



# Code of Conduct 2022

## PREFACE

As part of its 25th anniversary celebrations, ABIMED, maintaining the entity's commitment to fulfilling our strategic axes of Business System Sustainability and Environment, Technology and Innovation, Ethics and Compliance, ESG and Education, launches the 6th Edition of its Code of Conduct, reviewed and updated.

This is one of the main documents that guide the activities of the Association and, especially, of the associates, allowing the existence and coexistence of companies, in a fair, transparent and regulated business environment with the best practices in the sector. Upon assuming the Presidency of the Board of Directors of ABIMED for the biennium (2022/2023), I would like to thank the members of the Legal and Compliance Committees, the Ethics Committee that performed brilliantly in the years 2020 to 2021 and all the representatives of the associates who contributed to the review and update of this Code.

**Antonio Nasser**

*Chairman of the Board of Directors*

## PREFACE

I proudly present this new, revised and updated 6th edition of the ABIMED Code of Conduct, a pioneering and reference instrument for the Medical Devices sector.

This edition brings new and compelling contributions to the regulation of our business environment, highlighting – among others – the adequacy of the code to the terms of the General Data Protection Law, innovations in matters related to ESG, changes in the Bidding Law, as well as as well as the new scenarios arising from the post-Covid-19 pandemic period.

I also highlight the implementation of the Independent Ethics Committee, formed by members of reference in the academic world in the area of Compliance and in the medical sector, with ABIMED being the first entity to have this structure, which will provide a level of excellence in the conduct of topics related thereto, never achieved in the sector.

I also thank all those who collaborated until we reached this 6th edition, especially the members of the Legal and Compliance Committees, the Ethics Committee for the period 2020 to 2021, and the associates who sent their suggestions, which allowed us to arrive at a document updated, modern and which will be extremely important in carrying out the Association's objectives to provide members with a competitive business environment, but above all, increasingly ethical, safe and transparent in the market.

**Fernando Silveira Filho**

*Chief Executive Officer*



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## PREFACE

The 2020/2021 biennium undeniably becomes part of world history due to the relevant facts that marked it. Perhaps the most relevant and certainly unforgettable of them was the terrible Covid-19 pandemic, which devastated humanity worldwide, impacting the field in which ABIMED members develop their activities: human health.

The pandemic has brought with it a new horizon in terms of technological solutions, health products and unique challenges in the field of integrity, ethics and the market for health products. The remote operation of health product companies and the uncertainties about the new forms of work and health care opened space for questioning of concepts already consolidated and brought new forms of action and conduct of Governments, companies, health professionals and patients.


Along with the fluidity imposed by the pandemic and the reinvention required by it, we are witnessing an urgent concern for the environment and the consequences of its progressive degradation. The effects of the climate changes and the changes brought about by the deterioration of ecosystems have had an increasing impact on human health, further catalyzing the development of the health products sector. More and more patients are demanding innovative, more effective and shorter-term solutions in the healthcare field, boosting, in an unprecedented way, the research and development of new technologies.

Faced with such intense and pressing transformations, developers and manufacturers of high-tech healthcare products, many of whom are proud members of ABIMED, have been experiencing a transformation that is as accelerated and positive as it is unexplored. We are living in new times, which demand new approaches, better instruments and the necessary agility to ensure that companies adopt an honest, ethical and safe behavior, at the same speed of the transformations that challenge them.

It is in this exciting scenario that ABIMED finds itself inserted and challenged to always accompany the rapid transformation of the reality that houses the advanced technology industry of health products. And to overcome this challenge, ABIMED uses its declared institutional vision: to be the reference association in the health products sector, imbued with ethics, innovation and promotion of access to the population.

In order to put into practice the vision that guides its existence and operations, ABIMED is proud and pleased to present the 6th edition of its Code of Conduct. An edition that results from an in-depth and detailed work by the Ethics Committee and the Compliance Studies Committee of ABIMED, supported by the Board of Directors and the Chief Executive Officer of the association. This edition brings the best and most modern practices in terms of regulating integrity, ethics and conduct, keeping our Code of Conduct in line with the best in the world and capable of connecting to an increasingly transitory and fluid reality.

This 6th edition of the Code of Conduct can be considered a milestone in the history of ABIMED, as it deals with sensitive issues in a clear, detailed and forceful manner, standing alongside the most advanced codes of conduct of health product industry associations in the world. Among so many relevant topics, the new edition addresses relevant topics such as the performance and remote communication of associates and health professionals, fair competition, relationships with public entities, the environment, data



privacy and even nuances of corporate governance, which aims to dissipate the possibility of improper action by associates and the association itself within the scope of its institutional activities.

In addition to bringing a renewed Code of Conduct, which reinforces ABIMED's commitment to promoting a fair business environment, this 6th edition follows the profound transformations promoted at ABIMED in the 2020/2021 biennium, which range from its new visual identity, through its institutional brand and new internal structures, to a renewed approach to ethics and integrity.

**Fernando Bocchio**

*Chairman of the Ethics Committee 2020/2021*

## **PREFACE**

We present the revised and updated 6th edition of our Code of Conduct, which brings together guidelines that should guide ABIMED's actions. The Code of Conduct is a living document and, therefore, needs to be revised and updated to cover the new situations of our days, without, however, distancing itself from the essential values that compose it, values that are immutable.

This set of rules derives from the values and guiding principles of ABIMED and is one of the main documents that serve as a guide and reference for the activities of the Association and, especially, of the associates, creating an ethical, transparent and regulated business environment with clear principles, enabling best practices in the industry. It is, therefore, a valuable tool for the maintenance and development of an environment marked by mutual respect and understanding of all stakeholders.

Upon assuming the Presidency of the Independent Ethics Committee for the biennium 2022/2023, I would like to thank, on behalf of all the members, the Board of Directors and the Executive Presidency of ABIMED for our choice and to assure that we will perform our functions to the highest degree of commitment and collaboration that will be within our reach.

**Ligia Maura Costa**

*President of the Independent Ethics Committee*





## THANKS

We thank all the members of the Legal and Compliance Committees for their efforts, especially the 2020/2021 Ethics Committee, for bringing so much technical knowledge, with so many resources to the medical device sector and the representatives of the Associated Companies, who somehow contributed to the revision and updating of this Code.

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## **ABOUT ABIMED**

ABIMED, an entity that brings together companies that represent about 65% of the medical equipment and devices market in Brazil, the segment has the equivalent of 0.6% of the national GDP, with a diversity of sizes and origin of capital and that the market generates approximately 140 thousand direct and qualified jobs, its purpose is to continuously contribute to the expansion of the population's access to advanced technologies for health, aiming at people's quality of life and longevity.

Our mission is to represent the interests of the health products technology industry, promoting the creation and maintenance of policies that guarantee a favorable environment for innovation and the competitiveness of the associates in the local and global markets, as well as contributing to the development of the healthcare sector health in the country.

Our Vision is to be the reference association in the Health Products sector, as an ethical, innovative institution that promotes the population's access to technology. We will do this based on our values, which are Integrity, Respect and Inclusion.





## OUR STRATEGIC AXES

- **SUSTAINABILITY OF THE SYSTEM AND BUSINESS ENVIRONMENT:**

Colaborar para um ambiente de negócios sustentável por meio do aprimoramento de processos e práticas de regulação pautadas por critérios técnicos. Além disso, participar e contribuir em todas as esferas pertinentes, no sentido de promover o desenvolvimento sustentável do país.

- **TECNOLOGIA E INOVAÇÃO:** To promote an environment favorable to innovation and the introduction of new technologies that benefit the entire health system through a more rational use of resources, greater effectiveness in treatments, contributing to a better quality of life for the population.

- **ETHICS AND COMPLIANCE:** Improve the sector's ethical environment through the practices of its members, promoting integrity programs, proposing public policies that promote ethics and transparency, in addition to strengthening the association's corporate governance.

- **ESG:** Contribute so that the sector is aligned with best practices for preserving the environment and committed to policies that promote the well-being of society as a whole.

- **EDUCATION:** Develop initiatives related to the dissemination of knowledge through courses and the provision of technical and academic content aimed at the employees of our associates and other interested parties.

## PURPOSE

The purpose of the Code of Conduct is to establish a minimum set of standards of conduct that should guide the activities of Associated Companies.

The purpose of this Code of Conduct is to promote reputable behavior on the part of Associated Companies and is not a legal guideline, under any circumstances. It must note that laws, rules and regulations applicable to Associated Companies may offer additional restrictions in relation to the topics discussed.

## SCOPE AND APPLICABILITY

**BUSINESS LINES:** ABIMED's Code of Conduct is mandatory for all Associated Companies, including their divisions and/or their activities related to equipment, devices and Health Products in general, regardless of any formality.

**RESPONSIBILITY:** Associated Companies are responsible for adopting processes that ensure that all their partners, managers, employees and service providers in general, including third parties, comply with the provisions of this Code of Conduct.

**LEGAL PRINCIPLES:** Associated Companies are responsible for knowing and complying with all laws, regulations, government guidelines and other self-regulatory rules applicable to their activities. The rules and principles of this Code of Conduct serve to supplement and not limit any other obligations of the Associated Companies.

## DEFINITIONS

The following terms, when used in capital letters, shall have the meaning indicated below. The examples presented for some of the definitions are merely illustrative and not exhaustive.

**ABIMED:** Associação Brasileira da Indústria de Tecnologia Para Saúde (Brazilian Health Technology Industry Association).

**SAMPLE:** Consumable, disposable or non-durable Health Product, offered free of charge to a Health Professional, to enable its experimentation by the Health Professional and/or their Patients.

**PATIENT ASSOCIATION:** Legal entity dedicated to the education, support, treatment and/or defense of interests in general of Patients with a certain pathology.

**PERSONAL DATA:** Information related to an identified or identifiable individual. Data is considered personal when it allows the identification, directly or indirectly, of the natural person who owns the data.

**SENSITIVE PERSONAL DATA:** Personal Data on racial or ethnic origin, religious conviction, political opinion, membership of a trade union or organization of a religious, philosophical or political nature, data relating to health or sex life, genetic or biometric data, when linked to a natural person.

**ASSOCIATED COMPANY:** Associated Company with ABIMED, operating within the Brazilian territory, and may represent its entirety or a division of the company and/or the company's activities related to Health Products, with applications in the clinical, medical, hospital, in vitro and clinical diagnostics fields, including companies with activities related to products and services for the development of technological solutions, applications and software for health (health-tech), laboratory, medical-hospital and clinical use.

**ENTERTAINMENT:** Actions or items offered to amuse or entertain a Healthcare Professional that represent value, are disconnected, or may override a legitimate reason or interest for interacting with an Affiliated Company. E.g. musical performances as a main attraction (not as background music during meals, receptions or events), artistic performances, sporting events, excursions or other events that are prominent or more relevant than the event or opportunity for legitimate interaction with the Health.

**GREENWASHING:** Pisleading promotion of policies, initiatives, programs and advertising of sustainability and ecological or socio-environmental responsibility, in order to demonstrate to society a false sustainability or responsibility implemented by the company, or to hide company actions that harm the environment.

**CONFIDENTIAL INFORMATION:** any information or data of a commercial or non-commercial nature that is restricted, confidential or non-public and that, if shared by the Associated Companies, among themselves or with third parties, may restrict, alter, unbalance or create commercial or non-commercial relationships. commercial products in the Health Products market, limiting free competition and free enterprise, such as, but not limited to, prices practiced at any time (past, present and future), market shares, costs, production levels, marketing plans, growth plans, discount policies, portfolios and information about customers and/or suppliers, new product launches, financial-accounting data when they are not public, such as billing/revenues, results, profits and profit margin, material commercial contracts (distribution, commercial representation, joint venture, commercial partnerships, manufacture on demand or to order, etc.), corporate transactions, participation in bids, among others.

**MEDICAL UTILITY ITEM:** Item of professional use that contributes to the education of Health Professionals and/or their Patients about medical conditions, therapies and/or Health Products. Eg: posters, scientific articles and books, anatomical models of Health Products or parts of human anatomy.

**LDC:** Means the Law for the Defense of Competition (Law 12.529/11).

**APPROPRIATE LOCATION:** Appropriate place for a legitimate interaction, promotional or non-promotional, between an Associated Company and a Health Professional and that favors the exchange of information and the professional relationship between the parties.

**GOVERNMENT OFFICER:** Natural person who holds a position, job or public function in a body, company or department of the direct or indirect public administration. For the purposes of this Code of Conduct, representatives of foreign public administration bodies in Brazil will be considered Government Officials.

**HEALTH ORGANIZATION:** Legal entity, constituted for the performance of Health Professionals, or that is in any other way inserted in the chain of use of Health Products, performing activities such as import, transport, storage, purchase, evaluation, recommendation, handling, sale, resale, distribution and/or application of Health Products, including, but not limited to, hospital, clinic, laboratory, pharmacy, university, optician, health education and/or research institution, professional or sectoral societies ( with the exception of Patient Associations) and similar entities. Such term will be extended to its partners, directors, executives, employees, contracted third parties, customers and business partners.

**PATIENT:** Natural person who has used, uses or will use any Health Products.

**DECISION POWER PERSONS:** Person who has the power to influence, choose and/or decide, over the sale, donation, acquisition, recommendation and use of Health Products, as well as over the contracting, cancellation or alteration of services provided by Health Professionals.

**CONSIGNED PRODUCT:** Health Product (Consigned Product) whose possession is transferred by an Associated Company (Consignor) to a Health Organization (Consignee) for the latter to store them in its own stock, without transferring its ownership. The ownership of the Consigned Product remains under the property of the Associated Company (Consignor) until the Health Organization (Consignee) uses or resells the Consigned Product until then under its custody and responsibility, at which time the ownership of the Consigned Product of the Associated Company is transferred to the Health Organization or to the Patient, as the case may be.

**DEMONSTRATION PRODUCT (DEMOS):** Durable Health Product, including equipment, provided free of charge and for a determined period of time to a Health Professional and/or Health Organization, to enable its experimentation by the Health Professional and/or their Patients.



**SINGLE USE PRODUCT:** Health Product for use in clinical, medical, surgical, dental, preventive, diagnostic, therapeutic, rehabilitative, contraceptive and/or aesthetic activity, usable only once, according to the manufacturer's specification (input, consumable or disposable).

**MULTI-USE PRODUCT:** Health Product for use in clinical, medical, surgical, dental, preventive, diagnostic, therapeutic, rehabilitative, contraceptive and/or aesthetic activities, which are not consumed or discarded in single use, such as equipment, appliances, instruments or accessories.

**HEALTH PRODUCT:** Equipment, device, material, article, device, input, material or system for medical, surgical, dental, laboratory, preventive, diagnostic, therapeutic, rehabilitative, contraceptive and/or aesthetic use or application, and which does not use pharmacological, immunological or metabolic to perform its main function in human beings, however it may be assisted in its functions by such means, duly registered, produced, imported, promoted and/or marketed by an Associated Company in Brazil.

**HEALTHCARE PROFESSIONAL:** Natural person who carries out their professional activities in the chain of use of Health Products, including, but not limited to, the activities of purchasing, evaluating, recommending, prescribing, handling and/or applying Health Products, including, but not limited to physicians, nurses, dentists, pharmacists, physiotherapists, scientists, researchers, health technicians, attendants, buyers and employees, including Decision-Making Persons, working in Health Organizations. For the purposes of this Code of Conduct, Representatives of the Associated Company, in the regular exercise of their duties, are excluded from the concept of Health Professional. For all intents and purposes whenever this Code refers to Health Care Professionals, this term will be extended to their family members, team members, friends, clients or business partners.

**SANITARY REGISTRATION OF THE PRODUCT:** Registration or enrollment of the Health Product with ANVISA – Agência Nacional de Vigilância Sanitária (National Health Surveillance Agency).

**REPRESENTATIVE OF THE ASSOCIATED COMPANY:** Natural person with a corporate or employment relationship with the Associated Companies.

**ABIMED MEETINGS:** Any meetings or official meetings, ordinary or not, recurring or not, of ABIMED councils, bodies, departments, committees, commissions, groups, task forces or similar in which Representatives of Associated Companies participate.

**PROCESSING OF PERSONAL DATA:** Any operation carried out with Personal Data, including, but not limited to, collection, receipt, production, classification, use, access, reproduction, transmission, distribution, processing, classification, archiving, storage, elimination, evaluation or information control, modification, communication, transfer, dissemination or extraction, defined and/or provided for in the General Law for the Protection of Personal Data, Law No. 13,709/2018 or any other relevant legislation.

**UNAUTHORIZED USE OF THE PRODUCT (OFF-LABEL):** Use, indication, recommendation or prescription of a Health Product that is not listed or has not been formally approved in the Sanitary Registration of the Product.

**FAIR MARKET VALUE:** Average value or average range of fair and adequate value, commonly used by the market to remunerate a Health Professional for the provision of a certain service or activity. The Fair Market Value can be measured by different criteria, such as, but not limited to, the sector, nature and/or location of the services, complexity, specialty and knowledge and technical and/or scientific experience of the professional, among others, considering historical data legitimate trading and/or independent market research.

**UNDUE ADVANTAGE:** Any and all unfair benefits in favor of an Associated Company, generally obtained through illegal and/or unethical acts. An Undue Advantage normally implies, but is not limited to, commercial or financial, such as the purchase, evaluation, recommendation, manipulation and/or application of products and/or services, not based on an independent technical decision or on the value, functionality or need of the product or service itself.

## CHAPTER 1 | FUNDAMENTAL PRINCIPLES

**1.1.** ABIMED is committed to fostering the ethical performance of Associated Companies, always bearing in mind the best interest of the Patient. For this, the following Fundamental Principles must guide all its actions and the norms of this Code of Conduct:

**A)** Austerity: Items of value delivered by Associated Companies to Healthcare Professionals, in the context of a legitimate interaction with each other, must meet objective criteria and be of modest and reasonable value.

**B)** Integrity: to act with integrity, in compliance with laws, rules and regulations, honestly, truthfully, fairly and with the highest ethical principles, in all activities;

**C)** Suitability: to ensure that all agreements, transactions, contracts and deals comply with ethical and appropriate commercial standards, are accurate and free from any proposal, implicit or explicit, of corruption.

**D)** Progress: to promote the continuous improvement of advanced technology products for health and medical, technical and scientific knowledge, as well as the access and safe and efficient use of these products.

**E)** Transparency: to ensure that relationships with Health Professionals and Government Officials have a clear and defined purpose, in order to avoid conflicts of interest.

**F)** Independence: to ensure the independence of Health Professionals and Government Officials, refraining from exerting influence to obtain Undue Advantages, in accordance with applicable laws, regulations and standards.

**G)** Image and Perception: to consider the image and perception of the advanced medical technology industry that will be projected to the public when the Associated Company interacts with Health Professionals, Health Organizations and the Government;

**H)** Equivalence: whenever an Associated Company hires a Health Professional to provide a service for, or on behalf of, the Associated Company, the remuneration of said Health Professional must be adequate and based on a Fair Market Value;

**I)** Documentation: All interactions between an Associated Company and a Health Care Professional, such as the contracting of services to be provided by a Health Professional for, or on behalf of, an Associated Company, must be the subject of a written agreement, which describes clearly, the purpose of the interaction, the services to be provided, the form and breakdown of reimbursement of expenses and the remuneration to be paid by the Associated Company to the Health Professional. The activities provided for in the contract must be substantiated and evidenced by activity reports and other similar documents. All required documentation, such as the contract, reports, invoices, vouchers and other documents, must be kept by the Associated Company for a reasonable period in order to justify the need for and performance of the services, as well as the reasonableness of the remuneration paid.

**J)** Free competition: ensure the independence of the Associated Companies, acting with loyalty and refraining from performing any acts that may infringe or restrict free competition and the economic order.

## CHAPTER 2 | CODE OF CONDUCT AND COMPLIANCE PROGRAM

### 2.1. Compliance Program

**2.1.1.** Associated Companies must have a Code of Conduct, or equivalent document, effectively implemented that provides for the principles, rules and ethical, integrity and conduct guidelines to be complied with by their partners, executives, directors, employees, representatives and third-party contractors, in order to comply with the laws, rules and regulations applicable to their activities, as well as to prevent, mitigate or repair illegal, illegitimate, unethical and disloyal actions or omissions.

**2.1.2.** Associated Companies must have a structured Compliance Program (Compliance) suitable for their activities that has been proven to be implemented and ostensibly communicated to their partners, executives, directors, employees, representatives and contracted third parties. The Compliance Program of Associated Companies must have the following minimum requirements, without prejudice to others that may be required by applicable legislation:

- A)** Senior management commitment (“tone at the top”);
- B)** Implementation and compliance with written policies and procedures;
- C)** Implementation and compliance with a consistent, periodic and auditable training plan;
- D)** Conducting evaluation (due diligence) of contracted third parties, including in the context of mergers and acquisitions;
- E)** Appointment of a person responsible for compliance (compliance) and/or a Compliance Committee, with the necessary technical training, autonomy, independence and necessary resources;
- F)** Conducting compliance risk assessments, monitoring and auditing (compliance);
- G)** Implementation and maintenance of a whistleblower channel and an independent whistleblower investigation process, with the necessary preventive and/or corrective actions; and
- H)** Availability and communication of the Whistleblower Channel to all partners, executives, directors, employees, representatives and contracted third parties of the Associated Companies, with the existence of an effective device to guarantee anonymity, secrecy and confidentiality of the complaints, as well as effective anti-retaliation policies for the whistleblower.

**2.1.3.** If the Associated Companies do not have a Code of Conduct, or equivalent document, or a Compliance Program previously, at the time or after their admission to ABIMED, a period will be granted to them to prepare one and prove its effective elaboration and implementation. If the Associated Company does not comply with the deadline granted by ABIMED, ANBIMED may apply the necessary measures provided for in its bylaws, rules, regulations and/or internal regulations.

### 2.2. Interaction with Third Parties

**2.2.1.** Associated Companies must maintain a robust management program for third parties and possible subcontractors in particular, but not only, those who participate in Health Product promotional and/or commercial activities, such as distributors, sales representatives / agents, wholesalers, marketing and independent sales representatives.

The third-party management program must include an evaluation process (due diligence), training in anti-corruption / anti-bribery and other practices related to relevant risks, formalization of the relationship between the parties in a written contract and recurrent monitoring of the activities of the third party, especially when representing the Associated Company before public administration bodies, Health Professionals, Health Organizations and/or Patients.



## CHAPTER 3 | COMPETITION

**3.1.** The Associated Companies must compete in the market in a fair and compatible way with the high ethical, integrity and legal standards in force, in order to obtain success in their business based on the merit and quality of their products and services, always aiming primarily at the good -being to the health and quality of life of Patients and consumers. Associated Companies are prohibited from engaging in illegitimate, illegal, unethical competition practices aimed at Undue Advantage, including, but not limited to, practices that target the abuse of economic power, illegitimate restriction and prejudice to free competition, as well as the creating and maintaining of barriers to entry or competition in the Healthcare Products market.

**3.2.** Whenever current and applicable laws, regulations and rules on competition are more stringent than the requirements of this Code, such laws, regulations and rules shall prevail over this Code and be applied in primacy.

**3.3.** Prohibition of Anticompetitive Agreements. The commercial strategies of the Associated Companies must be developed and implemented independently of any agreement or cooperation with competitors, being prohibited the signing of agreements with anti-competitive purposes or with possible anti-competitive consequences.

**3.3.1.** Associated Companies are prohibited from adopting “coordinated practices”, which reflect deliberate and intentional collaboration between themselves and other companies, aimed at eliminating or restricting competition in a given market or markets. The prohibition applies regardless of whether the agreement is based on a written agreement, an oral agreement, or a simple exchange of business information or Confidential Information.

**3.3.2.** Partners, managers, officers, directors, employees and contracted third parties of the Associated Companies must not initiate or participate in discussions about anti-competitive activities or exchange confidential information or commercial dealings with competitors (ex: discussions about prices, discounts, forecasts, margins of profit, cost structure, business strategies, customers, territories, strategic plans). If a competitor attempts to involve partners, managers, officers, directors, employees and contracted third parties of the Associated Companies, formally or informally, in such a discussion, such persons of the Associated Companies must stop the interaction immediately and communicate it internally to their leadership and/or, if they so wish, to the Ethics Committee, via the Abimed Complaint Channel.

The following are examples of agreements that typically violate applicable competition laws:

- Agreements involving the fixing of prices or terms of sale of products or services,
- Agreements involving fixing of prices or terms to be demanded from suppliers,
- Agreements involving division or allocation of geographic markets, customers or product lines,
- Agreements involving group boycotts or concerted refusals to deal with certain customers, suppliers or competitors, and
- Agreements involving coordination or allocation of bids, quotations or responses to Requests for Proposals (“RFPs”).

**3.3.3.** From time to time, the Associated Companies may consider possible agreements with competitors, however, these must serve a legitimate business objective and promote competition, innovation or economic efficiency. The partners, managers, officers, directors, employees and contracted third parties of the Associated Companies must not get involved in or agree to these types of agreements without first surrounding themselves with the necessary precautions or if they know, expect or verify that discussions in this regard may lead to agreements in any anti-competitive way. Some examples of these agreements include:

- Collaborations in research and development,
- Joint purchase or production agreements,
- license agreements,
- Agreements for joint promotional or marketing initiatives, and
- Joint ventures and partnerships.

**3.4. Meetings and Business Events.** The meetings and business events in which the Associated Companies participate offer them legitimate benefits for and, generally, the participation of partners, managers, officers, directors, employees and contracted third parties of the Associated Companies in such meetings and events is permitted. However, any meeting or other activity involving the sharing of Confidential Information between competitors may give rise to potential violations of competition laws, regulations and rules.

**3.4.1.** All requirements and prohibitions stated in this Code apply to Affiliated Companies' interactions with competitors at business meetings and events, whether formal or informal.

**3.4.2.** If Confidential Information is discussed or shared during a meeting or business event, a partner, manager, officer, director, employee or contracted third party of the Associated Companies must immediately protest, leave the meeting and ensure that both the protest and departure are documented in writing. Such fact must be immediately communicated internally to the leadership of the Associated Company with whom it has a link and/or, if desired, to the Ethics Committee via the Whistleblower Channel.

**3.5. ABIMED Meetings.** Class associations, such as ABIMED, play a fundamental role, constitutionally recognized, bringing together companies and individuals that have and share common interests with each other, in order to legitimately represent them in various spheres and forums of debate, both economic, political and social. However, despite the recognized beneficial aspects, ABIMED brings together competing companies in its staff, which are exposed to considerable risks of being involved in anti-competitive practices and of being subject, together with Associated Companies, to penalties provided for in the LDC, as well as damages to reputation and image. Possible discussions and/or adjustments between competitors within the scope of ABIMED can characterize infractions to the economic order and constitute a crime, being fundamental, the adoption of precautions to prevent such risks. Therefore, the following rules are mandatory and must be observed by all Associated Companies and their Representatives within the scope of ABIMED Meetings:

**3.5.1.** Discussion, deliberation or decisions at ABIMED Meetings that involve the exchange of Confidential Information or the mere possibility of anti-competitive agreements between Associated Companies or Associated Companies with competitors not associated with ABIMED are prohibited.

**3.5.2.** All requirements and prohibitions stated in this Code apply to the interactions of Associated Companies with competitors in ABIMED Meetings, whether formal or informal.

**3.5.3.** It is forbidden for any Associated Company to make use of ABIMED Meetings or the links established on the occasion of them, organize events or meetings that aim to seek possible agreements with purposes contrary to fair competition, aimed at harming free competition and free initiative and/or that aim to offer and/or obtain Undue Advantages.

**3.5.4.** If Confidential Information is discussed or shared during an ABIMED Meeting, the Associate Company Representative participating in the Meeting must immediately protest, leave the meeting and ensure that both the protest and departure are documented in writing. This fact must be immediately communicated to the ABIMED Ethics Committee, to the ABIMED Board of Directors or, preferably, via the ABIMED Whistleblower Channel.

**3.5.5.** As a way of preventing Confidential Information and possible anti-competitive practices from occurring within the scope of ABIMED Meetings, the following governance rules are mandatory for all Associated Companies and their Representatives:

**A)** Mandatory presence of an ABIMED employee at ABIMED Meetings. An ABIMED employee must always be present at ABIMED Meetings, whether formal or informal, in person or remotely, even when they take place outside ABIMED's headquarters.

**B)** Communications at official meetings. Representatives of Associated Companies may discuss, deliberate and communicate with each other only on appropriate occasions for each situation, on a previously established and scheduled day and time, with a pre-established agenda, to be held at ABIMED's headquarters or outside it, personally or remotely.

**C)** Permitted communication vehicles. The Representatives of the Associated Companies may discuss, deliberate and communicate with each other, by telephone, e-mail, audio and/or video conference tools or any other form of communication expressly approved by ABIMED. In any case, the ABIMED employee responsible for the topic, meeting, group or Meeting must always be copied and present in the communications. Such communications must comply with the following requirements:

- The use of private e-mails from the Representatives of the Associated Companies or of third parties unrelated to the Associated Companies or ABIMED, or other means of communication that do not identify and link the Representatives of the Associated Companies with their respective employers is prohibited.

- ABIMED may, at any time, contract and make available electronic means of communication, such as, but not limited to, messaging applications, electronic messaging services, virtual environments or websites provided by third parties, so that the Representatives of the Associated Companies can communicate.

**D)** Meeting agendas and topics not covered. Legitimate topics to be dealt with and discussed by the Representatives of the Associated Companies in appropriate situations in favor of ABIMED must always be included in the agenda/convention agenda, with the Association's letterhead and the name/signature of the responsible ABIMED employee, to be previously sent to each one of the Representatives of the Associated Companies and kept/archived at ABIMED's headquarters.

- Matters or themes not provided for in the agenda/convention agenda should not be dealt with or discussed, even though they may seem apparently "harmless" from a competition point of view.

- The convening agenda/schedule must be observed and complied with and the ABIMED employee or person in charge designated by ABIMED must draw up the respective minutes, including the discussions and deliberations that took place, including the Association letterhead and the list of those present, for filing at the headquarters from ABIMED.

**E)** Generic guidelines. It is forbidden to indicate or include generic topics or agendas for meetings and assemblies (eg "Other Topics of General Interest", "Other matters", etc.).

**F)** Unlegitimate discussions. Non-legitimate discussions (or, even if legitimate, that have the potential to be perceived as illegitimate discussions) about possible adjustment and/or standardization of performance of Associated Companies in the market or indication of exchange of commercially sensitive information are prohibited.

- Any illegitimate discussions or exchange of commercially sensitive information must be immediately interrupted and ceased and be recorded in the respective minutes, with the record of the intervention carried out, the indication of the Representatives of the Associated Companies involved and the list, with signature, of all those present. The fact must be communicated immediately through the available channels and detailed in Chapter 15 of this Code of Conduct, for the appropriate measures. If, despite the warning and intervention, illegitimate discussions and/or exchanges of Commercially Sensitive Information persist, the meeting must be formally and immediately closed and the facts that follow must be fully reported in the minutes, and such facts must be communicated as described above.



**G) ABIMED's Antitrust Statement.** At the beginning of all meetings, ABIMED's Antitrust Statement must be read aloud, all participants must expressly agree to its terms and such facts must be recorded in the minutes.

**3.6. Agreements with Customers and Suppliers.** Associated Companies are free to set and change prices for their own products and/or services, provided they are not predatory or harm fair and free competition. All information provided to the market on prices charged by Associated Companies, whether disclosed directly to interested parties or through publication of price lists, must be clear, true, accurate and compatible with the actual practices of the respective Associated Company. Certain restrictions on customers or suppliers may lead to non-compliance with laws, regulations or competition rules, such as:

- Establishment of exclusivity of purchase or supply and/or service,
- Restrictions on territory or customers to which a buyer may resell products,
- Prohibitions or imposition of terms for selling products over the Internet,
- Require customers or suppliers to disclose the commercial terms negotiated with the Associated Company's competitors. (Example: prices and discounts),
- Discount programs, primarily discounts given as rewards for purchases (e.g. "rebates" and guaranteed prices on demand),
- Commercial programs that use a product to force or encourage a buyer to purchase another product,
- Commercial programs that sell two or more products, only together as a bundle, or that price the bundle less than the sum of the individual prices,
- Imposing direct and exclusive purchase commitments on buyers, and
- Imposing obligations on suppliers not to sell to competitors.



## CHAPTER 4 | TRANSPARENCY IN BUSINESS PRACTICES

### 4.1. Intellectual property

**4.1.1.** With regard to intellectual property, the Associated Companies and/or their Representatives:

- A)** Must observe the laws, rules and regulations applicable to the subject, when acting on behalf of ABIMED; and
- B)** May only use ABIMED's brands and distinctive signs when acting as legal representatives of ABIMED and always aiming at ABIMED's institutional interests, which should never be superimposed by their own personal or professional interests.

**4.1.2.** Any material or other document developed within the scope of ABIMED, including within the scope of Councils, Assemblies, Departments, Working Groups, Committees, Task Forces, Events or any administrative activities of ABIMED, directly or by third parties, is and will always be the exclusive property of ABIMED, and all related intellectual property rights belong to it.

### 4.2. Confidential Information

**4.2.1.** Any Confidential Information to which the Associated Company, its Representatives and/or its contractors may have access due to participation in the Councils, Assemblies, Departments, Working Groups, Committees, Task Forces, Events or any administrative activities of ABIMED, is of exclusive property of ABIMED or the Associated Company that owns such Confidential Information, and its disclosure to any third parties is prohibited, except in cases required by law or by court order.

### 4.3. Access to Health Products

**4.3.1.** The Associated Companies must commit and act in order to contribute to the access to Health Products by Patients and Health Professionals throughout the national territory.

**4.3.2.** Associated Companies shall avoid price variations between purchasers of Health Products that do not arise from legitimate negotiations and other objective criteria, such as, but not limited to, purchase volume, payment term, delivery conditions and related costs.

### 4.4. Health Products Coverage by Supplemental or Complementary Health Institutions and Health Economics Information.

**4.4.1.** The Associated Companies may work with representatives of public agencies, the Ministry of Health, Health Departments, Health Professionals and/or Health Organizations in the legitimate defense of their commercial interests, either by providing subsidies for decisions regarding coverage (and payment amounts by) supplementary and complementary health institutions and/or by the SUS itself - Sistema Único de Saúde. To this end, the Associated Company may provide studies and technical information on medical conditions, therapeutics and/or Health Products, as well as economic data that help decision-making for the safe and efficient use of available technologies.

**4.4.2.** Promotional or non-promotional information to be disclosed and provided by Associated Companies about Health Products must be clear, truthful, balanced and consistent with available technical and scientific studies. Under no circumstances, promotional information, whether oral or written, may be directed to Health Professionals in disagreement with the Health Registry and with the authorized use of the Product.

**4.4.3.** An Affiliated Company may not interfere with a Healthcare Professional or Healthcare Organization's independent decision-making regarding coverage, reimbursement, and healthcare economic support.

### 4.5. Financial discount

**4.5.1.** Financial discounts for the purposes of this Code are those;

- A)** Granted by manufacturers, importers or distributors of Health Products;
- B)** Received by Healthcare Organizations or Healthcare Professionals healthcare providers, public or private, profit or non-profit purchasers of the Healthcare Product whose value is being discounted;
- C)** Incidents on direct billing to health services, owners, managers or persons responsible for the places where clinical, medical, surgical, dental, preventive, diagnostic, therapeutic, rehabilitative, contraceptive and/or aesthetic procedures are performed;
- D)** Granted in a clear, transparent manner, provided for in the contract and/or demonstrated in the invoice; and
- E)** Granted to/received by the same Health Organization or the same Health Professional purchasing the Health Product that is the object of the financial discount, with the use of the financial discount by a Health Organization or Health Professional other than the purchaser being prohibited.

**4.5.2.** In the regular course of their activities, the Associated Companies may grant financial discounts to Health Professionals and Health Organizations that purchase Health Products in the following situations:

- A)** When the cash discount is motivated by a legitimate business reason. Ex. 1: a Health Organization purchased surgical equipment and brought forward the payment term, causing the selling Associated Company to grant it a discount; or
- B)** When the financial discount is granted on an exceptional, occasional and sporadic basis, in the renegotiation of overdue or delayed-payment titles, considering the need for supply or replacement of products and the precariousness of the debtor's financial situation, under the commitment that it will not distribute the amount of the discount.

**4.5.3.** The financial discount may be granted by means of a bank slip or other financial means regulated by the Central Bank, and must be expressly stated in a specific field on the invoice.

**4.5.4.** In the case of a financial discount for the settlement of defaulted amounts, in which case the sales invoice has already been issued, the Associated Company must guarantee the signature of a formal document by the Health Organization or Health Professional, buyer and beneficiary of the discount, in which there must be original value and discount granted.

**4.5.5.** Where applicable, any fees charged by the buyer are equivalent to financial discounts, deducting part of the amount due for the purchase of Health Products. Such fees will only be allowed when they refer to legitimate services, provided for in the contract and effectively provided by the buyer to the Associated Company.

#### **4.6. Product Consignment**

**4.6.1.** The consignment of Health Products by the Associated Companies (Consignor) to their customers (Consignees) must be formalized by means of a written contract, which provides for the terms and conditions of the consignment.

**4.6.2.** Associated Companies must establish and ensure:

- A)** Clear and objective criteria to identify customers who can receive Health Products under the Consignment modality, in order to guarantee equity in the treatment of its customers; and
- B)** Procedures that guarantee transparency and legality in the consignment of Health Products, with the implementation and fulfillment of the following minimum requirements being mandatory, to ensure that there is no inappropriate transfer of valuable goods to the customer:

- Regular periodic checking of consigned product inventories, with issuance of a written report signed by Consignor and Consignee,
- Collection by the Consignor of products used by the Consignee, at a frequency clearly determined in the contract,
- Reconciliation of discrepancies between Consignor's records and the quantity of products used by Consignee or verified during inventory, with issuance of a written report signed by Consignor and Consignee, and
- Return or disposal of expired products by the Consignee to the Consignor.

## **CHAPTER 5 | INTERACTION WITH THE GOVERNMENT, PUBLIC TENDERS AND CONTRACTS**

**5.1.** The Associated Companies must observe the laws and rules applicable to public bidding and contracting ("Bidding Laws") when participating in any type of bidding or when entering into contracts with the direct, autonomous and foundation Public Administrations of the Union, States, Federal District and Municipalities and other bodies subject to such rules under waiver or unenforceability of bidding.

**5.2.** Without prejudice to other practices also prohibited by applicable legislation, including the Bidding Laws, Associated Companies and any of their partners, executives, directors, employees or contracted third parties, directly or indirectly, are prohibited from:

**A)** Giving gifts of any value to Government Officials, regardless of the purpose;

**B)** Making an offer, promise to pay or authorization of payment and/or donation of any sum of money or item of value (capable of influencing an action or decision) to Government Officials, with the purpose of inducing the beneficiary to perform or fail to perform any action, in violation of his/her legal obligation;

**C)** Use the offer, promise or authorization of payment and/or donation as an instrument to obtain and/or maintain business and/or undue advantages with government agencies;

**D)** Fix prices with competitors before or during the bidding process;

**E)** Committing fraudulent acts in order to obtain undue advantages through a public bidding or contract, such as, but not limited to:

- Organizing a company and its CNPJ, to participate in bids restricted to Small Businesses;
- Participating in bidding with the presentation of a fictitious or covering proposal. A fictitious or hedging proposal is understood to be one in which a competitor adopts at least one of the following conducts;
  - Agreeing to submit a higher bid than the winning candidate;
  - Presenting a proposal already aware that it is too high to be accepted;
  - Submitting a proposal that contains specific conditions that it knows in advance will not be accepted by the buyer;
  - Submitting a bid that is designed to give the appearance of genuine competition among bidders;
  - Asking its distributors/business partners to submit proposals, at pre-defined values, allowing them to win the bid among themselves. In order to prevent a manufacturer from directing its distributors to submit a proposal for the same bidding process.

**F)** Influencing the Government Official responsible for the public notice to include, change or modify a specification in order to target a specific manufacturer, distributor, brand or product, or to harm a specific competitor or company.



**G)** Assist in the preparation or writing of a public notice and/or intervene in any other stages of the bidding process and in auxiliary procedures, except when the buyer requests subsidies or technical details about products and/or services and provided that it is expressly authorized by the applicable legislation, including the Bidding Laws.

**5.3.** Provided that it is expressly required by the purchaser and admissible by applicable law, including the Bidding Law, Associated Companies are permitted to offer Samples and/or Demonstration Products to the purchaser, to enable the testing of the respective products by Health Professionals and/or by its Patients, subject to the rules in **Chapter 11**. In the case of Demonstration Products, they must return within a reasonable period, after the demonstration, in order not to characterize them as granting an improper benefit

## **CHAPTER 6 | INTERACTION OF ASSOCIATED COMPANIES WITH HEALTH PROFESSIONALS AND HEALTH ORGANIZATIONS**

**6.1.** ABIMED does not propose or suggest, in this Code of Conduct or in specific policies, spending limits per person on meals with Health Professionals or Health Organizations. Associated Companies, when implementing their Policies, must consider objective criteria to establish limit values per meal, considering, for example, variations between regions in Brazil and abroad. It is important to note that this Code seeks to balance the cordial treatment of Health Professionals and the need to ensure that the provision of meals and drinks, as well as hospitality and logistical support to Health Professionals are modest, reasonable and adequate, and not a way of inducing the Health Professional to buy, use, prescribe or recommend the products of the Associated Companies.

**6.2.** Associated Companies must ensure that all their relationships with Health Professionals and Health Organizations are reputable, in accordance with the laws, rules and regulations that apply to them, as well as the Fundamental Principles and other rules of this Code of Conduct. Affiliated Companies may interact with Healthcare Professionals and Healthcare Organizations for promotional or non-promotional purposes.

**6.3.** Non-promotional interactions.

**6.3.1.** Non-promotional interactions of Affiliated Companies with Healthcare Professionals and Healthcare Organizations must be aligned with one or more of the following purposes:

**A)** Research and Education: encourage research and education in the area of Health through legitimate support for research and education actions developed by Health Professionals and Health Organizations, contributing in a relevant way to the Health sector as a whole;

**B)** Advancement of Medical Technology: promote the development of advanced technology products for health, through innovation and improvement, an activity that often requires a collaborative process with Health Professionals and Health Organizations;

**C)** Safe and Effective Use of Medical Technology: Advanced technology Healthcare Products often require training, provision of educational services and technical support to Healthcare Professionals and Healthcare Organizations in order to ensure and continually improve their safe, efficient and more current use;

**D)** Access: Expand access by underserved populations to medical products, information and services. Associated Companies play an important social role, being able to work together with Health Professionals and/or Health Organizations to provide care products, educate patients and provide other services in the scope of charity in favor of needy populations, contributing with the public health system.

**6.4.** Promotional interactions.

**6.4.1.** Promotional interactions of Associated Companies with Health Professionals and Health Organizations must be cumulatively based on the following requirements:

**A) Legitimate Necessity:** Any promotional interactions of Associated Companies with Health Professionals and Health Organizations must be based on a valid, lawful and integral need to achieve a fundamentally commercial objective, such as, but not only, the presentation of resources and functionalities of a Health Product or medical technology, clarification of sales terms and conditions, disclosure of product and/or service offerings and their impact on Health care, launching new products and/or services, updating equipment, devices and supplies for health, providing information on health economics or procurement contract plans, visiting establishments or factories, holding meetings to demonstrate Health Products, among others.

**B) Provision of meals:** either in cases of promotional interaction in which Associated Companies promote products to Health Professionals or Health Organizations, or in cases where Health Professionals or Health Organizations provide services to Associated Companies to promote their products, the provision of meals and beverages must always be subject to the duration and legitimate purpose of the interaction and the presentation of information and/or services, as well as being modest, reasonable and appropriate for the interaction both in form and location, with no intention of entertainment or luxury.

**C) In the case of remote and virtual promotional events,** the offer of meals by Associated Companies to Health Professionals or Health Organizations is prohibited. In the case of hybrid promotional events (involving in-person and remote presentations and participation), the offer of meals by Associated Companies to Health Professionals or Health Organizations that are in person and physically at the event location is allowed.

**D) Environment and Location:** meetings may take place at the Health Professional's or Health Organization's workplace or in an external space that is favorable to interaction, such as, but not limited to, a restaurant, if it is an interaction during mealtimes, provided that objective criteria are observed. In this case, companies must implement written policies with the rules and criteria for providing such meals as part of promotional interactions.

**E) Hospitality and logistical support:** Associated Companies may provide hospitality (stay and meals during the stay) and logistical (transport) support, provided that objective criteria of modesty, reasonableness, necessity and professionalism are observed and that such support does not consist of undue advantages or anything of undue value or influence.

**F) Participants:** the Health Professional is not allowed to be accompanied by personal guests, family members or people who are not directly connected or are not indispensable and whose participation has no legitimate professional interest in the promotional interaction.

**G) Information:** Promotional information about Health Products must be truthful, balanced and consistent with available technical and scientific studies. Under no circumstances may promotional information, whether oral or written, be directed to Health Professionals in disagreement with the Sanitary Registration of the Product.

**H) Remuneration:** Any remuneration for the time spent by the Healthcare Professional in promotional interactions is prohibited, unless the Healthcare Professional is hired by the Associated Company as a speaker or presenter.

## **6.5. Conflict of interests**

**6.5.1.** Associated Companies must avoid situations of conflict of interest between their partners, executives, directors, employees, representatives and contracted third parties, especially sales representatives, and Health Professionals or Health Organizations. Ex.: Sales professional of the Associated Company negotiates and makes sales with Health Professional or with individual responsible for purchases and supplies of Health Organization with whom it has a relationship of friendship or kinship.

**6.5.2.** Associated Companies must:

**A)** Guide, through ostensible communications and periodic training, its partners, executives, directors, employees, representatives and contracted third parties to report actual and potential conflicts of interest with Health Professionals;

**B)** Whenever possible, adopt effective measures to prevent, identify, eliminate, mitigate and/or correct conflicts of interest; and

**C)** To the extent possible and appropriate, provide transparency and communicate cases of conflicts of interest, to educate and raise awareness among its partners, executives, directors, employees, representatives and contracted third parties.

**6.6.** Presence of an Associated Company Representative during medical, surgical, dental, laboratory, preventive, diagnostic, therapeutic, rehabilitative, contraceptive and/or aesthetic practice.

**6.6.1.** It is possible that a partner, executive, director, employee, representative or third party contracted from an Associated Company may be present and interact with a Health Care Professional during medical, surgical, dental, laboratory, preventive, diagnostic, therapeutic, rehabilitative, contraceptive and/or aesthetics practice, for a unique and strictly technical need and linked to the Health Product manufactured, imported, distributed and/or sold by it, contributing with its knowledge about such Products, provided that the following purposes are observed:

**A)** Explaining the operation of the exclusive settings, specific features and technical controls of the product;

**B)** Technically guiding the Healthcare Professional, their team and/or the operating room or care room, regarding the Associated Company's product and/or service, to ensure that the appropriate devices and accessories are available during the procedure, within the limits authorized by law, rule or regulation;

**C)** Acting transparently on behalf of the Associated Company to provide the necessary and adequate technical support; and

**D)** Complying with the requirements and policies of the healthcare facility where the interaction takes place, including patient accreditation and privacy requirements.

**6.6.2.** Partners, executives, directors, employees, representatives or contracted third parties of the Associated Companies are prohibited from:

**A)** Influencing the independent decision of a Health Professional with respect to their Patient;

**B)** Touching the Patient and/or physically intervening in the ongoing procedure;

**C)** Providing medical, surgical, dental, laboratory, preventive, diagnostic, therapeutic, rehabilitative, contraceptive and/or aesthetic advice or guiding the Health Professional in such practices; and

**D)** Issuing opinions or advice on competing products.

**6.7.** Hiring Health Professionals

**6.7.1.** Associated Companies may hire Health Professionals to provide services and/or meet a legitimate demand. Non-exhaustive examples of contracting or meeting legitimate and illegitimate demands are as follows:

**A)** Legitimate demand: hiring a Health Professional by an Associated Company to meet the need (I) to train Health Professionals in technical components and accessories for the safe and effective use of a Health Product; (II) for technical and specific knowledge in conducting research and product development; (III) to prepare an expert opinion on medical, surgical, dental, laboratory, preventive, diagnostic, therapeutic, rehabilitative, contraceptive and/or aesthetic issues associated with the product.

**6.7.2.** The Affiliated Companies may pay the hired Health Professionals a Fair Market Value proportional and

appropriate to the services provided. Such payment must be made, whenever possible, after the services have been performed. The Fair Market Value cannot be influenced by elements of the commercial relationship existing or under negotiation between the parties, such as the volume of products purchased, any amounts due and not paid.

**6.7.3.** Under no circumstances, the hiring of a Health Professional by an Associated Company may occur in order to obtain an Undue Advantage. Eg: hiring the Health Professional under the condition that he/she undertakes to buy, use or recommend a certain Health Product from the Associated company.

**6.7.4.** When hiring Health Professionals, Associated Companies must observe the following requirements:

**A)** The Associated Company must have an objective and adequate selection process to hire a Health Professional, based on objective and strictly technical criteria. The commercial area may contribute to the process, but, for conflicts of interest, it cannot be responsible for the decision to elect the Health Professional;

**B)** The object, conditions, remuneration and expenses related to the contract must be clear, transparent and formalized in a written contract;

**C)** Any and all payments to a Health Professional must be made in their own name or to the company for which they provide services, by means of a bank transaction (never in cash/currency), and duly recorded in the accounting books of the contracting Associated Company;

**D)** The Associated Company must keep evidence of the effective provision of the contracted services, such as reports of the activities carried out;

**E)** If the Health Professional hired is a Government Official, the Associated Company must notify the public entity that employs the Health Professional about the hiring and/or make the contract expressly include the Health Professional's duty to inform the public entity of which he/she is an employee, as well as obtaining his/her agreement with such contracting. The Associated Company must do the same if the hired Health Professional is employed by a private entity, especially if the hired Health Professional's employer maintains a business relationship with the Associated Company; and

**F)** The Associated Company may pay or reimburse the necessary and reasonable expenses incurred by the Health Professional hired to provide the contracted services, such as transportation, accommodation and meals, subject to the limits set forth in this Code.

## **6.8. Payment of Royalties to Health Professionals**

**6.8.1.** Associated Companies may agree to pay royalties to Health Professionals as consideration for the assignment or license to use a patent, trade secret, intellectual property or know-how.

**6.8.2.** In establishing the basis for calculating royalties to be paid to a Health Professional, the Associated Companies must ensure the implementation and compliance with mechanisms that ensure the objectivity of medical decision-making and avoid inappropriate influences

## CHAPTER 7 | EVENTS

### 7.1. Educational Events Organized by Third Parties

**7.1.1.** Associated Companies may sponsor and participate in educational events organized by third parties, aimed at Health Professionals, to meet legitimate needs for educational, technical, scientific and/or professional improvement of Health Professionals, such as symposia, seminars, conferences and scientific congresses.

**7.1.2.** If the organizer of the Educational Event chooses to delegate the organization and/or management of the event to a company/marketing agency/event organization, such delegation must have a contract signed between the organizer and the delegated company. The contract referred to herein must contain, at a minimum, the justification for the delegation, the scope of the delegated services, the amount to be paid for the services and the form of payment. If the payment of any amounts by any Associated Company to the delegated company/agency is allowed, such payments must be supported by a written contract previously signed by the Organizing Company, by the delegated company/agency and by the Associated Company, with the same requirements of the contract between the Organizing Company and delegated company/agency, plus the purpose of the payment to be made by the Associated Company, in order to ensure due transparency.

**7.1.3.** Associated Companies are prohibited from granting financial and/or in-kind support directly to Health Professionals to participate in educational events organized by third parties, that is, Associated Companies cannot pay for the registration, travel and accommodation of Health Professionals for such purposes..

#### **A) Promotional Activity**

- Associated Companies can purchase packages offered by the Educational Conference organizers, which include promotional and advertising services, such as advertising spaces to present the company, its brand and for the exposure of its products and brands. Packages must always have reasonable and appropriate values to achieve these objectives and must involve a tangible and measurable consideration to the Associated Company.

- Associated Companies must ensure that promotional activity at educational conferences Organized by Third Parties must always be guided by professionalism and respect the environment, event participants and competitors of Associated Companies, so as not to discredit or diminish the degree of confidence in the industry of medical high technology.

#### **B) Satellite Symposia**

- Satellite Symposia are symposia in addition to those provided by the organizers of educational conferences. Affiliated Companies can purchase Satellite Symposium packages offered by educational conference organizers and provide presentations with appropriate form and themes that fit into the overall content of the event.

- The Associated Companies will be able to determine the content of the Satellite Symposia to which they are entitled due to the purchase of packages from the organizers of the educational conferences, being responsible for the selection of the speakers.

- The Affiliated Companies must enter into a written service agreement with the speakers they select, being able to pay for their travel expenses, accommodation and registration of a Health Professional who must perform some type of legitimate activity at the Satellite Symposium, such as, but not only, participation as a speaker at the Symposium and advisory board meetings.

- The Associated Company is prohibited from paying for the expenses of Health Professionals who will work at the Satellite Symposium only as listeners.

- The Associated Company is responsible for controlling and ensuring that the content presented in the Satellite Symposia is administered and offered only to duly accredited Health Professionals.



## **7.2. Events Organized by Associated Companies**

**7.2.1.** The Associated Companies may organize and promote their own events, with the participation of Health Professionals, to meet the legitimate need, under the following forms of training and instruction of Health Professionals about their products and their medical technologies and promotional, sales and other business meetings

### **7.2.2. Training and instruction provided by the Associated Company**

**A)** Objective: to improve (I) knowledge and the safe and effective use of its products and related services, (II) the techniques and practices developed with their use and (III) the result of the procedures performed with such products, (IV) awareness about illness;

**B)** Context: the rapid and constant evolution of medical technology leads to changes, updates and new releases of complex equipment, devices and/or sophisticated software platforms that require proper technical instruction;

**C)** The procedures and practices in which advanced technology Health Products are used can be complex and delicate, requiring highly qualified and constantly improved clinical instruction;

**D)** Health Care Professionals need training and education on disease states and treatment options, patient eligibility and selection criteria, standards of care and procedural outcomes, clinical trajectories, and how medical technologies benefit certain patient populations, among other important topics, covered in appropriate training and instructions promoted by the Associated Companies.

**E)** When organizing events for the training and instruction of Health Professionals, the Associated Company must cumulatively observe the following requirements:

- **Information:** Information shared must be truthful and not misleading. The training content must respect the Sanitary Registration of the Products, refraining, for example, from disclosing Unauthorized Use of the Product (Off-Label), unless the law, regulations or applicable rules expressly allow it.

- **Location:** the events must be held in an Appropriate Location, as necessary, notably educational institutions, training centers of the Associated Company or third parties, place of professional practice of the Health Professional, among others.

- **Programming:** the event program must be rigorous from a scientific and/or educational point of view. The content of the program must include up-to-date technical and scientific information of a nature and quality suitable for Health Professionals.

- **Transparency:** information about the event's program must clearly indicate the company that will organize the event and must be made available early enough so that the invited Health Professionals can analyze the rigor and quality of the program.

- **Duration and Prohibition of Entertainment:** the program must not contemplate time intervals that allow other activities outside the purpose. It is important to emphasize that Associated Companies cannot provide, under any circumstances, entertainment and leisure to Health Professionals.

- **Qualified team:** the event must be conducted by a technically qualified team or professional, who may be representatives of the Associated Company's commercial area, provided they have the necessary qualifications.

- **Support for the participation of Health Professionals:** the Associate Company is entitled to offer hospitality and logistical support (ticket, accommodation and food) to the Health Professional, when he/she participates in an event for training and instruction and/or that requires "hands-on" activity. organized by it.

- **Product training:** the provisions of this item are only applicable when such product really requires practical training for its correct, safe and adequate use

- Procedure training: the provisions of this item are only applicable when such procedure really requires training for its performance.
- In cases where the Associated Company does not have the expertise and/or structure to train and instruct Health Professionals on products and/or procedures, requiring the support of a third party to organize and deliver the training and instruction event, the event will be considered proper to the Associated Company (only executed by a contracted third party) and, therefore, the Associated Company can offer logistical and hospitality support to Health Professionals.
- Criteria for selecting participants: Associated Companies must ensure that absolutely technical criteria are applied when selecting participants for training and instructional events organized by them, with the adoption of criteria based on commercial interests being prohibited.

## **CHAPTER 8 | SUPPORT FOR EDUCATION, SUPPORT FOR INDEPENDENT RESEARCH AND DONATIONS**

- 8.1.** Under no circumstances, the granting of educational support, research support or donations (in cash or in products and/or services) by an Associated Company to a Health Organization may occur in order to obtain an Undue Advantage
- 8.2.** Any and all support or donations must be made in compliance with applicable laws, regulations and standards and with this Code, in addition to being clear and transparent.
- 8.3.** No support or donation should be made to influence purchase decisions or Undue Advantage, nor should it be subordinated or related to commercial transactions or the use or recommendation of products of an Associated Company.
- 8.4.** No support or donation should be made considering the volume or value of purchases made or anticipated by a Health Organization.
- 8.5.** The sales, marketing and/or teams that have purposes, objectives or commercial interests of the Associated Company must not be involved in the selection process or decision to carry out any support or donation to be made.
- 8.6.** The support contract between the Associated Company and the Health Organization that is the beneficiary of a support or donation shall provide for the rendering of accounts by the beneficiary Health Organization whenever requested, as well as the maintenance of all records related to the receipt and to the use of resources arising from a support or donation, whether in terms of receipt, use and results related to the use of such resources.
- 8.7.** An Affiliated Company may not provide educational, research or donation support directly to or on behalf of Healthcare Professionals.
- 8.8.** Associated Companies must implement independent decision-making processes that allow them to identify, prevent or mitigate risks of corruption, bribery or granting of Undue Advantage related to the granting of support or donation. Therefore, the Associated Companies must have implemented and complied with the following requirements:
- A)** The processes must include the prior and documented evaluation of the support and/or donation, based on objective, adequate and strictly technical criteria for the selection of its beneficiaries.
- B)** Requests for support and/or donation must be made in writing by the eligible Health Organization, containing clear, transparent and sufficient information to allow objective assessment of the request and purpose.

**C)** The object and the terms and conditions for the implementation of the support and/or donation must be clear, transparent and formalized in a written contract signed by the Associated Company and the eligible Health Organization before they are carried out.

**D)** Any and all support or donation to a Health Organization must be made in its own name, by means of a bank transaction (never in cash), and duly recorded in the accounting books of the supporting or donor Associated Company.

**E)** The Associated Company will be responsible for maintaining evidence of the proper use of the support and/or donation resources.

## **8.9. Support to Education**

**8.9.1.** Associated Companies are allowed to grant financial and/or in-kind support to third-party organizers of educational events by the following means:

### **A) Support for Education:**

- Support for Education can be made in the form of a grant (transfer of financial resources and/or species) directly by the Associated Company to the organizer of the educational conference, so that the latter can use it fully and demonstrably in the Event).

- Support for Education must be the subject of a written contract, entered into between the Associated Company and the organizer of the educational conference, and the express provision of the Associated Company's right to request information and proof of the use of the provided resource for the intended purposes is mandatory and awake. The Associated Companies shall, guaranteed in the contract, have guaranteed the right to audit, at any time, the use of the resource provided.

- If requested by the Associated Company, the educational conference organizer must provide a written report on the full use of the Support for Education, duly supported by documentary evidence.

**8.9.1.1** The Education Support granted by the Associated Companies must meet the following purposes, on a non-cumulative basis:

**A)** Events organized by third parties;

**B)** Granting of postgraduate graduate scholarships; or

**C)** Support for public awareness campaigns.

## **8.10. Events organized by third parties**

**8.10.1.** An Affiliated Company may support an educational event organized by a third party directly to its organizer or to another entity designated by its organizer.

**8.10.2.** The educational event organizer may use the support to:

**A)** Cost or reduce the costs of holding the event;

**B)** Hire Health Professionals to provide services at the educational event. In this case, the Health Professionals hired with the resource of educational support cannot be identified nor identifiable to the supporting Associated Companies. However, the event organizer may reveal the identity of the Health Professionals hired with the educational support resources on the date or after the event, through the disclosure of a list to the Associated Company granting the educational support, whenever there is a legitimate need to do so, such as, but not limited to, auditing and compliance with applicable transparency laws. Such requirements must be included in the written agreement for the granting of support between the Associated Company and the event organizer.

**C)** Associated Companies must ensure that educational support is not granted to Health Organizations that allow the early identification of Health Professionals who will be hired to provide services at the educational event. Sponsor the participation of Health Professionals in the educational event. In this case, (i) the supporting Associated Company

shall not influence, guide or direct the decision of the organizer of the educational event on which Health Care Professional will be sponsored, and (ii) Health Professionals sponsored with the resource of educational support cannot be identified or identifiable to the supporting Company. However, the event organizer may reveal the identity of the Health Professionals sponsored with the educational support resource on the date or after the event, through the disclosure of a list to the Educational Support Associated Company, whenever there is a legitimate need to this, such as, but not limited to, auditing and compliance with current transparency laws. Such requirements must be included in the written agreement for the granting of support between the Associated Company and the event organizer.

**8.11. Commercial sponsorship.** Affiliated Companies may support a third-party event through commercial sponsorship, i.e. provide financial support to the third party event organizer in exchange for marketing and promotional benefits, such as space to display their brand at the venue event (or digital environment if it is a webinar), space to present its products, publicity in the promotion and in materials of the event and or other promotional opportunities. The level of this support in the form of commercial sponsorship must be based on a Fair Market Value, established by the event organizer, and there may be banners or packages available to companies that are willing to sponsor the event in the form of commercial sponsorship. Commercial sponsorship may occur for both face-to-face and virtual events, and the rules described herein apply to both modalities.

#### **8.12. Undergraduate and Postgraduate Scholarships**

**8.12.1.** Associated Companies may provide support to education by granting or supporting Health Organizations to award undergraduate and graduate scholarships to support the development of medical training for Health Professionals.

**8.12.2.** Only Health Organizations that host Health Professional training programs will be eligible to apply for or receive this type of education support.

**8.12.3.** Associated Companies cannot support undergraduate and graduate scholarships requested individually and directly by Health Professionals, nor can they be involved in the selection of Health Professionals who will benefit from the scholarships. Therefore, undergraduate and graduate scholarships can only be awarded to Health Organizations and not to Health Professionals.

**8.12.4.** Affiliated Companies may not directly pay or reimburse any costs or expenses incurred by Healthcare Professionals in connection with their education. If the Associated Company intends to support such costs, these must be provided by the accepted means of support for education, provided for in this chapter of the Code. To prevent conflicts of interest between Associated Companies and Health Professionals related to education support, Associated Companies must not have or request information from the Health Professional who intends to attend, is attending or has completed an educational course, even if taught or conducted by Eligible Health Organization, except in specific cases that are restrictive and perfectly provided for by the transparency law.

#### **8.13. Support for Third Party Independent Research**

**8.13.1.** Associated Companies may offer support to research programs of unequivocal initiative of third parties, through the provision of research grants in kind, in order to foster and encourage independent research with scientific merit:

**A) Goals and Milestones.** An Associated Company may support research that is independent and has defined goals, objectives and milestones. Research grant applications to Associated Companies must always be in writing, containing, as a minimum, the nature, scope, budget, approximate duration of the research and, if applicable, independent authorization or approval requirements.

**B) Limitations.** Research support may include amounts in kind, to defray expenses, products, materials and/or services previously and expressly specified, related to the research activity. Such amounts must be legitimate and reasonable, involving quantities of products and/or services in adequate quantities for the limited and exact duration of the research.

**C) Control of the Associated Company.** The eligible Health Organization must have independent control of the research, without interference or influence from the Associated Company granting the support. However, the Associated Company must have the right to verify that the support is correctly used and if it is used exclusively within the scope of the supported research, which may include the request for documents related to the bureaucratic part of the research.

#### **8.14. Donations**

**8.14.1.** Associated Companies may make financial donations or donations of Health Products from their manufacture, import, distribution or sale to philanthropic or non-profit institutions. E.g.: support for financial care for the health care of the needy population, financial support or in the form of products for the education of Patients and/or the general public, financial support or in the form of products for awareness actions posts about illness and treatment, sponsoring events for altruistic, charitable purposes, improving healthcare, providing disaster relief, supporting communities in need, supporting public awareness programs, driving or supporting diversity activities and inclusion.

**8.14.2.** In addition to serving the legitimate purposes described above, donations must be made only to philanthropic or non-profit organizations.





## CHAPTER 9 | MEDICAL UTILITY ITEMS

**9.1.** Associated Companies may offer Medical Utility Items to Health Organizations and/or Health Professionals that, under the law, regulations and applicable rules, are entitled to receive them, for the following purposes:

- A)** Educate Healthcare Professionals, Patients and/or consumers about medical conditions, therapies and/or Healthcare Products;
- B)** Assist Patients in understanding and administering their treatment or managing their health condition; or
- C)** When the Medical Utility Items are related to a disease state or therapeutic focus that is treated by the Associated Company's Health Product.

**9.2.** It is prohibited to offer Medical Utility Items to a Health Organization or a Health Professional by an Associated Company in the following situations:

- A)** Situations in which the offering of Medical Utility Items aims to obtain an Undue Advantage, such as obtaining a commitment to purchase, use or recommend a certain Health Product;
- B)** Situations in which Medical Utility Items compensate operating expenses or other routine expenses of the Health Organization or Health Professional, thus becoming relevant or meaning an Undue Advantage; and
- C)** Situations in which Medical Utility Items exceed the value limits set forth in this Code.

**9.3.** When offering Medical Utility Items, Associated Companies must observe the following value limits, otherwise they will be considered personal gifts or things of value, with the purpose of influencing the Associated Company for Undue Advantage:

- A)** Books and anatomical models may not exceed the individual net value of \$200.00 (USD) converted to national currency, with annual adjustment of PTAX +1.
- B)** Other Medical Utility Items (medical articles and studies, figures, charts and informative diagrams about diseases and therapies, etc.) cannot exceed the individual net value of \$30.00 (USD), converted to national currency, with annual PTAX +1.

**9.4.** Associated Companies may deliver up to 3 (three) Medical Utility Items per year to each Health Professional.

**9.5.** The purchase and distribution of Medical Utility Items by third parties hired by the Associated Companies on their behalf is permitted, and the rules of this Code apply to such activities. It will be considered a serious violation of this Code the purchase and distribution of Medical Utility Items by third parties contracted by an Associated Company without clear and transparent discrimination that they were for this purpose (e.g. an Associated Company contracts a third party for other activities and includes in the price of its remuneration the value for the purchase of anatomical models above the values provided herein, without specifying such amount).

**9.6.** Medical Utility Items must be purchased by Associated Companies through a purchase process and documented in the Associated Company's books and records, and the acquisition of Medical Utility Items at the personal expense of partners, executive officers, employees or third parties contracted by the Associated Companies.

The values of Medical Utility Items must be properly tracked, documented and, when necessary, disclosed in accordance with applicable laws, regulations and standards and/or the requirements of this Code.

## CHAPTER 10 | GIFTS, GIVEAWAYS OR OBJECTS OF PERSONAL VALUE

**10.1.** Associated Companies and their partners, directors, executives, employees or contracted third parties are prohibited from offering gifts, giveaways, objects that may have personal value and/or any other benefits to a Health Professional, even in the context and in a secondary way to a legitimate interaction. This means that Associated Companies will not be able to offer Healthcare Professionals:

**A)** Items that the Health Care Professional may use for non-educational or non-Patient purposes, such as, but not limited to, materials for everyday use and that form part of the fixed costs and expenses of their office, clinic or workplace, exfoliants, electronic equipment and devices (computers/notebooks/laptops, tablets, headsets, smart-watches, smartphones, artificial intelligence personal management devices, high-capacity storage devices, etc.);

**B)** Articles and promotional materials of the Associated Company or of a company represented by it that are not primarily educational and of a famous brand (even if the article is of minimal value) and that are related to the activity of the Health Professional, whether or not containing the name or the Associated Company's logo or one of its products.

**C)** Gifts and consumables such as alcoholic beverages, food, flowers, gift baskets, electronic equipment or devices, clothing items, watches, cash or cash equivalents (eg, gift cards);

**D)** Items related to Entertainment or entertainment, such as airline tickets, hotel and resort stays, sporting events, artistic shows.

**10.2.** Associated Companies may provide basic stationery items to support Health Professionals at events, such as pens and notepads, of low value and effectively necessary for such circumstances.

**10.3.** The prohibitions referred to above include any form of delivery of the items described herein, including delivery, donation, raffle or any other means.

**10.4.** Associated Companies and their partners, directors, executives, employees or contracted third parties are prohibited from receiving gifts, giveaways, things that may have personal value and/or any other benefits of a Health Professional, even if in the context and secondary to a legitimate interaction. The same items provided for in this Chapter are included herein.



## CHAPTER 11 | SAMPLES AND DEMO PRODUCTS

**11.1.** Associated Companies are permitted to offer, distribute and/or deliver Samples, and/or Demonstration Products to Healthcare Professionals and/or Healthcare Organizations, as long as permitted by applicable laws, regulations and standards and in compliance with the rules and other requirements set forth in this Code.

**11.2.** Exceptionally, Associated Companies may also offer, distribute and/or deliver products from other companies together with their Samples, and/or their Demonstration Products:

**A)** If the products of that other company are necessary for the evaluation, demonstration or correct and effective use of the Samples, Evaluation Products and/or Demonstration Products of the Associated Company; or

**B)** If the Associated Company is a legitimate distributor or representative of that other company; and

**C)** If the products of that other company are regularly registered with ANVISA and can be offered, distributed and/or delivered in Brazilian territory or in territories to which the Associated Company sells such products.

**11.3.** Samples. The laws, regulations and rules applicable to Drug Samples will be applicable to Health Product Samples with due interpretation and adaptation, keeping their particularities, characteristics and differences.

**11.4.** Products that require a medical prescription. Prescription of Health Products that:

**A)** Require prescription by a Healthcare Professional must not be offered by Affiliated Companies directly to Patients or Consumers, whether as Samples, Evaluation Products or Demonstration Products.

**B)** Do not require a prescription by a Healthcare Professional ("OTC" – "Over The Counter" or over-the-counter products) may be distributed directly to Patients and consumers, or made available for distribution by clients of the Associated Companies, provided that it is authorized by law, by contract or by this Code (e.g. pharmacies, drugstores, doctors, distributors, among others).

**11.5.** Labeling, quantities, tracking and return of Evaluation and Demonstration Products.

**A)** Samples must be

- Labeled as required by law (eg, "Free sample. Prohibited Sale");;
- Distributed in legally permitted packaging sizes and supplied only in quantities necessary to meet the purpose of evaluation or demonstration;
- Duly screened; and
- If applicable, promptly removed from the Health Care Professional's or Health Organization's premises at the end of the evaluation period, if no lease or purchase and sale agreement for the equipment has been entered into with the Associated Company.

**B)** Demonstration Products must be:

- Labeled as required by law
- Provided only for a period of time consistent with appropriate anticipated limits, according to the anticipated frequency of use and the number of Health Care Professionals who will require training and experience;
- Duly tracked; and
- If applicable, promptly removed from the Health Care Professional's or Health Organization's premises at the end of the demonstration period, if no lease or purchase and sale agreement for the equipment has been entered into with the Associated Company.

**11.6.** . The offering, distribution and/or delivery of Samples, Demonstration Products shall not be made:

**A)** In order to improperly reward, induce and/or encourage Healthcare Professionals and/or Healthcare Organizations to purchase, rent, recommend, prescribe, use or order products or services from the Associated Company and/or any other companies;

**B)** As part of the commercial negotiation or purchase price of a Medical Device. Eg: discount on the sale of a product; replacement of a product as part of its warranty; early delivery of a product to be purchased.

**11.7.** Receipt and documentation. Associated Companies must:

**A)** Maintain record of distribution and/or delivery of Samples, Evaluation Products and/or Demonstration Products; and

**B)** Retain the return receipt for Trial Products and/or Demonstration Products after trial and/or demo is complete.

**11.8.** The Affiliated Companies must inform Health Professionals and/or Health Organizations, in writing, of the free nature of the Samples and/or Demonstration Products, as well as the following conditions that must be applicable to their offer, distribution and/or delivery, and others that may be necessary, such as:

**A)** TDuration, return or destruction time. Use for a limited time, expressly provided for in a contract or in a formal document that determines the duration of the evaluation, demonstration or validity, after which such products must be consumed or destroyed (if it is a Single Use Product) or returned to the Company Associate (if Multi-Use Product);

**B)** The impossibility of selling, assigning, lending or leasing such products; and

**C)** Prohibition of use on humans, if they are Demonstration Products.

**11.9.** Quantity of Samples and/or for Demonstration Products provided for the purposes set forth in this chapter shall not exceed the quantity reasonably necessary to meet the assessment and/or demonstration by Healthcare Professionals and/or Healthcare Organizations (or, if permitted, by Patients or consumers).

**11.10.** Associated companies must have a clear policy in which they provide for which Demonstration Products may or may not be used in human patients, in which situations and under which criteria, in accordance with Brazilian laws and regulations.

**11.11.** This Chapter only applies to the offering, distribution and/or delivery of Health Products for evaluation and/or demonstration purposes, and does not apply to the supply of products for other purposes or ends, subject to other contracts, such as the supply of Health Products as a donation, for clinical studies and investigations, educational or research support, objects of commercial contracts as a way of granting commercial discounts or other price incentives.

## CHAPTER 12 | INTERAÇÃO DAS EMPRESAS ASSOCIADAS COM PACIENTES

### 12.1. Apoio a Associações de Pacientes

**12.1.1.** Associated Companies may interact and contribute financially or through products and/or services with reputable Patient Associations, to support a legitimate action of an educational, research and/or medical treatment/clinical condition clarification, such as actions raising awareness of issues related to health, diagnosis, prevention and treatment of pathologies;

**12.1.2.** Under no circumstances may the support of a Patient Association by an Associated Company be aimed at obtaining Undue Advantages, such as, but not limited to, obtaining a commitment to purchase, use, recommend or advertise a certain Health Product.

**12.1.3.** When granting support to Patient Associations, Associate Companies must observe the following:

**A)** The Associated Company must adopt strictly technical, objective, adequate and expressly documented criteria for evaluation (due diligence) and selection of Patient Associations to provide support;

**B)** The commercial area may contribute to the selection process of a Patient Association, but may not have any privileges or decision-making powers, in order to avoid conflicts of interest;

**C)** The Patient Association supported will be responsible for receiving, using and material proof of the support received, as well as remaining absolutely independent in relation to the object of support. E.g.: not using the support for purposes that do not directly benefit the Patients associated with it; use of support for awareness actions on issues related to health, diagnosis, prevention and treatment of pathologies;

**D)** The object, conditions and consideration related to the support must be clear, transparent, expressly stated in a written contract;

**E)** Any and all financial support granted by an Associated Company to a Patient Association must be carried out in its own name, by means of a bank transaction (never in cash), and duly recorded in the Associated Company's accounting books; and

**F)** The Patient Association must maintain evidence of receipt and use of the support granted, for the period established by law, and must provide reports and documentary evidence whenever requested by the granting Associate Company. The Associated Company must also maintain evidence of support being provided and its proper use.

### 12.2. Judicialization in Health

**12.2.1.** Associated Companies shall respect the independence of Patients and consumers in their interactions and possible disputes involving rights of access to Health Products before the public and private, supplementary and complementary health systems.

**12.2.2.** Associated Companies are prohibited from encouraging or financing Patients, consumers, health professionals, Health Organizations or Patient Associations to adopt litigious measures within the scope of any of the health systems described above, such as administrative and/or judicial initiatives, to claim any Health Products, such as experimental therapies, which do not have health registration or authorization.

### 12.3. Patient Data Privacy

**12.3.1.** Whenever Personal Data is processed, regardless of whether or not it is a Patient, the Associated Companies must strictly observe the rules and principles established in the LGPD.

**12.3.2.** In addition to other applicable rules and legislation, in all their direct interactions with Patients, the Associated Companies must guarantee the privacy of Personal Data, in order to preserve their intimacy, honor and their image.



**12.3.3.** Associated Companies are allowed to interact with Patients for the purposes of a legitimate action of an educational, research and/or medical treatment support nature, especially in the context of clinical research and support programs for Patients, the Processing of Personal Data of the Patient for their own benefit or that of third parties, except in the legal cases provided for in the LGPD.

**12.3.4.** In carrying out the activities, the Associated Companies must take the appropriate measures to ensure that the Personal Data are accessed and/or processed only by people who need this information, in the performance of their tasks, and that the data strictly necessary for the carrying out the intended activity, in particular, in relation to Sensitive Data, provided that the respective Processing of Personal Data is permitted under a legal hypothesis.

## **CHAPTER 13 | ENVIRONMENT**

**13.1.** Associated Companies must contribute to an ecologically sustainable development, continuously seeking to reduce the effects of their activities, their inputs, operations, products and services on the environment, through the implementation of internal environmental policies always in line with the legislation in force, aiming to avoid, minimize or compensate the negative environmental impacts related to their business.

**13.2.** In the regular course of their activities, Associated Companies are expected to make a conscious use of natural resources, as well as to maintain cooperative relationships with consumers, communities, suppliers, partners and governments in favor of environmental conservation.

**13.3.** Associated Companies must respect and comply with the provisions of current environmental legislation, being responsible to environmental agencies and society for any and all environmental damage or loss resulting from their activities and operations, as well as performing services and/or activities respecting the related legal, normative, administrative and regulatory acts at the Federal, State and Municipal levels, including, but not limited to, compliance with the following laws:

- Federal Law No. 6,938/81 (National Environmental Policy),
- Law No. 9.605/98 (Environmental Crimes Law) and
- Law No. 12,305/10 National Solid Waste Policy.

**13.4.** Associated Companies must implement efforts with their partners, officers, directors, employees, contracted third parties, business partners and suppliers of inputs and services, so that they also strive to protect and preserve the environment against harmful practices to it and observe the environmental legislation applicable to their activities.

**13.5.** It is advisable that the Associated Companies manage their supply chain of inputs and services, in order to identify critical links from the point of view of sustainability and environmental protection so that goals for improvements in the environmental indicators are established together with these ones. Maintaining business relationships with suppliers that are known to be inconsistent with environmental legislation should be avoided, as well as adopting measures to measure and periodically audit their activities.

**13.6.** The certification of environmental management systems is seen as good management practice and its implementation is recommended.

**13.7.** It is forbidden for Associated Companies to practice Greenwashing, and they must maintain auditable, truthful and objective information and data in relation to sustainability attributes related to their products and services.

## CHAPTER 14 | FINAL PROVISIONS

**14.1.** Compliance with the provisions of this Code is mandatory for all Associated Companies, in their divisions and/or activities related to equipment, devices and health products in general, regardless of any formality.

**14.2.** By being part of ABIMED, all Associated Companies assume the duty to observe, implement actions and controls so that all their partners, managers, officers, directors, employees and/or contracted third parties know, comply with and disseminate the rules of this Code, as well as undertake to deliver a copy of it to all its employees and third parties.

**14.3.** All Associated Companies, including those that are associated in the validity of this Code, must adapt to the rules within a period of up to 6 (six) months from the publication, through an internal ABIMED circular or on the **ABIMED website**, whichever occurs first. Until the deadline set forth in this item, the provisions contained in the 5th edition of the Code of Conduct remain in force.



## CHAPTER 15 | INTERPRETATION AND APPLICATION OF THE CODE OF CONDUCT

**15.1.** ABIMED's Ethics Committee will be responsible for providing interpretation, clarification, guidance and institutional positioning in cases not directly provided for in this Code, as well as for proposing periodic reviews of this Code. The update must be approved by the Board of Directors.

**15.2.** • In case of violation of this Code, ABIMED encourages all interested parties to submit substantiated and evidenced complaints through its complaint channel on the website [www.abimed.org.br](http://www.abimed.org.br)

## **ANNEX I | NON-EXHAUSTIVE LIST OF MAIN LAWS, REGULATIONS AND RESOLUTIONS RELATED TO THE SECTOR**

The Annex to this Code of Conduct presents a non-exhaustive list of laws, regulations and resolutions that were considered in the preparation of this Code of Conduct.

- Federal Constitution of 1988.
- Law No. 6,360, of September 23, 1976 - Provides for the Sanitary Surveillance to which Medicines, Drugs, Pharmaceutical and Related Inputs, Cosmetics, Sanitizing Products and Other Products are subject, and makes other provisions.
- Law No. 6,437, of August 20, 1977 - Defines violations of federal health legislation, establishes the respective sanctions, and makes other provisions.
- Law No. 9,279, of May 14, 1996 - Regulates rights and obligations related to industrial property.
- Law No. 10,406, of January 10, 2002 - Brazilian Civil Code.
- Law No. 12,529, of November 30, 2011 - Structures the Brazilian System for the Defense of Competition; provides for the prevention and repression of infractions against the economic order; amends Law No. 8,137, of December 27, 1990, Decree-Law No. 3,689, of October 3, 1941 - Criminal Procedure Code, and Law No. 7,347, of July 24, 1985; revokes provisions of Law No. 8,884, of June 11, 1994, and Law No. 9,781, of January 19, 1999; and takes other measures.
- Law No. 12,846, of August 1, 2013 - Provides for administrative and civil liability of legal entities for the practice of acts against the public administration, national or foreign, and other provisions.
- Law No. 13,709, of August 14, 2018 - General Personal Data Protection Law (LGPD).
- Law No. 14,133, of April 1, 2021 - Administrative Procurement and Contracts Law.
- Decree No. 8,077, of August 14, 2013 - Regulates the conditions for the operation of companies subject to sanitary licensing, and the registration, control and monitoring, within the scope of sanitary surveillance, of the products referred to in Law No. 6,360, of 23 of September 1976, and makes other provisions.
- RDC ANVISA nº 185, of October 22, 2001 - Technical Regulation that deals with the registration, alteration, revalidation and cancellation of the registration of medical products at the Agência Nacional de Vigilância Sanitária (National Health Surveillance Agency – ANVISA).
- RDC ANVISA No. 36, of August 26, 2015 - Risk classification, registration and registration control regimes and labeling requirements and instructions for use of in vitro diagnostic products, including their instruments.
- RDC ANVISA No. 40, of August 26, 2015 – Defines the requirements for the registration of medical products.
- CREMESP Resolution No. 273, of February 3, 2015 - Establishes the guiding criteria for the physicians' relationship with the orthotics, prostheses, special materials and medicines industries.



## ANNEX II | DECLARATION OF RECEIPT AND COMMITMENT

I received the 6th Edition of the ABIMED Code of Conduct and, hereby, I confirm the commitment to comply with its guidelines and prove the delivery of the code to all employees and third parties, and also to authorize that this submission be carried out directly by ABIMED.







[www.abimed.org.br](http://www.abimed.org.br)

