



# CODE OF INTERACTION

WITH HEALTH CARE
PROFESSIONALS 2025

# **CODE OF INTERACTION** WITH HEALTH CARE PROFESSIONALS





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The Mexican Association of Innovative Medical Device Industries (AMID) is a non-governmental and non-profit group of leading companies in Medical Devices and diagnostic systems, which promotes the advancement of health services in Mexico through access to medical advances that promote the improvement of people's quality of life.

AMID's member companies include the world's leading Medical Device and diagnostic systems companies, and are required to comply with the ethical standards set out in the Codes.

Medical devices and diagnostic systems often rely heavily on the active participation of health care professionals from start to finish, as opposed to drugs or biological substances that act on the human body by pharmacological, immunological, or metabolic means.

Medical Devices and diagnostic systems in general function as an extension of the physician's hands, in circumstances they assist in the diagnosis, monitoring and treatment decisions of Health Care Professionals; under other conditions they generate synergy with other technologies or other products, guaranteeing a safer and more effective use of them.

The scope of beneficial relationships between Healthcare Professionals and companies is broad and includes intended interactions. Among the objectives of these interactions we can mention:



## Promoting the advancement of Medical Devices and diagnostic systems.

The development and improvement of state-of-the-art medical devices and diagnostic systems are collaborative processes between companies and healthcare professionals. Innovation and creativity are essential aspects for their development and evolution, which usually occur outside the laboratories of companies.



## Reinforcing the safe and effective use of Medical Devices and diagnostic systems.

For the safe and effective use of Medical Devices and diagnostic systems, companies are generally required to provide Health Care Professionals with appropriate instruction, education, training, service, and technical support. Sometimes, regulatory authorities require such training as a condition of product approval.



#### Promoting research and education.

The support that companies provide in good faith to medical research, education and the promotion of professional skills increases patient safety and increases access to medical devices and diagnostic systems.



This Code establishes standards for the ethical promotion of Medical Devices and diagnostic systems for Health Care Professionals to ensure that Associates' relationships with such Health Care Professionals are appropriate and perceived as such. The guidelines described in this document are aligned with provisions issued by international organizations such as MedTech Europe, AdvaMed, and APEC; and are based on the following principles:





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



• **Separation:** Relationships with Health Care Professionals should not be used to influence or bias, through improper or improper advantage, their therapeutic, purchasing, use, or recommendation decisions; nor should such interaction be dependent on sales transactions or the use or recommendation of products by ASID's associates.



• Consistency: Agreements with Health Care Professionals must meet commercial standards, be accurate, fair, and free from corrupt intent



• **Development:** Relationships with Healthcare Professionals are intended to drive Medical Devices, innovation, and care and improvement of patients' quality of life.



• **Transparency:** The interaction of Health Care Professionals must have a clear purpose and scope; always complying with national and local laws, regulations or professional codes of conduct.

It is the responsibility of each of the associated companies to ensure that all its employees are aware of these obligations and that all necessary measures are taken to prevent, detect and report any violation of the AMID Codes.

It is a requirement that all AMID Associates adhere to and comply with the Association's Codes.

It is a known fact that Associates may interact with Health Care Professionals directly or through the Commercial Intermediaries through which the Associates act by virtue of a distribution scheme, integration, commercial agency, commission, or any other provided for in the Mexican regulatory framework.

In this regard, AMID Associates are expected to enter into contracts with their Business Intermediaries, in which each third party explicitly acknowledges their acceptance and commitment to comply with the AMID Codes, in addition to observing the applicable legislation of the country where the contract is concluded.

AMID Associates shall be responsible for ensuring compliance with this Code by their Commercial Intermediaries. Any violation of the AMID Codes by them shall be attributable to the relevant Associate who may be subject to the sanctions provided for in the AMID Codes.

In the event that the Associates' internal codes contain provisions or interpretations different from those contained in the AMID Codes, the Associates are obliged to apply the stricter ones.

AMID Associates will be responsible for monitoring and verifying that violations of this Code are corrected, as well as ensuring that internal structures and procedures (including appropriate training of their employees and their Business Intermediaries) are in place to ensure that interactions with Health Care Professionals are conducted in a comprehensive manner, congruent and transparent.



AMID is open to receiving complaints, regardless of the source, in relation to any aspect of this Code, in accordance with the provisions of the Procedure for Complaints of Non-compliance with the Existing Codes of the AMID. Where it is determined that a violation of this Code has occurred, the aim shall be to correct the violation as soon as possible.

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## To whom does the AMID Code apply?

The AMID Code is intended to apply to all Associates (including their employees) and their business intermediaries.

# CHAPTER 1

#### 1.1 Definitions

- AMID: Asociación Mexicana de Industrias Innovadoras de Dispositivos Médicos A.C.
- i. **Promotional Items:** Low-value items used to promote the Associates' brand and that may be given to Health Care Professionals. Books and anatomical models are not considered Promotional Items.
- ii. **Associates:** They are all those legal entities that make up the AMID by agreement of the Board of Directors of the association.
- iv. **Asset of Value:** It will be any quantifiable benefit in money or in kind including but not limited to: movable or immovable property, travel, donations, contracting of services or the promise of the granting of these.
- Medical Devices: Any instrument, apparatus, utensil, machine, implant, diagnostic agent, material, substance, or similar product, including software for its operation, to be used, alone or in combination, in human beings; with any of the following intentions of use:
- Diagnosis, prevention, surveillance and/or aid in the treatment of diseases;
- Diagnosis, surveillance, treatment, protection, absorption, drainage or aid in the healing of an injury;
- Research, substitution, modification or support of anatomy or a physiological process;

Life support;

Control of conception;

- Disinfection of other Medical Devices;
- Disinfectant substances;
- Provision of information through in vitro examination of samples taken from the human body, for diagnostic purposes;
- Devices that incorporate tissues of animal and/or human origin;
- Devices used in in vitro fertilization and assisted reproductive technologies;

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And whose primary intention of use is not through pharmacological, immunological or metabolic mechanisms, however, they can be assisted by these means to achieve their function. Medical Devices include health supplies in the following categories: medical equipment, prostheses, orthoses, functional aids, diagnostic agents, dental supplies, surgical and healing materials, and hygienic products.

- vi. **Government Entities:** National, state, or local agencies, dependencies, or public bodies, as well as government-controlled enterprises.
- vii. **Events:** These are congresses, symposiums, courses and their complementary educational events also called satellite symposiums, scientific or professional regardless of their face-to-face or virtual form, which must aim to support the advancement of medical science, the education of Health Care Professionals and the patient; or independent medical research.
- **Entertainment Events:** Any activity or event of cultural, recreational or leisure content, including but not limited to: Sporting events, tourism, theater, golf, skiing, vacation activities, among others, regardless of the value that the activities themselves have, their recurrence and the time dedicated to them.
- ix. Collaborative Events: Any event held in conjunction with Health Care Professionals or any formally constituted medical organization, association, institution, or foundation that one of its purposes is to promote education or awareness of medical conditions.
- covernment Official: Any employee of the national or foreign government who works in a government entity, including, but not limited to: public servants of the federal, state, and municipal public administration; legislators, representatives of the judiciary, employees of the national or foreign health sector, personnel of customs offices, tax collection offices, and all authorities related to laws and regulations; health regulations and other applicable regulations. Any employee of hospitals affiliated with public or military educational institutions will also be considered a Government Official; as well as any employee of government institutions working in health care facilities or those involved with Government Entities and members of political parties, officials thereof or candidates for officials.
- xi. Virtual Interaction: These will be understood as interactions with Health Care Professionals through the use of telecommunications, information technologies and digital platforms whatever they may be, in order to inform, promote, share and disseminate educational content and material.
- Commercial Intermediaries: They will be those natural or legal persons, of Mexican nationality or foreigners, who act in the name, on behalf of or in the interest of any of the Associates, with Health Care Professionals in the Public and/or private sector and who therefore may influence the conduct or decision of said third party in order to attract or retain business, such as: Distributors, sub distributors, agents, sales representatives, representatives, principals or representatives, attorneys-in-fact, commission agents, managers, consultants, advisors, subcontractors, sales representatives or employees, value-added resellers and/or channel partners and integrators.
- xiii. Paradise Places: All those mentioned in Annex I "Paradise Places in national territory" of this Code.



- Educational and/or scientific material: Articles of design or didactic content, whose purpose is to make available to Health Care Professionals tools to educate patients or Health Care Professionals. We can mention anatomical models, books or material in optical, magnetic, electronic support, etc.
- **Related Parties:** Any person who is linked to the Associates or Health Care Professionals either by filiation, sentimental relationship, labor, professional or business relationships, including ascendants, descendants, collateral relatives up to the fourth degree, spouses, common-law partners, friends in general, partners or societies of which the Associates or Health Care Professionals are a part.
- xvi. Commercial Sponsorship: A payment or support in cash and/or in kind provided to a third party in exchange for opportunities for advertising, promotion, or company presence (e.g., a "booth" in a Third Party Program).
- Third-Party Program: An independent, bona fide educational, scientific, business, and policy-making conference, meeting, or event related to health care, organized by a third party other than a partner.
- Health Care Professionals: They are all those professionals, technicians and auxiliaries of the disciplines for health care, who can work within the public or private sphere, including managerial, administrative, operational and warehouse personnel; which include but not limited to the following: doctors (including all specialties and subspecialties of medicine), laboratory personnel, dentists, veterinarians, biologists, bacteriologists, nurses, social workers, chemists, psychologists, sanitary engineers, biomedical engineers, nutritionists, dieticians, pathologists. For the purposes of the provisions of this Code, any person who directly or indirectly purchases or exerts an influence on the prescription and recommendation of Medical Devices shall be equated to Health Care Professionals.
- xix. Satellite Symposium: A program organized and funded by the company that is attached to a Third Party Program, but is not controlled by the third party organizer.

  These programs typically take place during meal breaks in the Third-Party Program and may address education and training topics that align with the Third-Party Program's focus.
  - A Satellite Symposium shall be held in close physical and temporal proximity to a Third-Party Program and shall be included in the official agenda of the Third-Party Program.
- Educational Subsidy: A payment or support in cash or kind to a third party (such as medical organizations, continuing education institutions) in order to reduce the costs related to the participation of Health Care Professionals in the scientific or educational event organized by that third party.
- Bribery and/or Improper Payment: Any unlawful action consisting of: Offering, suggesting, promising, delivering or receiving any Asset of Value to Health Care Professionals and/or Government Official, in exchange for any of them performing or refraining from performing an act related to their functions, for the purpose of obtaining, Obtain or retain business in the institutions in which they provide their services. It is considered Bribery and/or Undue Payment regardless of the acceptance or receipt of the money, gift or Asset of Value, or the result obtained.



Fair Market Value: The value of an in-kind payment or benefit as fair and adequate remuneration to Health Care Professionals for their services rendered, rights supplied, or work performed that are considered commercially legitimate factors and can be objectively demonstrated, without regard to aspects such as sales volume or the value of any returns or purchases.

#### **ADDITIONAL INFORMATION**



For the purpose of the AMID Code, "Health Care Professionals" are not necessarily limited to a licensed clinician, it may vary depending on the facts and circumstances.



# **Consulting Agreements with Healthcare Professionals**

# 2.1 Relationship with Health Care Professionals

Compliance with the principles set forth in this Code is the cornerstone of the relationship between Associates and Health Care Professionals. In this relationship, impartiality must always prevail, putting innovation and Medical Devices for the benefit of care, and the improvement in the quality of life of patients.

All Associates agree to abide by the following principles when interacting with Health Care Professionals:

- Separation: Interactions with Healthcare Professionals must always leverage innovation and Medical Devices for the benefit of care and improvement of patients' quality of life, may never be misused to influence purchasing decisions through inappropriate or improper advantages, and such interactions must not depend on sales transactions or product use or recommendation.
- Non-granting of Valuable Goods for the purpose of exerting undue influence or advantage: AMID Associates agree to refrain from directly or indirectly making (through their Commercial Intermediaries), offers, promises or authorizations for the delivery of any Valuable Goods that are intended to exert undue influence on any act or decision of Health Care Professionals and/or Government Officials, with whom they interact. Likewise, all Associates are obliged to comply with the anti-corruption and anti-bribery provisions contained in federal and local laws, the anti-corruption conventions to which Mexico is a party, the codes of ethics of the institutions and the provisions of this Code.
- Objective Advertising: AMID Associates undertake that the promotion of their products will encourage the proper use of Medical Devices and diagnostic systems by presenting them in their advertising in an objective manner; avoiding misleading advertising or exaggeration of their properties, avoiding misleading decision-making.



Standards and policies: Likewise, Associates must have internal policies that contain a definition of requirements by item mentioned in this document; in line with local regulations and what is mentioned within this Code. Associates may request from Health Care Professionals and/or Government Officials the necessary documentation to make their relationship transparent.

#### **KEY CONCEPTS**

Companies rely on the expertise of Healthcare Professionals in a variety of important ways, such as training in the safe and effective use of Medical Devices, conducting research, and developing product advancements that lead to safer and more effective treatments for patients.

Based on legitimate need, companies hire Health Care Professionals through written contracts that document the Health Care Professionals' services and any compensation at Fair Market Value.

# 2.2 Hiring Health Care Professionals to Provide Consulting Services

Associates may hire face-to-face or virtual consulting and/or advisory services from Health Care Professionals to provide a wide range of valuable services in good faith, such as: presentations at trainings sponsored by any of them, the delivery of workshops, conferences, tutorials, preceptorships, referral center services or centers of excellence, participation in advisory boards or focus groups, Medical Device development agreements and research services (such as research and development, clinical studies, clinical research services, collaborative research, and post-market research), agreements for the development or transfer of intellectual property, product demonstration, for which Associates shall compensate within Fair Market Value to the Health Care Professionals.

Associates must apply the following principles to all consulting agreements with Health Care Professionals:

- **Legitimate need.** There must be a previously identified and legitimate need for the contracted services, and they must not be intended to induce service providers to purchase or recommend products from the Associates.
- Selection of consultants. Associates must select only appropriately credentialed Health Care
  Professionals to act as consultants, based on the qualifications of Health Care Professionals to meet
  the identified need. Examples of these qualifications include the Health Care Professionals'
  specialty, years of experience, location, practice setting, clinical research experience, podium
  presence, conference and publishing experience or experience with, use of, or familiarity with
  specific Medical Devices, among other capabilities.

Associates should not select or compensate consultants for prior use or as an illegal inducement
for future purchases or referrals.



Associates must have internal controls in place so that consultants are not selected based on past or future sales considerations.

- **Number of consultants.** Associates should hire only the number of consultants necessary to meet the previously identified legitimate need. Fully justifying the reason for aspects such as the program of the event, the number of participants, number of sessions, among others.
- Compensation of Fair Market Value. Associates must compensate a consultant in accordance
   with Fair Market Value in a transaction of services provided under market conditions taking into account the consultant's qualifications. Associates should not base compensation on the volume or value of the consultant's past, present, or anticipated business.

#### **ADDITIONAL INFORMATION**

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A legitimate need arises when a company requires the services of Health Care Professionals to achieve a specific objective, such as the need to train Health Care Professionals in the technical components in a safe and effective manner using a product; the need for clinical expertise in conducting research and development of a product; or the need for a doctor's expert opinion on clinical issues associated with a product. The design or execution of an agreement to generate business or to reward referrals from contracted Health Care Professionals are not legitimate needs of a consultation agreement.

When determining whether Health Care Professionals are qualified to act as consultants, is it appropriate to consider aspects such as being an expert or thought leader on the specific topic?



Yes. There is no single appropriate method for evaluating the qualifications of Health Care Professionals to act as a consultant. Factors such as the number of years of practice, familiarity with the company's products, educational and training background, or geographic location, among others, can be taken into account. Associates may also consider other factors, such as recognition as a thought leader or the ability to effectively convey training content.

How can a company establish the "Fair Market Value" of goods or services?

There are different appraisal methods that can be used to establish Fair Market Value. For example, a large number of third-party vendors or other experts may assist an Associate in developing a method for assessing Fair Market Value offset.





In all cases, Associates must use a method that incorporates objective criteria; for example, the Health Care Professionals' specialty, years and type of experience, geographic location, practice setting, type of services provided, etc. Associates are encouraged to document their methods for evaluating whether compensation represents the Fair Market Value of the services provided.

- Expense. Associates may pay documented, reasonable and actual expenses incurred by a consultant that are necessary for the conclusion of the consulting agreement, such as travel, lodging and modest meals. See chapters 6 and 7 of the Code for information on how to provide travel, lodging, and meals to Health Care Professionals.
- **Documentation.** Associates must maintain appropriate evidence, which may include documentation relating to the process to determine legitimate necessity, compensation of Fair Market Value, and other relevant factors about hiring.
- Written agreement. Associates must sign written agreements outlining all consulting services to be provided and compensation to be paid in exchange for the services. When Associates engage a consultant to perform clinical research services, there must also be a written research protocol.
- Involvement of the sales, marketing and sales team. Commercial, marketing, and sales teams
   should not unduly control or influence the decision to hire a particular Health Care Professional as a consultant. The company's sales staff can provide insight into the qualifications of a proposed consultant. Associates should consider implementing appropriate controls to promote compliance with this section.

# Why does the AMID Code restrict the participation of the sales, marketing and sales team in the selection of consultants?

The Code requires this separation so that an associate or its business intermediary is not thought to have entered into a contract with Health Care Professionals to secure or reward the Associate for the purchase, use, or recommendation of the Associate's Medical Devices or other sales considerations.



#### 2.3 Clinical Trials

Agreements involving clinical research services by Health Care Professionals in exchange for compensation are also a type of consultation agreement, subject to the principles of this section of the Code. The clinical program for which services are provided must serve a legitimate research purpose described in a protocol.

A clinical trial agreement is typically entered into between an associate and a health care professional through the institution or practice group, with compensation paid to that entity for clinical research services. Health Care Professionals may act as study investigators, but may also provide services in their individual capacity that are outside the scope of the services covered in the clinical trial agreement (e.g., protocol development, providing education and presentations on behalf of Associates). In that case, it may be appropriate to enter into a separate consulting agreement with that health care professional.

# 2.4 Continuing Education Programs/Events

Associate continuing education programs must be conducted in environments conducive to the effective transmission of information, including but not limited to Associate facilities, independent educational facilities, such as medical institutions or conference centers. Programs that provide hands-on product training must be conducted in training centers, medical institutions, laboratories, or other appropriate facilities that have the appropriate permits.

In the event that lodging, food and/or transportation is provided to the participants, the provisions of chapters 6 and 7 of this Code must be complied with.

In the event that Health Care Professionals provide services for a public institution, they will be responsible for having the corresponding prior authorization in accordance with current regulations.

Associates may pay or reimburse food, transportation, and lodging expenses incurred by Health Care Professionals in connection with the provision of services based on Chapters 6 and 7.



# Educational and research grants, donations to charities, and commercial sponsorships

#### **KEY CONCEPTS**

Associates play an important role in educating health care professionals and patients, providing community support and supporting research.



Associates can support educational, charitable and research programs through monetary and in-kind contributions.

Associates must establish processes and instructions so that decisions to support Third-Party Programs are made objectively and are not used as unlawful incentives to Health Care Professionals.

Associates can support Third-Party Programs for many valid reasons, such as advancing medical education and training of Health Care Professionals, increasing patient and public awareness of health issues. As such, Associates may provide monetary, in-kind and other contributions to third parties in support of their educational, charitable and research programs, taking into account the following limitations:

- It is strictly prohibited to finance the attendance of Health Care Professionals at Events in Paradise Places, referred to in Annex I "Paradise Places in national territory" of this Code. Where permitted, Associates shall ensure that any funding provided to facilitate the attendance of Health Professionals (scholarships) at events abroad is used exclusively for Events held in appropriate locations, and whose agenda effectively promotes science education and clinical practice. This obligation is intended to prevent such financing from being interpreted or used as an inappropriate incentive
- Sponsorship of Entertainment Events is strictly prohibited.
- It must be ensured that the appropriate documentation is maintained in relation to all the activities to be carried out, for example: agendas or educational programs, among others.
- In the Collaborative Events, scholarships will not be allowed to be awarded by any of the parties.

# 3.1 Support for Third-Party Programs through Educational Grant and/or Commercial Sponsorship

Third-Party Programs allow Associates to support the training and education of Health Care Professionals and patients; participate in clinical, research, and scientific exchanges related to your Medical Devices; and advertise and promote its products and services.

Associates must apply the following principles when supporting Third-Party Programs through either the award of an Educational Grant or a Commercial Sponsorship:



# 3.1.1 Support for Third-Party Program through Educational Subsidy

#### **REVIEW PROCESSES**

Partners are encouraged to adopt controls to review requests for support to Third Party Programs. Associates should consider the following questions when reviewing such applications:

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- Is the request for support reasonable and reflects the educational purpose of the program?
- Do the topics, faculty, attendees, and educational materials reflect an objective and legitimate educational purpose?
- Are the place and environment conducive to the exchange of educational information?
- Does the agenda reflect the legitimate educational, medical, scientific, or policy purpose of the meeting?
- Does the Third-Party Program appear to primarily promote the medical services of a specific provider (e.g., a program focused on highlighting the medical services of a particular medical practice group)?

#### Does the Code allow Associates to host a satellite symposium?



Yes. The opportunity to host a satellite symposium may be offered to Associates who provide a Commercial Sponsorship in support of a Third-Party Program. Although satellite symposia are generally included in the agenda and promotional materials of the Third Party Program, these are Associate-led events.



As part of the financial support of Third Party Programs, the organizer has offered me four scholarships. Can my company transfer them to Health Care Professionals?

No. An Associate may not offer these scholarships to Health Care Professionals.





# Can a partner company sponsor a meal with entertainment or recreational or protocol activities during a Third Party Program?

No. The funds provided by the associated companies must not be used to finance recreational, entertainment or protocol activities. All funding from industry should be directed exclusively to medical-scientific or educational activities that constitute the primary purpose of the meeting.



# Can Associates or their Business Intermediaries sponsor food during a Third-Party Program through the program organizer?

No, Associates may not sponsor food during a Third-Party Program through the Program organizer, as it is perceived as a direct benefit to the Health Care Professionals who attend those meals.

Associates may provide an Education Grant in support of a Third-Party Program only directly to the organizer of the Third-Party Program or, in some cases, to a training institution formally constituted for such purposes. Never directly to Health Care Professionals. Nor indirectly, through its Commercial Intermediaries or through the use of a third party.

The Third-Party Program organizer (or training institution) can use an Education Grant:

- To pay for or reduce the costs of conducting the educational components of a Third Party Program.
- To allow Healthcare Professionals in training (e.g., medical students, nurses, residents, and fellows) to attend the Third-Party Program, provided that Associates do not select or control the selection of these Healthcare Professionals.
- To cover reasonable compensation, travel, lodging, and food for Health Care Professionals who serve as faculty in the Third-Party Program and unaccompanied (see chapters 6 and 7).
- To provide Health Care Professionals attending the Third-Party Program with items and hospitality permitted by the Code.

Sales personnel should not control or influence the decision of whether a particular entity will receive a grant or educational support. The company's sales staff can provide information about the proposed Education Grant recipient or program.



# 3.1.2 Supporting the Third-Party Program through Commercial Sponsorships

When Associates provide Commercial Sponsorship in support of a Third-Party Program, the amount of the sponsorship shall correspond to a commercially reasonable rate, based on the marketing and promotional benefits they receive in return, such as advertising, signage, exhibition or exhibition space, or other promotional opportunities.

Associates may provide a Commercial Sponsorship, even if they determine not to provide an Education Grant to the organizer of the Third-Party Program.

**No Direct Support to Health Care Professionals:** Associates shall not provide any type of contribution, whether monetary or in-kind, directly to Health Care Professionals, or directly cover their enrollment, fees, travel or lodging expenses to attend a Third Party Program.

**Compliance with the rules of the program** Associates must comply with all the rules established by the organizer of the Third Party Program or by the body that accredits it, as applicable.

Where permitted by applicable rules, Associates may select and send a consultant (speaker) to participate in the Third-Party Program and speak on behalf of the company, provided that such consultant is retained by one of the Associates as set forth in Chapter 2. In such cases, attendees should be clearly informed that the consultant is participating on behalf of the partner and has been hired and remunerated by the partner, even if the event takes place in a so-called Paradise Location.

## 3.2 Donations to charities

Donations are part of Associates' commitment to the community and reflect our identity as responsible corporate citizens. All donations must be made in accordance with the following:

- There must be an appropriate evaluation that guarantees that it is not granted to unduly influence, or for inappropriate activities; in the same way, it can obey an express request or a proactive offer.
- b) Donations must be made to private assistance institutions or other non-profit organizations formally constituted and authorized for this purpose under the applicable Law in Force. In no event should donations be made to individuals, either on behalf of, or on the recommendation of, Health Care Professionals.
- c) The donation must not represent the obtaining of commercial advantages or be conditional on past, present or future sales.

# ADDITIONAL INFORMATION

#### Documentation.

Associates must document grants, donations, and sponsorships in writing, as applicable, depending on the program and the type of support provided. This may include, for example, a written agreement.

#### Funding applications.

Associates may receive requests for support to Third-Party Programs that include applications for both educational grants and Commercial Sponsorship. Sometimes, these requests can be combined.



It will be the responsibility of the Associates to implement policies and procedures within their organizations to ensure compliance with the above.



# Company Programs and Meetings with Healthcare Professionals

#### **KEY CONCEPTS**

Associates have a legitimate need to provide significant training and education to Health Care Professionals on the safe and effective use of Medical Devices.

Associates may also have a legitimate need to hold other business meetings with Health Care Professionals (e.g., a visit to manufacturing plants, a product training meeting, or meetings to discuss service offerings or terms of sale).

All programs conducted by Associates and meetings with Health Care Professionals must be aimed at information exchange, and all attendees must have a legitimate need to attend the program or meeting.

Associates have a legitimate need to conduct training and education for Health Care Professionals and to hold other important business meetings with Health Care Professionals. This section of the Code provides Associates with guidelines for organizing and conducting these meetings and programs.

# 4.1 Partner-led training and education

Associates are responsible for training and educating Health Care Professionals on the safe and effective use of their Medical Devices, the procedures in which those Medical Devices are used, and related information:

- Medical devices can involve complex equipment, devices, and sophisticated software that requires technical instruction.
- The procedures in which Medical Devices are commonly used are complex and require specialized clinical instruction.
- Healthcare Professionals need training and education on disease states and treatment options, patient selection criteria, clinical treatment standards and outcomes, pathways of care, how Medical Devices benefit certain patient populations.



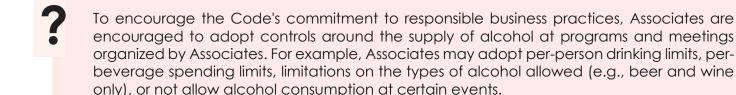
Associates must apply the following principles when conducting Medical Device training and education programs for Health Care Professionals:

• Environment: Associates must carry out live or virtual training and education programs in environments that favor the effective transmission of information. In addition to virtual settings, appropriate in-person locations may include clinical, educational, conference, or other settings, such as hotels or other commercially available meeting facilities, with the exception of Paradise Locations listed in Schedule I "Domestic Paradise Locations" of this Code unless it is the location of Health Care Professionals.

Programs that provide hands-on technical training and instruction on Medical Devices (e.g., a cadaver laboratory) must be conducted in training centers, medical institutions, laboratories, or other appropriate facilities.

- **Consultant:** Associates should only hire faculty who have the appropriate credentials and experience to conduct training or education. This may include Health Care Professionals or qualified employees of the company (including field sales personnel) who have the technical knowledge and experience necessary to conduct the training.
- Participants. Health Care Professionals must have a legitimate need to attend a training or education
  program organized by Associates (e.g., the need to obtain technical instruction on how to use a new
  Medical Device).
- **Foods.** Associates will be able to pay for food for participating Health Care Professionals with whom they are exchanging information.

#### Can Associates provide alcohol at programs and meetings organized by Associates?



The cost of food for Health Care Professionals or employees of the medical institution who are not present at such event will not be covered; nor expenses for the meals of other companions or Related Parties, or of people who do not have a professional interest in the information to be shared at the meeting.

# **4.2 Company Business Meetings**

Associates may identify a legitimate need to hold other types of business meetings with Healthcare Professionals to discuss, for example, the characteristics of Medical Devices, terms of sale, Associates' service offerings and their impact on the delivery of health care, product line offerings, information on the economics of health or purchase contract agreements.



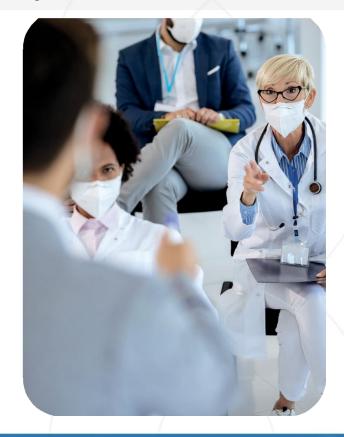
Other examples could be training of Associates' staff, visits to plants or facilities, meetings to demonstrate the equipment, meetings to explore product development or clinical testing needs, or meetings to discuss solutions, services.

Associates must apply the following principles when organizing and conducting business meetings

- Legitimate need. Associates must have a legitimate need to conduct the meeting. For example,
  Associates may identify the need to show Healthcare Professionals how they manufacture
  Medical Devices, their quality control systems, or other aspects of their manufacturing processes
  through a site visit.
- **Environment.** Associates may hold meetings at or near the workplace or at a Health Care Professional's facility; at another centralized location; at the Associates' own premises; or virtually. In all cases, the environment of a program or meeting conducted by the Associates must be conducive to the analysis of the corresponding information.
- **Participants.** Each of the Health Care Professionals attending must have an objective and legitimate need to attend a business meeting with the Associates.
- **Travel and lodging.** See Chapter 6 of the Code for information on the provision of travel and lodging to Health Care Professionals attending an Associate business meeting.
- **Foods.** Refer to Chapter 7 of the Code for information on the provision of meals to Health Care Professionals attending an Associate business meeting.

If a public procurement process requires interactions contrary to the guidelines of the Code, for example, the direct financing of the assistance of the Professionals of the Care, the avalanche to Third-Party Programs or in a paradisiacal place, can I do it?

Yes, Associates will be able to fulfill contractual obligations in a bidding event. An AMID partner should warn about this circumstance during the corresponding stages in the bidding event. And in no case should it offer it proactively or as a negotiation strategy.







# Education programs conducted in conjunction with Health Care Professionals

Medical Device Associates may partner with Healthcare Professionals to jointly conduct education programs. These programs serve an important purpose that allows Associates and Health Care Professionals to educate patients and other Health Care Professionals about medical conditions and the range of testing or treatment options available, including the availability of Medical Devices and the ability of Health Care Professionals to diagnose or treat related medical conditions. Associates must apply the following principles:

- There must be a genuine and legitimate need for Associates to engage in the activity for their own educational benefit.
- Associates must establish controls that help ensure that decisions to participate in these agreements are not made as illegal or improper solicitation.
- Associates should also require Health Care Professionals participating in these agreements to comply
  with Associates' guidelines on providing information related to product labeling and guidelines to
  provide appropriate information on health economics, among other controls.
- Jointly conducted education programs should be balanced and promote both Associates and their Medical Devices, as well as Health Care Professionals and the range of services offered for the diagnosis and treatment of related medical conditions.
- Associates and Health Care Professionals must act as bona fide partners in the program and must make equitable contributions to activity and costs (e.g., content development, invitations, space rental, logistics, and other production costs).
- The agreement must be documented in writing that describes the purpose of the agreement and the roles, responsibilities, and contributions of each party, including the payment of costs.
- They must be limited to promoting knowledge of medical science, surgical techniques and knowledge and use of products without being allowed to promote or incorporate entertainment, recreation and leisure activities, regardless of the duration of the event.

#### ADDITIONAL INFORMATION

A documented and jointly conducted program between Associates and Health Care Professionals should involve both parties making equitable contributions to the costs of the program. While costs need not be divided equally between the parties (e.g., monetary or in-kind contributions from both parties), each party must contribute to the program in a manner proportional to the benefits it receives.



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These programs could include, for example, an event where Associates share information about their Medical Devices with an audience of Health Care Professionals or patients, and a physician discusses the medical conditions the Medical Devices are intended to treat, the procedures that use them, and the physician's ability to perform these procedures.



# Travel and lodging; headquarters

There may be programs or meetings for which Associates determine that it is appropriate to pay travel and lodging expenses for Health Care Professionals. This section of the Code provides Associates with guidelines on the payment of travel and lodging expenses for Health Care Professionals. Associates must apply the following principles:

**Legitimate need.** There must be objective and legitimate reasons justifying travel outside the Health Care Professional's location, as provided in Chapter 2, sections 2.1 and 2.2. Alternatively, Associates should consider whether such a need can be met through a virtual program.

**Modest and reasonable travel and lodging.** Travel and lodging expenses should be modest and reasonable under the circumstances. Associates shall establish controls on the appropriate class of travel service and the appropriate level of accommodation.

- First class flights are not permitted. All participants will travel in economy class. When there is a duly documented medical impediment or trips of more than six continuous hours of flight; that requires the participant to travel in "Business-Class", it will be the power of the AMID Associates to approve and document it in accordance with their internal policies.
- Travel, lodging and food expenses may be covered from the day before the event and until one day after its conclusion, provided that the itinerary justifies it.

**Companions.** Associates may not pay for or subsidize the travel or lodging of spouses or guests of Health Care Professionals or any other person who does not have a professional interest in the information shared at the associate's meeting.

**Personal travel and lodging.** Associates cannot pay for travel or personal lodging for Health Care Professionals.

**Environment.** The environment for a program organized by Associates or a meeting of Health Care Professionals should always be conducive to the exchange of information and should not be the main attraction of the event. If the event is in-person, Associates should consider the following principles when choosing a venue:

• The venue should be centrally located and easily accessible (e.g. considering proximity to airports and roads) in relation to the place of origin of the invited participants.



- Associates should not select a location for its entertainment or recreation facilities (considering, for example, the season or time of year of the event, including Paradise Locations).
- Associates should avoid upscale or luxury hotels or resort facilities without proper justification.
- No excursions, recreational activities or additional expenses such as laundry, room-service, movie rentals or other services will be paid.
- Other laws. Associates should be aware that other laws or regulations may apply to pay for travel and lodging for Health Care Professionals.
- Associates will follow their internal processes and may use the services of their contracted travel
  agencies for the organization of these activities, thus avoiding, as far as possible, reimbursements
  or direct payments to Health Care Professionals for such concepts. Cash payments are not
  allowed.
- In the case of events aimed at Health Care Professionals, they should not be held in Paradise Places.
- In the case of hiring Health Care Professionals (speakers) to participate in internal events organized by the Associates aimed at employees or Commercial Intermediaries, they may be held in Paradise Places.

#### **ADDITIONAL INFORMATION**

When does the Code ALLOW Associates to pay for the travel and lodging of Health Care Professionals?

- To provide consulting services to Associates.
- To attend a company training or medical device education program.

To speak on behalf of the company in a Third-Party Program.

- Associates may determine that there are other types of qualifying programs or
- meetings, examples of which may include plant visits, equipment demonstrations, and more.

In all cases, there must be an objective and legitimate reason justifying the assistance

• in-person Health Care Professionals to the program.

#### **ADDITIONAL INFORMATION**

In events held outside the national territory, the Associates must ensure that the principles and spirit of this Code are respected, particularly those aimed at avoiding any form of undue influence on the independent judgment of the Health Care Professionals.





## Food Provided to Health Care Professionals

Associates may occasionally provide food to Health Care Professionals, based on the following principles:

#### **Purpose**

The provision of food must be subordinated, in time and focus, to the discussion or presentation of scientific, educational or commercial information in good faith. In no event should it be intended to offer an inappropriate incentive, including in the case of Events within Third-Party Programs. Food should facilitate and not distract from the presentation or discussion of the content.

#### Place and location.

Food should be provided in an environment conducive to good faith scientific, educational, or business discussions. This may include, for example, the Healthcare Professionals' workplace or an external space that is conducive to discussion, such as a restaurant, without exceeding the stated amounts:

# Can an Associate offer food at a satellite symposium?

Yes, an Associate may offer food at a satellite symposium, as long as they meet the following requirements:

(a) the rules of the organizer of the Third Party Program or the relevant accreditation body.

# Meals in national territory.

Breakfast	\$660.00 (six hundred and sixty pesos 00/100 M.N.) /or its equivalent in US dollars)
Lunch or dinner	\$2,000.00 (two thousand pesos 00/100 M.N.) /or its equivalent in US dollars)

<sup>\*</sup>Excludes gratuities and taxes

<sup>\*</sup>Prices per person

<sup>\*</sup>It is not allowed to add up the unused amounts per day to make a single payment for food

<sup>\*</sup>This is a guide for Associates that can be updated annually or as appropriate according to variation in the exchange rate of dollars against Mexican pesos and inflation costs



**Participants.** Associates may provide food only to Health Care Professionals who actually attend and have a legitimate purpose for attending the meeting.

#### Associates may not provide food:

- For office staff where not everyone attends the meeting;
- If a company representative is not present or
- For guests of Health Care Professionals or for any other person who does not have a bona fide professional interest in the information being shared at the meeting.
- In the case of virtual events, refer to numeral 12.6.



## Items Awarded to Health Care Professionals

Associates may from time to time provide discreet and appropriate educational items to Health Care Professionals that benefit patients or that have a genuine educational function for Health Care Professionals.

The amounts authorized to grant educational items will be limited to the amount of \$750.00 (seven hundred and fifty pesos 00/100 in national currency), except in the case of anatomical models whose amount of grant may not exceed \$2,000.00 (two thousand pesos 00/100 national currency) / or its equivalent in US dollars. (Both amounts do not include taxes).

Associates may not provide gifts to Health Care Professionals. This means:

- Items that Health Care Professionals (or their family members, office staff, or friends) may use for non-educational or non-patient purposes (e.g., office supplies, uniforms, a tablet, a "Smart-phone," a laptop, or other mobile device that is for personal use).
- Branded promotional items, not educational, even if the item is of minimal value, related to the work of Health Care Professionals or for the benefit of patients.
- Gifts such as cookies, wine, flowers, chocolates, gift baskets, holiday gifts, or cash or equivalents (e.g., gift cards).



Yes, pens and notebooks may be provided to Health Care Professionals in the context of Educational Events for the purpose of taking notes during the meeting. These should not bear the name of any product, but may include the name of the company that provides them. In addition, they must be of minimum value and only distributed in the necessary quantity. Examples of prohibited Promotional Items include sticky notes, mouse-pads, calendars, etc.

#### Other important principles are:

- Any items given to Health Care Professionals personnel must be subject to all applicable provisions of the Code.
- Associates may not raffle or give away an item that they could not otherwise give to Health Care Professionals under the Code.



Can a company or its representative make a gift to recognize an event in the life of a Health Care Professional, such as a wedding, birth, anniversary, or death of a family member?

No. A company or its representative acting on behalf of the company may only provide items to Health Care Professionals that are intended to benefit patients or have a true educational function for the Health Care Professional. Gifts such as flowers, fruit baskets, wine, etc. do not meet this requirement, even if they are provided to recognize a significant life event.



# Does the AMID Code include any restrictions on an employee or company representative accepting a gift from Health Care Professionals?

The AMID Code does not address whether an employee or company representative may accept a gift from a Health Care Professional. Companies are encouraged to develop their own internal policies on this concept, recognizing that the giving and acceptance of gifts could create a real or perceived conflict of interest.



#### Is it possible to provide surgical scrubs with a logo?

Yes. Within the framework of continuing medical education or product training events organized by the Associates that justify it, for example, by virtue of being carried out in hospital environments, or hospital simulation.





## Prohibition of entertainment and recreation

Associates may not provide or pay for any entertainment or recreational events to Health Care Professionals.

Entertainment and recreational activities are incompatible with the proper business purpose of Associates' interactions with Health Care Professionals. Examples of entertainment and recreation activities include, but are not limited to, theater, sporting events, golf, skiing, hunting, or vacation travel.

This prohibition applies regardless of (1) the value of the activity; (2) whether Associates engage Health Care Professionals as consultants; or (3) if the entertainment or recreation is secondary to an educational purpose.



## **Demo, Product Evaluation**

### 10.1 Demo and Evaluation Products

What are examples of appropriate reasons to provide single-use or multi-use evaluation products to Health Care Professionals?



Examples may include the Health Care Professional not having recently purchased or used the products (i.e., the Health Care Professional is not familiar with the product); or that the product is marketed for a new indication or a new surgical technique; among other reasons.

Providing products free of charge to Health Care Professionals for evaluation or demonstration purposes can improve patient care, facilitate the safe and effective use of products, increase patient awareness, and educate Health Care Professionals regarding the use of products. In certain circumstances, Associates may provide reasonable quantities of products to Healthcare Professionals at no charge so that they can evaluate the proper use and functionality of the product and determine whether and when to use, order, purchase, or recommend the product in the future.

Associate products that may be provided to Health Care Professionals for evaluation include single-use products (e.g., samples of consumable or disposable products) and multi-use products (sometimes referred to as capital goods).

Associate products provided for evaluation are typically used in patient care.



# Single use / Consumables / Disposables.

The number of single-use products supplied free of charge must not exceed the amount reasonably necessary for the proper evaluation of the products in the circumstances.

# Multiple Use / Capital.

Multiple-use products that are supplied without transfer of title for evaluation purposes should be supplied only for a period of time not exceeding six months, with the aim of being reasonable in the circumstances to allow for an appropriate and compatible evaluation.

The conditions for an evaluation of such multiple-use devices should be set out in advance and in writing, specifying the duration of the evaluation period and taking into account the effects of products that have not been returned within the evaluation period.

Associates must maintain ownership of multi-use products during the evaluation period and must have a process in place to promptly remove the multi-use products from the location where the Health Care Professionals are located at the conclusion of the evaluation period, unless the Products are purchased or rented by the Health Care Professionals.

#### Demonstration.

The company's demonstration products are typically non-sterile, single-use products or mock-ups that are used for health care professional and patient awareness and education. For example, Healthcare Professionals can use a demonstration product to show a patient the type of device that will be implanted.

Demonstration products are not normally intended to be used in patient care.

Demonstration products are typically identified as not intended for patient use through designations such as "Sample" or "Not Intended for Human Use" on the product, packaging, or documentation accompanying the product.

#### What additional asset management principles should Associates consider?



Partners may also consider other controls relating to asset management, including products provided free of charge (e.g., demonstration and evaluation units, loaned products, grants/in-kind donations) or charged (e.g., rental products, invested capital, consignment product).



Possible examples of such controls include:

• Written policies, procedures, and work instructions governing when assets may be supplied to Health Care Professionals, including related audits and monitoring;

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- Specialized training and education for company representatives; and
- Clear documentation, record-keeping, and asset tracking requirements, including any obligations to offset or return Medical Devices to the company, as the case may be.

# 10.2 Samples

Associates must have internal policies and procedures that protect the issuance and proper use of samples.

To the extent permitted by local laws and regulations, Healthcare Professionals may be provided with free samples of a product for demonstration, evaluation, familiarization, and/or education of Associates' products to improve patient care. Such samples may not be sold or used inappropriately, i.e. outside the previously stated objectives. All samples:

- They must contain a label that identifies it as such, thus differentiating it from products authorized for sale.
- They must be provided in quantities and frequencies that allow an adequate evaluation to be carried out based on what each associate determines based on the medical criteria that apply to the device in question.
- They should not be conditioning factors for the making of a sale or be understood as compensation for a service.
- The issuance of samples must be properly documented before and after delivery.



# Associates' Business Intermediary Obligations in Their Interaction with Health Care Professionals

AMID Associates recognize that, in their business and interaction with Health Care Professionals, they are represented by the associate's Business Intermediaries and that it is of vital importance that these Intermediaries are aware of the provisions of this Code in order to ensure compliance.



All the provisions contained in this Code shall be applicable to the Commercial Intermediaries of the Associates; in this sense, the Associates are obliged to transmit and train their employees and Commercial Intermediaries in the provisions of this Code and will each establish the necessary mechanisms to ensure that their Intermediaries adopt these provisions as part of their internal regulations and that consequently they observe a conduct consistent with them.



#### **Virtual Interaction**

The Associates recognize the need to maintain high standards in the interaction with these professionals with regard to the use of digital platforms, information technologies and telecommunications, which do not escape the observance of certain regulations, but above all ethical principles to ensure a healthy coexistence. In this sense, the Associates submit to the principles for Virtual Interaction as the basis for this type of interaction, without this implying the non-observance of higher standards that may be established in accordance with the internal regulations of each of them.

## **Principles for Virtual Interaction**

# 12.1 Data Privacy Consideration

Almost all countries currently have data privacy legislation or regulation on the collection, processing, use, disclosure, transfer, storage and deletion of personal information. Such laws require the organizer to obtain consent from Health Care Professionals and other attendees for the use of your personal information for educational, marketing, or other purposes. For cross-border events, Associates should consider any conflicts regarding the requirements in the different countries that require openness and process management for the different participants. Any other standards in data privacy management should also be considered and adhered to.

Associates are required to have policies and procedures in place in compliance with data privacy laws.

# 12.2 Hiring Healthcare Professionals in Connection with Virtual Events

The credentials of Health Care Professionals must be consistent with the services to be provided with the number of Health Care Professionals hired and must not be in greater numbers than reasonably necessary. For a panel discussion with several speakers or moderators, the amount of time spent by each participant should be a differentiating factor in measuring the consistency of the number of consultants or speakers hired.



# 12.3 Fair Market Value for Services Provided by Health Care Professionals

As with any contract for the provision of services, the consideration to be paid to Health Care Professionals must be limited to the Fair Market Value of the jurisdiction where they practice or provide their professional practice. Services provided by Health Care Professionals must be compensated according to the time spent performing those services and the time spent preparing to perform them.

All contracts must be consistent with the provisions of this Code, with interactions between Associates and Health Care Professionals being under the highest ethical standards, preserving the independence of the Health Care Professional.

#### 12.4 Access control to virtual events

The organizers of virtual events must consider whether the technologies and platforms used allow them to have sufficient control over the access and verification of participation of attendees. Associates' employees shall refrain from joining events of their competitors or any other associated company without express permission.

# 12.5 Event Recording

Before recording any Event for subsequent reproduction or distribution, Associates must consider the need to inform participants about it, and must obtain consent and appropriate data protection measures. Greater care should be taken before recording any content that involves the disclosure or discussion of patient records and/or their procedures.

# 12.6 Food/meal ban at virtual events.

Associates may provide food/meals in accordance with Chapter 7 of this Code only to Health Care Professionals who meet at a venue to participate in a virtual event, which must be consistent with the timing of the event.

In the case of educational activities through Virtual Interaction, it will not be allowed to send meals to the place where the Health Care Professionals are located, such as their home, hospital, private practice, or university. This provision is applicable even when food delivery is made through prepaid vouchers or food cards.

# 12.7 Regulatory restrictions on virtual events

Associates should consider applying restrictions on the marketing of Medical Devices in countries where they have not been approved for sale by regulatory authorities.

Where a product has been approved for different uses in different markets, promotion considerations may arise outside of its labelling in cross-border programs.



For Events involving participants from multiple countries, Associates should consider whether disclaimers or warnings about the use or handling of unapproved products are appropriate. In addition, Associates should consider whether regulations in some countries consider it inappropriate for Healthcare Professionals to attend such Events.



# **Legal framework**

The provisions of this Code constitute the agreement of the Associates to a self-regulatory scheme for the interaction between them either directly or through their Commercial Intermediaries and the Health Care Professionals. The purpose of the above is to promote relationships based on ethics and transparency in business. In addition, the Associates reaffirm their commitment to comply with the national and international regulatory framework in the fight against corruption, such as the rules that make up the National Anti-Corruption System, the Foreign Corrupt Practices Act (FCPA; and the UK Bribery Act).

# 13.1 Validity and modifications to the Code

This version of the Code will enter into force on May 29, 2025 and will be subject to review every two years.

This Code may not be modified or altered in whole or in part, unless such modifications are in writing and accepted by the AMID Associates, in accordance with the bylaws.

The Associates will sign annually during the first quarter of each calendar year a communication subscribing to their adherence and commitment to compliance with the Code. Failure to sign the above communication will entitle the AMID not to renew the member's membership.

In the same way, they will be responsible for requiring compliance with this Code to their Commercial Intermediaries.

# Annex I. Paradise places in national territory.

