [item 4.2](#).

4.1.3. Conflicts of Interest

Member Companies should avoid conflicts of interest among its associates, particularly sales representatives and healthcare professionals, such as friendship, parentage, or professional relationships.

It is recommended that Member Companies instruct their associates to report effective and potential conflicts of interests with healthcare professionals, as well as, whenever possible, to adopt measures to eliminate or, at least, mitigate and offer transparency to such conflicts.

4.1.4. Presence During Clinical Practice

It is possible that a representative of a Member Company interacts with a healthcare professional during his/her clinical practice, contributing with his knowledge on the products.



Notwithstanding, if the mentioned interaction is necessary exclusively for technical reasons, the Member Company representative must follow the medical action and refrain from interactions with the surgical field.

It is inadvisable for a Member Company representative to interact with a healthcare professional during clinical practice, particularly during procedures involving insertion or change of orthoses, prosthesis, and materials in a patient, avoiding therefore any influence over the healthcare professional.

4.2. Hiring Healthcare Professionals

Member Companies can hire healthcare professionals to deal with a legitimate demand, such as initiatives involving research, development, consulting, and presentation of promotional or nonpromotional matters.

Member Companies may pay the healthcare professionals a proportional, appropriate, and fair market value and, whenever possible, after the service delivery. The value shall not be influenced by elements of commercial relationship among the parties, such as product purchase volume, whether present, past or future.

Under no circumstances should a member company hire a healthcare professional to take undue advantage, such as commitment to use, buy, or recommend a given healthcare product.

When hiring healthcare professionals, Member Companies must observe the following:

- Member Companies must have an objective and appropriate recruitment criteria for hiring healthcare professionals, based on strictly technical criteria; the commercial department may contribute to the process, but not directly appoint healthcare professionals, in order to avoid conflicts of interest;

- the object, conditions, compensation, and expenses related to the contract must be transparent, duly formalized through a written contract/agreement; each and every payment to healthcare professionals must be performed in their own name or the company through which they provides services, using bank transfer (never in cash), and properly recorded in the contracting Member Company's accounting book; finally, Member Companies are responsible for keeping evidence of the effective service provision, for example through reports on the performed activities;
- when hiring healthcare professionals who are also government employees, the contracting Member Company must inform the respective public entity or explicitly report in contract the healthcare professionals' duty to perform the mentioned report; this practice is also recommended towards the private employer of a healthcare professional, moreover if the latter entertains business relationships with the contracting Member Company.

Member Companies may pay or reimburse the contracted healthcare professional for reasonable expenses related to these interactions, such as accommodation, meals, and transport, provided the limits indicated in [Chapter VI](#).

4.2.1. Payment of Royalties to Healthcare Professionals

Member Companies can pay royalties to healthcare professionals, such as compensation for patent concession, commercial secret, intellectual property or know-how, complying with the same rules expressed in the previous item.



Events

5.1 Events

5.1.1 Self-organized Events

Member Companies can promote self-organized events, including training initiatives for healthcare professionals to meet a legitimate demand for personal qualification, such as classes, lectures, debates, workshops, round-tables and live surgeries, particularly related to their own technologies, promoting a safe and efficient use of healthcare products.

Under no circumstance should a healthcare professional be invited to a Member Company's self-organized event to take undue advantage, such as commitment to use, buy, or recommend a given healthcare product.

When promoting self-organized events, Member Companies must observe the following:

- training content must respect the Product's health inspection certificate, avoiding the dissemination of Unauthorized Use of Product (Off Label), for instance, except for non-promotional initiatives, according to applicable laws and regulations;
- self-organized events must be held in proper locations, according to the need, namely in educational institutions, in the company's or third party training centers, or in the healthcare professionals' place of practice;
- a technically skilled team or professional must conduct self-organized events; Member Company's commercial department representatives may conduct self-organized events, provided they meet the required qualification.

Member Companies may pay or reimburse healthcare professionals for reasonable costs related to such interaction, such as accommodation, meals, and transport, provided the limits indicated in [Chapter VI](#) are complied with. However, compensating healthcare professionals for the time they spend in such interactions is forbidden.

5.1.2 Third Party Events

Member Companies can sponsor third party events organized by healthcare organizations and aimed at healthcare professionals in order to meet a legitimate demand for professional qualification, such as symposia, workshops, conferences, and scientific congresses.

Member Companies may obtain a sponsorship quota through the payment of a promotional, appropriate, and fair market value considering the characteristics of such events and paid compensation, such as space for a stand and/or exhibition of the company's brand and/or its products. The value should not be influenced by elements related to the business relationship between the parties.

Under no circumstances shall the sponsorship to healthcare organizations aim to take Undue Advantage, namely to surpass an independent technical decision over a given healthcare product.

When sponsoring third party events, Member Companies must observe the following:

- sponsored healthcare organizations must be **accountable** for and **autonomous** towards the organization of the event, especially when it comes to the schedule and lecturers.
- it is inadvisable for Member Companies to sponsor events that include entertainment items for healthcare professionals; notwithstanding, in case they do, the sponsoring value of a Member Company should not be directed to an entertainment item; similarly, Member Company representatives must refrain from taking part in any entertainment actions, such as musical presentations as main attraction (differently from ambient music during meals), art performances, sports events, tours, etc.;



- the object, conditions, and compensation related to sponsoring must be transparent, duly formalized in a written contract; each and every payment to healthcare organizations must be made in their own name, through bank transfer (never in cash), and duly recorded in the sponsoring Member Company's accounting book. Finally, Member Companies shall be responsible for keeping evidence of the received compensation, such as photos of their participation in the event.

5.1.3 Direct Sponsoring of Healthcare Professionals

Member Companies shall not directly sponsor the participation of healthcare professionals in third party events, whether through the payment of registration fees, or payment or reimbursement for related expenses, such as accommodation, meals, and transport.

Notwithstanding, Member Companies can provide an educational subsidy in favor of a health organization responsible for a third party event or non-profit health organization, so it can partially or completely sponsor the participation of healthcare professionals in a third party event. Such healthcare professionals should be selected by the organization, according to **objective criteria**, in response to a legitimate demand for professional qualification. Such educational subsidy must observe dispositions presented in **Chapter VIII**.



Expenses, Hospitality and Entertainment

6.1 Expenses

6.1.1 Direct Payment and Reimbursement

If the interaction between a Member Company and a healthcare professional prompts the payment of **reasonable expenses**, such as accommodation, meals, and transport, the member company, whenever possible, will directly perform the consequent payment. If that is not possible, the Member Company will reimburse the healthcare professional based on the respective original expense invoices.

6.1.2 Payment to Third Parties

Member Companies may only bear reasonable healthcare professionals' expenses, including meals, when there is a legitimate need of interaction. For example, without a **legitimate need**, the Member Company must not bear accommodation, meals, and transport costs related to healthcare professional's team members or relatives.

6.1.3 Period of Provision

Member Companies may bear healthcare professionals' reasonable expenses only during the period it takes to perform the legitimate and needed interaction.



For example, if a Member Company hires a healthcare professional for a presentation in an international congress, the airline tickets, accommodation and meals must coincide with the dates the event begins and ends, or a day before and a day after, respectively, if there is a reasonable logistical reason for that.

6.2 Meals and Drinks

In the context of a legitimate interaction, whether of a promotional or non-promotional nature, a Member Company may offer modest meals and drinks to healthcare professionals, in a proper location.

When offering meals to healthcare professionals, Member Companies must observe the following:

- meals and drinks must be **modest**, **occasional** and **secondary** in relation to legitimate interactions, whether of a promotional or non-promotional nature; for example, a Member Company representative may pay for lunch or dinner with a healthcare professional if it qualifies as a business meeting;
- meals and drinks must be adequate in relation to the schedule and time of the main interactions; for example, dinner at the end of the day of a scientific event, or a breakfast before a morning training is considered adequate.

6.3 Hospitality and Entertainment

In the context of a legitimate interaction, whether of a promotional or non-promotional nature, especially in the scope of a self-organized or third party event, Member Companies may offer hospitality items to healthcare professionals.

Meals and drinks offered by a Member Company to healthcare professionals fit the concept of hospitality, provided the limits indicated in the previous item are observed.

Under no circumstances shall a hospitality item be offered to a healthcare professional by a Member Company to take undue advantage, such as commitment to use, buy, or recommend a given healthcare product.

Member Companies shall not offer entertainment items to healthcare professionals, even in the context of and marginally addressed in a legitimate interaction.



Samples, Demonstration Products and Medical-Purpose Items

7.1 Samples and Demonstration Products

Member Companies can offer samples and/or demonstration products to healthcare professionals, so that healthcare professionals and/or their patients can test their respective products.

Under no circumstances shall a sample and/or of a demonstration product be offered to a healthcare professional by a Member Company to take undue advantage, such as commitment to use, buy, or recommend a given healthcare product.

When offering samples or demonstration products, Member Companies must observe the following:

- samples must be offered in reasonable quantity and demonstration products must be provided for a reasonable period of time, in order to enable healthcare professionals and/or their patients to test the respective products;
- Member Companies must not direct the use of samples and/or demonstration products to their own private interest or those of a healthcare professional; healthcare professionals must determine the trustworthy and independent selection of patients who shall receive related benefits.
- Member Companies must apply to samples and demonstration products the same obligations applicable to original products, especially regarding their quality and traceability.

7.2 Medical-Purpose Items

Member Companies can offer medical-purpose items to healthcare professionals in order to provide **relevant educational content** on medical conditions, therapies, and/or healthcare products to healthcare professionals or their patients.

Under no circumstances shall a medical-purpose item be offered to a healthcare professional by a Member Company to take undue advantage, such as commitment to use, buy, or recommend a given healthcare product.

When offering medical-purpose items, Member Companies must observe the following:

- books and anatomic models must not exceed the single value of BRL 975.00 (U\$ 300.00);
- further medical-purpose items must not exceed the single value of BRL 150.00 (U\$ 45.00);
- Member Companies may offer up to three (3) medical-purpose items to each healthcare professional a year.

Member Companies may offer basic and low-cost stationery items for supporting healthcare professionals in events, namely pens and notepads, which are effectively necessary for such circumstances, so that they are not considered gifts.

Member Companies shall not offer gifts and any other benefits to healthcare professionals, even in the context of and marginally addressed in a legitimate interaction. Member Companies are allowed to offer items of merely symbolic value, such as cards in culturally relevant dates, birthdays and religious holidays.



Subsidies

8.1. Subsidies

Member Companies can grant subsidies to a healthcare organization for supporting a **legitimate action of educational, research, and/or medical treatment nature**.

Under no circumstances shall the granting of a subsidy to a healthcare organization by a Member Company may aim to take undue advantage, such as commitment to use, buy, or recommend a given healthcare product.

Upon granting a subsidy, Member Companies must observe the following:

- Member Companies must rely on **objective** and **appropriate selection criteria** for granting subsidies, based on **strictly technical criteria**; the commercial department may contribute to the process, but may not directly appoint the healthcare organization to be sponsored, in order to avoid conflicts of interest;
- the sponsored healthcare organization must be **accountable** for and **autonomous** towards the object of the subsidy, such as medical residence programs, scholarships, clinical trials, scientific papers, awareness, diagnosis, and treatment campaigns; Member Companies shall not interfere in the appointment of healthcare professionals occasionally hired and/or benefited due to the subsidy;

- the object, conditions, and compensation related to the sponsorship must be transparent and duly formalized in a written contract; each and every payment to healthcare organizations must be made in their own name, through bank transfer (never in cash), and duly recorded in the sponsoring Member Company's accounting book. Finally, as much as possible, Member Companies will be responsible for keeping evidence regarding the proper use of resources.



Interaction with Patients

9.1 Support to Patient Associations

Member Companies can interact and fund trustworthy patient associations in order to support **legitimate actions of educational, research, and/or medical treatment nature**, especially **initiatives to raise awareness** on issues related to health, diagnosis, prevention, and treatment of diseases.

Under no circumstances shall the support to a patient association aim to take undue advantage, such as commitment to use, buy, or recommend a given healthcare product.

Upon granting a subsidy, Member Companies must observe the following:

- Member Companies must rely on **objective** and **appropriate selection criteria** for granting support, based on **strictly technical criteria**; the commercial department may contribute to the process, but may not directly appoint the patient association to be sponsored, in order to avoid conflicts of interest;
- the sponsored patient association must be **accountable** for and **autonomous** towards the object of the support, such as awareness initiatives on issues regarding health, diagnosis, prevention and treatment of diseases; Member Companies shall not interfere in the appointment of healthcare professionals occasionally hired and/or benefited due to the support;

- the object, conditions and the compensation related to supporting must be transparent and duly formalized in a written contract; each and every payment to a patient association must be made in their own name, through bank transfer (never in cash), and duly recorded in the sponsoring Member Company's accounting book. Finally, as much as possible, the Member Company will be responsible for keeping evidence regarding the proper use of resources.

9.2. Contentious Measures in Health

Member Companies must respect patients' **autonomy** in their interactions and occasional disputes involving rights to access healthcare products against public and complementary health systems.

Member Companies shall not encourage patients or patient organizations to adopt litigious measures in the scope of any of these health systems, such as administrative and judicial legal actions in order to seek any Healthcare Products, especially experimental therapies, that is, those without Product's health inspection certificates.

9.3. Patient Data Privacy

Member Companies can interact with patients for legitimate purposes of educational, research, and/or medical treatment nature, especially in the scope of clinical trials and patient support programs.

In all their interactions with patients, Member Companies must respect patient data privacy, in order to **preserve their intimacy, honor and image**.

Member Companies must use and/or maintain patients' personal data exclusively for legitimate purposes, for a period as short as possible, and with restricted access, according to a legitimate usage need.



Validity and Interpretation of the Code

10.1. Enforceability

The present ABIMED Code of Conduct will be enforced on **January 1st, 2018**.

Member Companies will be granted **six (6) months** to adapt to the rules of the present Code of Conduct that did not make part of the previous version. Newly Member Companies will equally be granted six (6) months to adapt to the rules of the present Code of Conduct, counting from the day their membership is accepted.

10.2. Interpretation and Updating

The **ABIMED Ethics Committee** will be responsible for settling doubts and for the interpretation of omitted cases, not explained in this document, as well as for regular updates of the present Code of Conduct, upon consulting Member Companies representatives. The ABIMED Executive Board must approve any updates.

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Associação Brasileira da Indústria de Alta
Tecnologia de Produtos para Saúde