AdvaMed Code of Ethics INDIA

ADVAMED CODE OF ETHICS ON INTERACTIONS WITH HEALTH CARE PROFESSIONALS IN INDIA

ADOPTED BY THE ADVAMED BOARD OF DIRECTORS

Effective October 1, 2021

SECTION I – INTRODUCTION

The Advanced Medical Technology Association (AdvaMed) is a global trade association of companies that develop, produce, manufacture, and market medical devices and products, technologies, digital and software platforms, and related services, solutions, and therapies used to diagnose, treat, monitor, manage, and alleviate health conditions and disabilities.

The AdvaMed India Executive Committee is an India-based AdvaMed governance group that consists of AdvaMed member companies' most senior company executives in India.

The India Executive Committee recognizes the obligation to facilitate ethical interactions between companies, health care professionals and health care institutions involved in the provision of health care services and/or items to patients in India. We are dedicated to advancing medical science; developing high quality, innovative medical technology; and improving patient care.

The Value of Interactions with Health Care Professionals

A health care professional's first and highest duty is to act in the best interests of their patients. Medical technology companies help health care professionals meet this duty through necessary, collaborative interactions without interfering with their professional autonomy and the autonomy of the medical institutions that the health care professionals may be associated with.

	*Companies and health care professionals collaborate to advance medical care and clinical science through **research, product development, and product testing** that results in new or improved, innovative medical technology*
	*Companies **instruct, educate, and train** health care professionals on the safe and effective use of complex Medical Technology*
	*Companies provide **product service and technical support** for health care professionals to help ensure the safe and effective use of Medical Technology*
	*Companies support health care professionals' **scientific and medical research, as well as the enhancement of clinical skills and educational opportunities** to improve patient care*
	*Companies promote **charitable giving of medical technologies and public awareness** of medical and health conditions through grants and donations in support of compassionate usage and patient education*

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The Purpose of the AdvaMed India Code & Its Cornerstone Values

The AdvaMed India Code ("the Code") provides medical technology companies with guidance on ethical interactions and relationships with health care professionals based on the following cornerstone values:

INNOVATION	**Advance the development and availability of safe and effective medical technology that health care professionals use to improve and save lives**
EDUCATION	**Deliver high-quality training and education to help ensure that health care professionals safely and effectively use medical technology**
INTEGRITY	**Conduct business with integrity at all times and avoid real or perceived conflicts of interest with health care professionals**
RESPECT	**Respect the independent clinical judgment of health care professionals to decide the best manner and method for treating patients**
RESPONSIBILITY	**Promote socially and ethically responsible business practices that protect patients, their rights and their safety**
TRANSPARENCY	**Conduct interactions with health care professionals fairly, openly and transparently**

Companies should review all interactions with health care professionals in light of these values and should always avoid interactions designed to circumvent the Code. The Code may be silent on a specific interaction or may not address all aspects of an interaction with a health care professional. All interactions between companies and healthcare professionals should comply with applicable laws, guidelines and codes. The Code is intended to help companies make reasonable and appropriate decisions that align with the Code's values.

Companies and their employees, agents and representatives should be mindful of their interactions and the perception of their interactions with health care professionals. Companies should communicate company policies consistent with the Code to their employees, agents and representatives with the expectation that they will comply.

Scope and Applicability of the Code

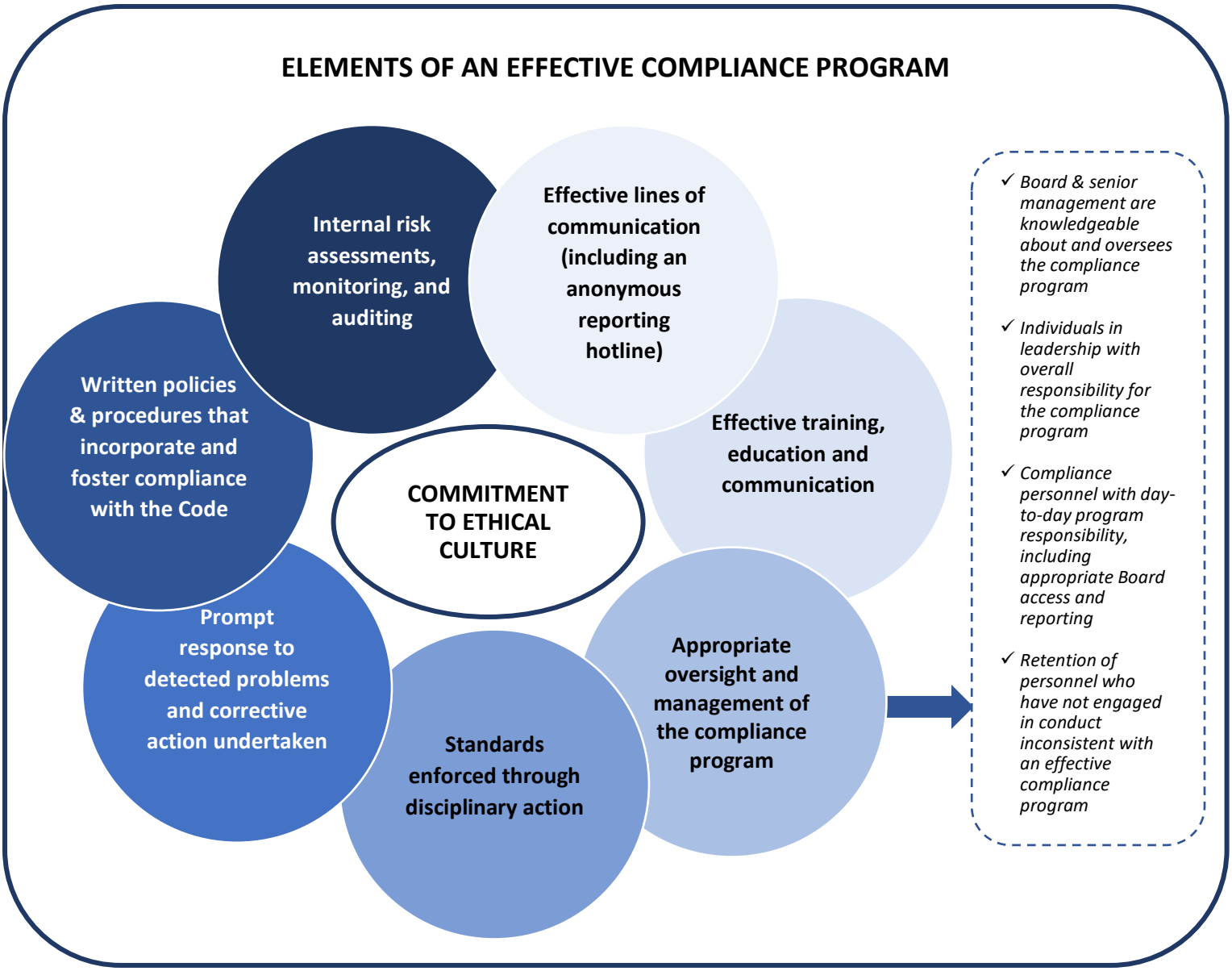
Legal Principles	The Code does not provide legal advice or create legal rights or obligations.
Geographic Reach	The Code applies to all company interactions with India health care professionals, whether occurring inside or outside India (such as at a conference or other event).

Interactions with Health Care Professionals	The Code applies to a company's interactions and a company's employees', representatives', and agents' interactions with India health care professionals, even if an employee or representative or agent pays for the interaction's associated costs himself/herself.
Representatives	A company adopting the Code is required to communicate the Code's provisions to its employees, agents, representatives, dealers, distributors, vendors, independent consultants acting on a company's behalf and to any other health care professionals engaged by or affiliated with a company with the expectation that they will adhere to the Code.
Multiple Business Lines	Companies with different business lines (for example, medical devices, pharmaceuticals, biologics, consumer items, and/or research-only products) may have other industry codes that apply to such different businesses. This Code applies to companies' interactions with the healthcare professionals linked to medical technology.
Combination Products	The Code also applies to all interactions with India health care professionals related to combination products that include a medical technology component (for example, those that are both biologics and devices or drugs and devices), which may also be subject to other trade association codes.

Complying with the AdvaMed India Code

The Code does not replace any applicable laws, regulations, or codes as notified from time to time that may contain stricter requirements. The Code requires companies to comply with all applicable laws, regulations, and codes. Companies are strongly encouraged to adopt an effective ethics and compliance program aimed at (1) promoting an organizational culture that encourages ethical practices and a commitment to comply with the applicable law, guidelines and codes and (2) preventing and detecting inappropriate conduct. Programs should be ***appropriately tailored*** for each company.

For assistance in evaluating a compliance program's effectiveness, companies may consider referring to government-issued or other industry guidance on what constitutes an effective compliance program. Elements of an effective compliance program can include:



All medical technology companies doing business in India are **strongly encouraged to adopt and certify to this Code** and to implement an effective compliance program.

A company that wishes to certify to the Code is **required to submit to AdvaMed a biennial certification** that the company has adopted the Code and has implemented a compliance program designed to uphold the principles of this Code. This certification must be signed by the most senior executive responsible for the company's medical technology operation in India. For companies headquartered in India, this would be the Chief Executive Officer or individual with equivalent responsibility within the certifying company. For companies headquartered outside of India, this would be the most senior representative of the certifying company's medical technology operation in India. This certification must additionally be signed by the company's Chief Compliance Officer for India or individual with equivalent responsibilities within the certifying company.

AdvaMed will publish on its website a list of those companies that have submitted this biennial certification. As part of this certification, companies must supply contact information for the company's compliance program or an anonymous hotline to facilitate reporting of possible violations of the Code. AdvaMed will publish on its website the contact information supplied by each company.

Glossary

Advertisements	Any activity undertaken, organized or sponsored by a company which is directed at health care professionals to promote the safe and effective use of medical technology.
Commercial Sponsorship	A payment or in-kind support provided to a third party in exchange for advertising or promotional opportunities for a company (for example, a company exhibit at a third-party program).
Company	A company that develops, produces, manufactures and/or markets medical technology.
Educational Grant	A payment or in-kind support to a third-party entity (for example, a third-party program organizer, training institution or health care organization) to reduce the costs of providing education. An educational grant is not offered for commercial sponsorship opportunities.
Health Care Professional	A health care professional is any person or entity (a) authorized or licensed in India to provide health care services or items to patients or (b) who is involved in the decision to purchase, prescribe, order, or recommend a medical technology in India. This term includes individual clinicians (for example, physicians, nurses, and pharmacists, among others), provider entities (for example, hospitals and ambulatory surgical centers), and administrative personnel at provider entities in India (for example, hospital purchasing agents). This term does not include health care professionals who are *bona fide* employees of a company, while acting in that capacity.
Medical Technology	Medical technology is a broad term that means medical devices and products, technologies, digital and software platforms, and related services, solutions, and therapies used to diagnose, treat, monitor, manage, and alleviate health conditions and disabilities. Some examples include: • Implantable medical devices that are placed in or on the human body to replace, repair, or strengthen a body part; • Surgical devices used to perform procedures; • Digital technology and software platforms that assist in monitoring, diagnosing, and treating patients; and • Non-invasive reagents, instrumentation, and/or software to aid in the diagnosis and treatment of patients; among other technology.
Modest	Moderate value; may differ depending on the local standards and the purpose.
Occasional	An interaction is considered occasional if it occurs infrequently and not on a routine basis.
Satellite Symposium	A satellite symposium is a company-organized and funded program that is appended to a third-party program agenda but that the third-party organizer does not control. These programs often take place during meal breaks at the third-party program and may address education and training topics that coincide with the third-party program's focus. A satellite symposium does not include a company-organized meeting, training, or educational session (such as an advisory board, consultant meeting, or product education session) that (a) may

	be held in close physical and temporal proximity to a third-party program and (b) is not appended to or included in the third-party program's official agenda.
Third-Party Program	A bona fide, independent health care-related educational, scientific, business, and/or policymaking conference, meeting, or event put on by a third party other than a company. This term includes programs that are accredited to provide continuing education credits and programs that are not accredited.
Third-Party Program Organizer	A third-party entity that organizes and/or oversees the development of the third-party program, including the selection of presenters, attendees, topics, materials, and methods. A third-party program organizer could include, for example, a health care professional society, institution, association, medical trust fund, continuing medical education provider, hospital or other health care entity.
Consigned Products	Medical technologies (a) that a company provides to a health care professional for use in and storage at the health care professional's patient care setting and (b) to which the company retains title until the product is used.
Demonstration & Evaluation Products	Products provided to health care professionals at no charge to assess the appropriate use and functionality of the product and determine whether and when to use, order, purchase, or recommend the product in the future. Company products that may be provided to health care professionals for such assessment include single use (for example, samples of consumable or disposable products) and multiple use products (sometimes referred to as capital equipment).

SECTION II – CONSULTING ARRANGEMENTS WITH HEALTH CARE PROFESSIONALS

A. Engaging a Health Care Professional to Provide Consulting Services

Companies engage health care professionals to provide a wide range of valuable, *bona fide* consulting services. Some examples include arrangements for a health care professional to provide education and training, speaking services, proctorships (evaluate), preceptorships (instruct), reference center or center of excellence services, participation on advisory boards or focus groups, medical technology development and research services arrangements (such as research and development, clinical studies, clinical investigator services, collaborative research, and post-market research), and arrangements for the development or transfer of intellectual property.

Companies should apply the following principles to all consulting arrangements with health care professionals:

- ***Legitimate Need.*** Companies should enter a consulting arrangement with a health care professional only if the company has identified a **legitimate need** for the health care professional's services in advance.

- ***Consultant Selection.*** Companies should select only duly vetted health care professionals to serve as consultants, based on the health care professional's qualifications to meet the identified need. Some examples of these qualifications include the health care professional's specialty, years of experience, location, practice setting, clinical research experience, podium presence, speaking and publication experience, or experience with, usage of, or familiarity with a specific medical technology, among other qualifications. Companies may not select or compensate consultants as a reward for past usage or as an unlawful inducement for future purchases. Companies should implement safeguards so that consultants are not selected based in whole or in part on sales considerations.

- ***Number of Consultants.*** Companies should engage only as many consultants as are necessary to fulfill the requirements for the *bona fide* services.

- ***Fair Market Value Compensation.*** Companies should compensate consultants consistent with the fair market value in an arm's length transaction of the services provided. Companies should not base compensation on the volume or value of the consultant's business generated by the consultant in the past, present or expected in the future. Companies should confirm that the services performed by the consultant are in accordance with the agreement.

- ***Expenses.*** Companies may pay for documented**,** reasonable, and actual expenses incurred by a consultant that are necessary to carry out the consulting arrangement, such as costs for travel**,** lodging, and modest meals. See Sections VI and VII of the Code for information on providing travel, lodging, and meals to health care professionals.

- ***Written Agreement.*** Companies should enter into written agreements that describe all consulting services to be provided and the compensation to be paid in exchange for the services. Such agreements with the healthcare professionals should be fully transparent and disclosed (when required to do so by the appropriate authority), should ensure that the professional integrity and freedom of the health care professionals are maintained and that the patients' interest is not compromised. When a company contracts with a consultant to conduct clinical research services, there should also be a written research protocol.

- ***Sales Involvement.*** Sales personnel cannot control or unduly influence the decision to engage a particular health care professional as a consultant. Companies' sales personnel may provide input about the qualifications of a proposed consultant. Companies should consider implementing appropriate controls to promote compliance with this section.

B. Royalties

Arrangements involving the payment of royalties to health care professionals should meet the standards listed in this section of the Code.

Health care professionals often make valuable contributions that improve products or medical technologies. They may develop intellectual property (for example, patents, trade secrets, or know-how), under a product or technology development or intellectual property licensing agreement.

Companies should enter a royalty arrangement with a health care professional only if the health care professional (individually or as part of a group) makes a novel, significant, or innovative contribution to the development of a medical technology or a combination product, process, or method, subject to intellectual property protections. A significant contribution by an individual or group, if it is the basis for compensation, should be appropriately documented.

Companies should base the calculation of royalties payable to a health care professional in exchange for intellectual property on factors that preserve the objectivity and autonomy of medical decision-making and avoid the potential for improper influence. For example, a company should not condition royalties paid in exchange for intellectual property on: (1) a requirement that the health care professional purchases, orders or recommends any use of medical technology of the company or technology produced as a result of the development project; or (2) a requirement to market the technology upon commercialization.

Companies are strongly encouraged to consider whether it is appropriate and practicable to exclude from the calculation of royalties the number of units purchased, used, or ordered by the individual health care professional and/or members of the health care professional's practice.

C. Clinical Studies & Research Arrangements

Arrangements that involve clinical research services by a health care professional in return for compensation are also a type of consulting arrangement, subject to the principles in this section of the Code. The clinical program for which the services are being provided should fulfill a legitimate research purpose, should have due permissions from the competent authorities, and should be transparent. A written services agreement should govern these arrangements, and companies should base compensation on the fair market value of the services provided.

A clinical study agreement typically is entered between a company and a health care professional that is a facility, institution, or practice group, and compensation for the clinical research services is paid to that entity. An individual health care professional may act as a study investigator but also provide related services in his or her individual capacity that is outside the scope of the services covered in the clinical study agreement (*e.g.*, protocol development, delivering education and presentations on the company's behalf, etc.). In that case, companies are strongly encouraged to enter a separate consulting arrangement with that individual health care professional.

SECTION III – COMPANY-CONDUCTED PROGRAMS & MEETINGS WITH HEALTH CARE PROFESSIONALS

Companies have a legitimate need to conduct training and education for health care professionals and to hold other important business meetings with health care professionals.

A. Company-Conducted Training & Education

Companies have a responsibility to train and educate health care professionals on their medical technologies, the procedures in which these medical technologies are used, and other related information:

- ✓ Medical technology may involve complex equipment, devices, and/or sophisticated software platforms that require technical instruction.
- ✓ Medical technology may have a new procedure of insertion and deployment technique and may require sufficient hands-on experience before application on patient.
- ✓ Medical technology may require analysis of new monitoring parameters.
- ✓ Medical technology may include breakthrough innovations.
- ✓ Procedures in which medical technologies are used may be complex and require skilled clinical instruction.
- ✓ Health care professionals need training and education on disease states and treatment options, patient selection criteria, clinical treatment standards and outcomes, care pathways, and how medical technologies benefit certain patient populations, among other important topics.

All of this information contributes to the safe and effective use of medical technology.

Companies should apply the following principles when conducting training and education programs concerning medical technologies for health care professionals:

- ***Setting.*** Companies should conduct live or virtual training and education programs in modest settings that are conducive to the effective transmission of information. These may include clinical, educational, conference, or other center of excellence developed by the company for such purposes, either in country, offshore, or other settings such as hotels or other commercially available meeting facilities. It could also include the health care professional's location. Programs providing hands-on technical training and instruction on medical technologies (for example, a cadaver lab) should be held at training facilities, medical institutions, laboratories, or other appropriate facilities.
- ***Faculty.*** Companies should only engage faculty that have the proper qualifications and expertise to conduct the training or education. This may include health care professionals or qualified company employees (including field sales staff) who have the technical expertise and experience necessary to perform the training.
- ***Attendees.*** Health care professionals must have a legitimate need to attend a company-conducted training or education program (for example, the need to obtain technical instruction on how to use a new medical technology

- ***Travel & Lodging.*** See Section VI of the Code for more information on providing travel and lodging to health care professionals to attend a company-conducted training or education program.

- ***Meals & Refreshments.*** See Section VII of the Code for information on providing meals and refreshments to health care professionals attending a company-conducted training or education program.

- ***Documentation.*** Companies are required to maintain documentation of the training to demonstrate that the purpose of the training has been sufficiently met. Documentation may include copies of the agenda, training content, photographs, attendees and any other such record.

B. Company Business Meetings

Companies may identify a legitimate need to conduct other types of business meetings with health care professionals to discuss, for example, medical technology features, sales terms, company service offerings and their impact on health care delivery, product line offerings, health economics information, feedback and advice on medical technologies or purchase contract arrangements. Other examples could include plant or facility tours, meetings to demonstrate equipment, or meetings to explore product development or clinical testing needs.

Companies should apply the following principles when organizing and conducting business meetings:

- ***Legitimate Need.*** Companies must have a legitimate need to conduct the meeting. For example, a company may identify a need to show health care professionals how they make medical technologies, their quality control systems, or other aspects of their manufacturing processes through a plant tour.

- ***Setting.*** Companies may hold meetings at or close to a health care professional's place of business or facility; another centralized location; or at a company's own facility or business centers that may be a more appropriate setting for the meeting, depending upon the topics discussed. In all instances, the setting for a company-conducted program or meeting must be conducive to the discussion of relevant information.

- ***Attendees.*** Each health care professional in attendance must have an objective, legitimate need to attend a company's business meeting.

- ***Travel & Lodging.*** See Section VI of the Code for information on providing travel and lodging to health care professionals attending a company's business meeting.

- ***Meals & Refreshments.*** See Section VII of the Code for information on providing modest meals and refreshments to health care professionals attending a company's business meeting.

- ***Documentation.*** Companies are required to maintain documentation of the meeting to demonstrate that the purpose of the meeting has been sufficiently met. Documentation may include copies of the agenda, meeting content, photographs, attendees and any such record.

SECTION IV – EDUCATIONAL & RESEARCH GRANTS, CHARITABLE DONATIONS, COMMERCIAL SPONSORSHIPS

Companies provide monetary, in-kind, and other contributions to third parties in support of their educational, scientific, charitable, and research programs.

Companies can support these programs for many valid reasons, such as advancing medical education and training for health care professionals, raising patient and public awareness on important health care topics, helping underserved or indigent populations through *bona fide* charitable programs, or funding independent scientific or clinical research.

A. Supporting Third-Party Programs Through Educational Grants and Commercial Sponsorship

Third-party programs allow companies to support health care professional- and patient-related training and education to participate in clinical, research and scientific exchanges related to their medical technologies and to demonstrate the safe and effective use of their products, services and technologies.

Companies should apply the following principles when supporting third-party programs through educational grants and/or commercial sponsorship:

SUPPORTING THIRD-PARTY PROGRAMS THROUGH EDUCATIONAL GRANTS	Companies may provide an educational grant in support of a third-party program directly to the third-party program organizer or, in some instances, to a training institution, health care professional association or other entity designated by the third-party program organizer. A third-party program organizer (or training institution or designee) may use an educational grant in a transparent manner: ✓ To defray or reduce the costs of conducting the educational components of a third-party program ✓ To allow health care professionals-in-training (for example, medical and nursing students, residents, and fellows) to attend the third-party program, provided that the company does not select or control the selection of the specific health care professionals-in-training who will benefit ✓ To cover the reasonable compensation, travel, lodging, and modest meals of health care professionals who serve as *bona fide* faculty at the third-party program. ✓ To provide health care professionals attending the third-party program with items of value permissible under the Code, such as modest meals, refreshments, and educational items. Sales personnel should not control or unduly influence the decision of whether a particular entity will receive an educational grant or the amount of the grant.
SUPPORTING THIRD-PARTY PROGRAMS THROUGH	When companies provide commercial sponsorship in support of a third-party program, the level of commercial sponsorship should reflect the fair market value of the benefits received by the company, such as signage, display/ exhibit space, electricity/ audio-visual equipment/ furniture to be used in display/ exhibit space or other opportunities to communicate/ display company specific products/

technologies/ services. Companies may provide commercial sponsorship even if the company determines not to provide the third-party program organizer with an educational grant.

- ***No Support to Individuals.*** Companies may not provide any contribution (whether monetary or in-kind) directly to an individual health care professional or pay directly for an individual health care professional's registration, fees, or travel or lodging expenses to attend a third-party program.

- ***Adherence to Program Standards.*** Companies should adhere to all standards established by the third-party program organizer or the body accrediting the third-party program, as applicable.

- ***No Direct Sponsorship.*** Direct sponsorship of a health care professional to a third-party program is not permitted. Companies are not permitted to pay, offer to pay or offer to reimburse any expense (e.g., travel, stay, local travel, honorarium etc.) in support of attendance of health care professionals to third-party programs as faculty. Companies must also preserve the independence of third-party programs and must not select or influence selection of health care professional attendance to third-party program. Companies may engage health care professionals under a professional services agreement for a company-conducted satellite symposium held alongside third-party programs and may compensate in accordance with fair market value. Travel and lodging should be considered only if the health care professional is travelling solely for the satellite symposia.

B. Supporting Other Third-Party Programs through Educational Grants

Companies may provide educational grants to training institutions (such as medical schools and teaching hospitals) and to other third-party entities in support of their legitimate scientific, educational and training programs and other activities. This includes, but is not limited to, educational grants to support the education and training of health care and medical personnel (for example, physicians, medical students, residents, fellows, or other health care professionals-in-training or in practice), patients, government officials and regulators (per approval from respective institutions and as per applicable laws and applicable service rules), and the selected patient group/public about important health care topics.

Companies may not make an educational grant to individual health care professionals or individual health care professionals-in-training, and companies may not select or influence the selection of the individual health care professionals who might benefit from the company's support.

Sales personnel should not control or unduly influence the decision of whether a particular institution will receive support or the amount of the support.

C. Supporting Independent Third-Party Research

Supporting third-party research programs and partnering with health care professionals to advance independent research can provide valuable scientific and clinical information, improve clinical care, lead to promising new medical technologies, promote improved delivery of health care, and otherwise benefit patients. To help meet these objectives, companies may provide in-kind or monetary research grants in support of independent research with scientific merit.

- ***Objectives & Milestones.*** Companies may provide support for research that has defined goals, objectives, and milestones. Requests for research grants should be accompanied by clinical protocols that outline these objectives and milestones. Requests for research grants should also transparently document the nature and scope of the research

activity, the budget, the approximate duration of the research, and where applicable, the requirements for independent authorizations or approvals.

- ***Limitations.*** Research grants may include in-kind or monetary support for legitimate, study-related, documented expenses or services and/or reasonable quantities of no-charge product for the limited duration of the research.

- ***Company Involvement.*** The recipient of a company's monetary or in-kind research support should retain independent control over the research.

- ***Company Review Processes.*** Companies should establish controls for reviewing requests for research grants and ensuring that there is compliance with applicable laws, guidelines and codes and applicable service rules, if any.

- ***Sales Involvement.*** Sales personnel should not control or unduly influence the decision of who will receive support or the amount of the support.

Company-initiated or directed research involving a company's medical technology (such as clinical study agreements) is addressed separately in Section II of the Code.

D. Supporting Charitable Programs through Charitable Donations

A company may make monetary or in-kind charitable donations of product or equipment for charitable purposes, such as compassionate usage, patient or public education.

- ***Charitable or Philanthropic Mission.*** Donations should be made for *bona fide* charitable purposes and should be made only to charitable organizations or other non-profit entities with *bona fide* charitable and/or philanthropic purposes. Companies should exercise diligence to ensure the charitable organization or charitable purpose is *bona fide*. Relevant factors to consider may include (1) the entity's tax status, (2) the entity's corporate status under local law, (3) whether the organization has a charitable mission or purpose, and (4) local laws and regulations [for example the Foreign Contributions (Regulation) Act, 2010 and the Rules made thereunder], among other factors.

- ***Use of Funds.*** Companies must require that any donation is used only towards charitable or philanthropic purposes.

- ***Compassionate Usage***. Companies may make charitable donations of product for compassionate usage, provided that these donations serve exclusively to benefit patients and are permitted under applicable laws [for example, Drugs and Cosmetics Act, 1940 and the Rules (Medical Devices Rules, 2017, New Drugs and Clinical Trials Rules 2019 & Drugs & Cosmetics Rules, 1945) made thereunder]. Companies should consider making product donations for compassionate usage cases contingent upon a hospital's agreement that no third parties will be billed for the donated product.

- ***Charitable Events.*** Companies may not pay for or provide tickets to health care professionals or their spouses or guests to attend charitable events, such as galas and golf outings.

- ***Sales Involvement.*** Sales personnel should not control or unduly influence the decision of whether a particular entity will receive support or the amount of the support.

SECTION V – JOINTLY CONDUCTED EDUCATION & MARKETING PROGRAMS

Companies may partner with health care professionals to jointly conduct education and marketing programs. These programs serve an important purpose by allowing companies and health care professionals to educate fellow health care professionals on medical conditions and the range of testing or treatment options available, including the availability of medical technology and the health care professional's ability to diagnose or treat related medical conditions.

Companies should apply the following principles:

- There must be a *bona fide,* legitimate need for the company to engage in the activity.

- Companies should establish controls to help ensure that decisions to engage in these arrangements are not made as an unlawful inducement. Companies should also require health care professionals participating in these arrangements to comply with company guidelines and local regulatory guidelines on providing all relevant regulatory and clinical information related to the product's labeling, safety, quality, instructions for use, performance, safety, side-effects and potential adverse-effects among other controls. Such programs shall be subject to the local law including but not limited to registration of the product by the relevant regulatory authority.

- Jointly conducted programs should be balanced to disseminate and exchange information to the health care professional and the range of services offered by the industry, the treatment of related medical conditions in that disease area as well as the range of technologies and services which are available in the competitive market.

- The company and the health care professional should serve as *bona fide* partners in the program. The arrangement should be documented in a written agreement that describes the purpose of the arrangement and the roles, responsibilities, and mutually agreed contributions of each party, including payment of costs.

SECTION VI – TRAVEL, LODGING & VENUE

There may be educational/training programs or other scientific meetings for which a company determines it is appropriate to pay for health care professionals' travel and lodging costs. This section of the Code provides companies with guidance on paying for a health care professional's travel and lodging costs. Companies should apply the following principles:

- ***Legitimate Need.*** There must be objective, legitimate reasons that support the need for out-of-town travel, such as the need to deliver training and education concerning medical technologies (for example, the non-availability of health care professionals who may not require travel, established expertise in a particular field/therapy/practice, the inability to effectively deliver the content of the program through means other than an in-person meeting, or the need to demonstrate equipment). Companies are encouraged to document the legitimate need for travel.

- ***Modest & Reasonable.*** Travel and lodging accommodations and costs must be modest and reasonable under the circumstances. Companies are encouraged to establish controls on the appropriate class of travel service and the appropriate level of lodging accommodations.

- ***Travel Time & Destination.*** Companies are also encouraged to ensure criteria's are established and taken into consideration while making such arrangements for healthcare professionals (for example, travel dates to be -/+ 24 hours from the start and end of the event date(s), respectively, or travel to and from the place of the healthcare professionals' official residence/practice unless there is a justified need to make arrangements from some other place).

- ***Guests.*** Companies may not pay for or otherwise subsidize the travel or lodging of spouses or 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 company's meeting.

- ***Personal Travel & Lodging.*** Companies may not pay for a health care professional's personal travel or lodging costs that are not connected to such company-conducted program.

- ***Setting*****.** The setting for a company-conducted program or meeting of health care professionals should always be conducive to the exchange of information, suit the particular purpose of the program/ training/meeting, and should not be the main attraction of the event. Companies should consider the following principles when choosing a setting:

    - ✓ The setting should be in a business/ clinical environment as deemed suitable for the purpose, centrally located and easily accessible (for example, considering proximity to airports and highways) in relation to the place of origin of the invited participants.

    - ✓ Companies should not select a setting because of its entertainment or recreational facilities (considering, for example, the season or time of year of the event).

    - ✓ Companies should avoid **top category or luxury hotels or resort facilities** without an appropriate justification.

- ***Other Laws.*** Companies should be aware that other laws or regulations may apply to paying for health care professionals' travel and lodging, including potentially more restrictive local laws, institutional rules and service rules applicable to the health care professionals.

SECTION VII – PROVIDING MODEST MEALS & REFRESHMENTS TO HEALTH CARE PROFESSIONALS

Companies may occasionally provide health care professionals with modest meals and refreshments subject to the following principles:

- ***Purpose***. The meal or refreshments should be subordinate in time and in focus to the *bona fide* discussion and presentation of scientific, educational, or business information. Companies should only provide meals and refreshments in a manner conducive to the presentation or discussion of such information. The meal or refreshments should not be part of an entertainment or recreational event.

- ***Setting & Location***. Meals and refreshments should be provided in a setting that is conducive to *bona fide* scientific, educational, or business discussions**.** This may include, for example, the health care professional's place of business, the company's office or an off-site space that is conducive to the discussion, such as a restaurant or business center.

- ***Participants***. Companies may provide a meal or refreshments only to health care professionals who actually attend and have a *bona fide* purpose for attending the meeting.

  Companies may not provide a meal or refreshments:

  - ✓ For an entire office staff where everyone does not attend 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 discussed at the meeting.

- ***Documentation***. Companies should establish controls to ensure the purpose and execution of the meeting is reasonably documented.

- ***Frequency***. Companies should establish controls to reasonably monitor and track the frequency of meetings with health care professionals involving meals and refreshments.

SECTION VIII – EDUCATIONAL & PATIENT BENEFIT ITEMS; PROHIBITION ON GIFTS

Companies may occasionally provide modest, appropriate educational items to health care professionals that benefit patients or serve a genuine educational function for health care professionals. Educational items can include but are not limited to product manuals and anatomical models.

Companies may not provide gifts to health care professionals. This means that companies may not provide health care professionals with the following:

- ✓ Items that the health care professional (or his or her family members, office staff, or friends) can use for non-educational or non-patient-related purposes (for example, office supplies, scrubs, a tablet, smart phone, laptop, or other mobile device capable of personal use)

- ✓ Non-educational promotional items, even if the item is of minimal value, related to the health care professional's work, or for the benefit of patients (for example t-shirts, hats, mugs, and other items with a company or product name or logo)

- ✓ Gifts such as wine, gift baskets, holiday gifts or cash or cash equivalents (for example, gift cards)

Other important principles include:

- ✓ Any item given to a health care professional's staff should be treated as though it is given to the health care professional and is subject to all applicable provisions of the Code.

- ✓ Companies may not raffle or give away an item that it could not otherwise give a health care professional under the Code.

SECTION IX – PROHIBITION ON ENTERTAINMENT & RECREATION

Companies should not provide or pay for any entertainment or recreational event for a health care professional, their staff or their family.

Some examples of entertainment and recreational activities include, among others, theater, live comedy or musicals, sporting events, golf, skiing, cruises, spas, or vacation trips.

This prohibition applies regardless of (1) the value of the activity; (2) whether the company engages the health care professional as a consultant; or (3) whether the entertainment or recreation is secondary to an educational purpose.

SECTION X – PROVISION OF HEALTH ECONOMICS & REIMBURSEMENT INFORMATION

As medical technologies become increasingly complex, so do payor coverage and reimbursement policies. Patient access to necessary medical technology depends on health care professionals and/or patients having timely and complete coverage, reimbursement, and health economic information. To promote patient access to medical technologies:

- Companies may provide this information to health care professionals regarding its medical technologies if it is accurate and objective.

- Companies may also collaborate with health care professionals, health economists, reimbursement experts and organizations representing their interests to achieve government and commercial payor coverage decisions, guidelines, policies, and adequate reimbursement levels that allow patients to access its medical technologies.

Permissible activities involving the provision of coverage, reimbursement, and health economic information may include, but are not limited to:

- Identifying the clinical value of the company's medical technologies and the services and procedures in which they are used.

- Collaborating with health care professionals, their professional organizations, health economists, reimbursement experts and patient groups to conduct joint advocacy on coverage, reimbursement, and health economics issues.

- Supporting health care professionals and their professional organizations in developing materials and otherwise providing direct or indirect input into payor coverage and reimbursement policies.

- Promoting accurate payor claims by providing accurate and objective information and materials to health care professionals regarding the company's medical technologies, including identifying coverage, codes, and billing options that may apply to those medical technologies or the services and procedures in which they are used.

- Providing accurate and objective information about the economically efficient use of the company's medical technologies, including where and how they can be used within the continuum of care.

- Providing information related to the company's medical technologies and available reimbursement and associated costs.

- Providing information relating to changes in coverage or reimbursement amounts, methodologies and policies and the effects of such changes to help a health care professional in the decision to use or recommend use of the company's medical technologies.

- Providing accurate and objective information designed to offer technical or other support intended to aid in the appropriate and efficient use or installation of the company's medical technologies.

- Providing accurate pricing and payment documentation on the company's medical technologies to the hospital and maximum retail prices to the relevant authorities and health care professionals.

- Facilitating patient access to a company's medical technologies by providing health care professionals with assistance in obtaining patient coverage decisions from payors, including providing information on payor policies and training on procedures for obtaining prior authorization, providing sample letters and information on medical necessity and appeals of denied claims.

  In addition, at the request and recommendation of a health care professional to facilitate patient access to the company's medical technology and subject to appropriate privacy safeguards, the company may assist the patient by facilitating the preparation and submission of requests for coverage determinations, prior authorizations, pre-certifications and appeals of denied claims relating to a company's own medical technology, however, such assistance should not be provided as an unlawful inducement.

Companies may not interfere with a health care professional's independent clinical decision making or provide coverage, reimbursement, and health economics support as an unlawful inducement. For example, companies should not provide free services that eliminate an overhead or other expense that a health care professional would otherwise have incurred as part of its business operations. Further, companies should not suggest mechanisms for billing for services that are not medically necessary, or for engaging in fraudulent practices to achieve inappropriate payment.

If a company comes across information on any patients' medical records while collaborating with a health care professional or patient in obtaining reimbursement, the company should maintain the privacy of the data as per applicable laws, regulations, guidelines, codes and applicable global standards. Similarly, the company should fulfil its other regulatory obligations such as initiating field corrective measures and/or informing the relevant regulatory authority.

SECTION XI – DEMONSTRATION, EVALUATION & CONSIGNED PRODUCTS

A. Demonstration & Evaluation Products

Providing products (approved medical technologies) to health care professionals at no charge for evaluation or demonstration purposes can improve patient care, facilitate the safe and effective use of products, enhance patient awareness, and educate health care professionals regarding the use of products. Under certain circumstances including tendering processes, a company may provide reasonable quantities of products to health care professionals at no charge to allow health care professionals to assess the appropriate use, safety and performance of the product.

Company products that may be provided to health care professionals for evaluation include single use (for example, samples of consumable or disposable products) and multiple use products (sometimes referred to as capital equipment).

Company products provided for evaluation are typically expected to be used in patient care. Companies should provide health care professionals with appropriate documentation to allow the health care professional to address any reimbursement reporting obligations, including providing information on the no-charge status of these products.

- ***Single Use/Consumables/Disposables.*** The number of single use products provided at no charge should not exceed the quantity reasonably necessary for the adequate evaluation of the products.

- ***Multiple Use/Capital.*** Multiple use products provided without transfer of title for evaluation purposes should be furnished only for a period of time that is reasonable under the circumstances to allow an adequate evaluation.

    - The ***length of time necessary*** for a health care professional to evaluate a multiple use product can vary among products and may depend on the frequency of anticipated use, the duration of required training, the number of health care professionals who need to evaluate the product, the length of time needed to evaluate different product features, and other considerations such as local laws, standards and regulations.

    - The ***terms of evaluation*** of such multiple use products should be set in advance in writing, specifying the length of the evaluation period and documenting legitimate reasons for products that would not be returned within the evaluation period.

    - Companies should retain title to multiple use products during the evaluation period and should have a process in place for promptly removing multiple use products from the health care professional's location at the conclusion of the evaluation period unless the health care professional purchases or leases the products.

- ***Demonstration.*** Company demonstration products are sometimes unsterilized single use products or mock-ups that are used for health care professional and patient awareness and education. For example, a health care professional may use a demonstration product to show a patient the type of device that will be implanted in the patient.

    - Company demonstration products are typically identified as not intended for patient use through designations like "Free Sample - NOT FOR SALE" or "Not for Human Use" on the product, the packaging, or documentation that accompanies the product. Sterilized products may be used in live demonstration only if done in an educational setting with company controls in place.

- ***Documentation.*** Company should maintain a system of control in respect of such demonstration products including traceability (such as product name, product code, quantity, batch number, lot number and, name of the healthcare professional to whom such demonstration products are given etc.).

B. Consigned Products

Consigned products are medical technologies (a) that a company provides to a health care professional for use in and storage at the health care professional's patient care setting and (b) to which the company retains title until the product is used.

- Consignment arrangements should generally be subject to an agreement that addresses the terms of consignment, for example, the number of products, any requirements to segregate consigned products from other products, and storage conditions and responsibility of ensuring the storage conditions of the products.

- Companies are encouraged to consider implementing appropriate controls. This could include (among other measures) taking periodic inventory of consigned devices for purposes such as billing and restocking; reconciling discrepancies between the company's records and the number of products used or verified during inventory; and return or removal of expired product.

SECTION XII – COMPANY REPRESENTATIVES PROVIDING TECHNICAL SUPPORT IN THE CLINICAL SETTING

Company representatives may play an important role in the clinical setting by providing technical support on the safe and effective use of medical technology. Some examples include:

- Company representatives may need to explain how a medical technology's unique settings and technical controls function and may make recommendations.

- Company representatives may assist the clinical/operating room team to ensure that the appropriate range of necessary devices and accessories are available during a procedure, especially when dealing with medical technology that involves multiple devices and/or accessories.

Companies should apply the following principles:

1. Company representatives should enter and be present in the clinical setting only at the request of and under the supervision of a health care professional.

2. Company representatives should be transparent that they are acting on behalf of the company in a technical support capacity only. The primary patient care responsibility lies exclusively with the health care professional.

3. Company representatives should ensure that the professional autonomy of the health care professional and/or autonomy of the medical institution is maintained by not interfering with a health care professional's independent clinical decision-making.

4. Company representatives should comply with applicable hospital or facility policies and requirements, including patient privacy and credentialing requirements as per the applicable laws, guidelines and codes.

5. A company's technical support should not cover an overhead or other expense that the health care professional would otherwise incur while providing patient care. For example, a company representative providing technical support for a procedure with regard to the company's medical technology may not function as a surgical technician for a hospital.

6. Company representatives may provide their personal contact details where required if the product requires consistent monitoring, programming or adjustment, but such support can only be provided per the health care professional's direction.

SECTION XIII – RELATIONSHIPS WITH THIRD-PARTY INTERMEDIARIES

Companies are encouraged to adopt a third-party intermediary management compliance program in addition to an overall compliance program. Taking into account a variety of risk-based factors, as well as local applicable laws, such programs should include the following elements:

1. **Written Anti-Bribery Policy/Procedure:** Companies should adopt and implement internal policies prohibiting all forms of bribery by any person or entity acting on a company's behalf, including company personnel, third-party intermediary representatives, health care professionals and other agents. Such policies should include more detailed measures for common risk areas such as travel, gifts, hospitality, entertainment, grants or donations, research, and capital equipment. Companies should consider communicating to health care professionals and other stakeholders their ethical business practices concerning third-party intermediaries.

2. **Risk Assessment:** Companies should evaluate the risk profile for proposed and utilized third-party intermediary arrangements including, for example:

    - **Companies** should assess (1) the local risk through published corruption indices as well as specific risk profiles of planned or utilized Third-party intermediaries; (2) international, national and local legal requirements, (3) information from third-party intermediaries for potentially unusual arrangements, such as unusually high commissions paid to sub-intermediaries, high degree of interaction with government officials or health care professionals associated with Government hospitals, marketing budgets, health care provider corporate affiliation or ownership, and/or off-shore payment accounts, and (4) information available from public sources or employees for potential issues associated with a third-party intermediary.

    - **Third-party intermediaries** should (1) support companies' risk assessments prior to and throughout engagement in activities conducted on the company's behalf, (2) assess and comply with international, national and local legal requirements, (3) disclose potentially unusual arrangements, and (5) maintain accurate records for review.

3. **Diligence Program:** Companies should establish a risk-based, pre-engagement and renewal due diligence program to identify, prevent, and mitigate risks relating to the market in which the third-party intermediaries is engaged to operate, as well as any specific activities the third-party intermediary deploys on behalf of the company. Companies are encouraged to engage with local industry associations to advance compliance training and best practices sharing.

4. **Written Contract:** Companies should reach contract terms with third-party intermediaries that implement anti-corruption policies including but not limited to:

    a. Compliance with international, national and local laws, ethical principles, and company policies;
    b. The ability to conduct independent audits and monitoring, including access to relevant books and records;
    c. The ability to terminate an engagement for failure to comply with international and local laws, ethical principles, and company policies; and
    d. Diligence rights upon renewal.

5. **Training and Education:** Companies should undertake initial and provide regular training and education for relevant third-party intermediary personnel on international and applicable national anti-corruption and anti-bribery laws, data privacy principles and other laws and regulations that may be relevant for third-party intermediaries to conduct their

business per ethical principles and company policies. Training should be conducted in the language most appropriate to the audience.

6. **Monitor/Audit:** Companies are encouraged to undertake risk-based, routine monitoring, auditing, and other assessments of their relationship for compliance with international and applicable national and local laws, ethical principles, and company policies as well as relevant contract terms.

7. **Appropriate Corrective Action:** Companies should take appropriate corrective action, consistent with applicable international and applicable national and local laws, if a third-party intermediary representative fails to comply with such international and applicable national and local laws, ethical principles, company policies, relevant contract terms, or engages in other impermissible or unethical conduct.