Comparison of the AdvaMed Code of Ethics (U.S. and China Versions) and the MedTech Europe Code of Ethical Business Practice and the APACMed Code of Ethical Conduct

	AdvaMed Code of Ethics on Interactions with U.S. Health Care Professionals	AdvaMed Code of Ethics on Interactions with Health Care Professionals in China	MedTech Europe Code of Ethical Business Practice (Introduction & Part 1)	APACMed Code of Ethical Conduct for Interactions with Health Care Professionals
	Effective January 1, 2020	Effective January 1, 2016; Revised effective January 1, 2017	Fully effective January 1, 2017; Q&A updated June 2019	Effective January 1, 2018
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Introduction / Preamble	**Section I – Introduction** The Advanced Medical Technology Association (AdvaMed) is a global trade association of Companies that develop, produce, manufacture, and market Medical Technologies. We are dedicated to advancing medical science; developing high quality, innovative Medical Technology; and improving patient care.	**I. Preamble: Goal and Scope of AdvaMed China Code** 1. The Advanced Medical Technology Association ("AdvaMed") represents companies that develop, produce, manufacture, and market medical products, technologies and related services and therapies used to diagnose, treat, monitor, manage and alleviate health conditions and disabilities ("Medical Technologies") in order to enable patients to live longer and healthier lives (collectively "Companies," and individually "Company"). AdvaMed is dedicated to the advancement of medical science, the improvement of patient care, and, in particular, the contributions that high quality, innovative Medical Technologies make toward achieving these goals. 2. The AdvaMed China Board is a China-based	**INTRODUCTION** **Promoting an Ethical Industry** MedTech Europe is the only European trade association representing the medical technology industry from diagnosis to cure. We represent In-Vitro Diagnostics and Medical Devices manufacturers operating in Europe. Our mission is to promote a balanced policy environment that enables the medical technology industry to meet the growing healthcare needs and expectations of its stakeholders. MedTech Europe recognises that compliance with applicable laws and regulations as well as adherence to ethical standards are both an obligation and a critical step to the achievement of the aforementioned goals and can enhance the reputation and success of the medical technology industry.	APACMed MISSION: Our mission is to improve the standards of care through innovative collaborations among stakeholders to jointly shape the future of health care in Asia Pacific **A. PURPOSE AND APPLICABILITY OF CODE** This Code of Ethical Conduct (“Code”) is effective as of 1 January 2016. The Asia Pacific Medical Technology Industry Association (“APACMed”) promotes ethical interactions between the medical technology industry and health care professionals to advance the APACMed Mission. The purpose of this Code is to facilitate ethical interactions between its corporate members that develop, manufacture, sell, market, or distribute medical technologies in Asia Pacific (“Members”) and those individuals and entities that use, recommend, purchase, or prescribe medical technologies in Asia Pacific

		governance group of AdvaMed that consists of AdvaMed member companies' most senior company executives in China. 3. The China Board recognizes the obligation to facilitate ethical interactions between Companies and institutions involved in the provision of health care services and/or items to patients, which purchase, lease, recommend, use, arrange for the purchase or lease of, or prescribe Companies' Medical Technologies in the People's Republic of China ("institutional Health Care Professionals") as well as the individuals employed by these institutions (and who are not full-time employees of a Company) who are also involved in the provision of health care services and/or items to patients and who also purchase, lease, recommend, use, arrange for the purchase or lease of, or prescribe Companies' Medical Technologies ("individual Health Care Professionals"). Unless otherwise specified, the term "Health Care Professionals" refers to individuals and institutions.	The Code sets out the minimum standards appropriate to the various types of activities carried out by the Members. The Code is not intended to supplant or supersede national laws or regulations or professional codes (including company codes) that may impose more stringent requirements upon Members and all Members should independently ascertain that their activities comply with all current national and local laws, regulations and professional codes. Furthermore, Member Companies must be mindful of the fact that they may be liable for the activities of third party intermediaries who interact with Healthcare Professionals or Healthcare Organisations in connection with the sale, promotion or other activity involving Member Companies' products. Accordingly, it is recommended that where such arrangements are entered into, the relevant contractual documentation impose obligations upon the third party (for example, third party sales & marketing intermediaries (SMIs), consultants, distributors, sales agents, marketing agents, brokers, commissionaire commercial agents and independent sales representatives) to comply with provisions set out in the Code or equivalent guidelines. **QI: Is the Code applicable to activities of an Affiliate of a Member Company located outside the MedTech Europe Geographic Area? (Added in September 2018)** AI: "With regards to activities of an Affiliate of a Member Company located outside of the MedTech Europe Geographic Area; The Code is applicable: • whenever they support an Event taking place in the MedTech Europe Geographic Area or • whenever they interact with Healthcare Organisations located, or Healthcare Professionals registered or practising inside the MedTech Europe Geographic Area. The Code is not applicable:	("HCPs"). Members commit to adhere to this standard by adopting and abiding by the ethical principles outlined in this Code. This Code is subject to the laws of each country, province, or region, and other codes of conduct, applicable to a Member. If a provision in law or another code of conduct applicable to a Member is more restrictive than the corresponding provision in this Code, the Member shall adhere to the more restrictive provision in the law or other code of conduct. Likewise, if a provision in this Code is more restrictive than the corresponding provision in law or another code of conduct applicable to a Member, the Member shall adhere to the more restrictive provision in this Code.

			• whenever they support an Event taking place outside the MedTech Europe Geographic Area (for the avoidance of doubt and as stated in the above paragraph; except if they are supporting participation of Healthcare Professionals registered or practicing inside the MedTech Europe Geographic Area to attend the Event) or • interact with Healthcare Organisations located, or Healthcare Professionals registered or practising outside the MedTech Europe Geographic Area. However, in the interest of increased transparency, it would always be preferable for the Affiliate of the Member Company based in the MedTech Europe Geographic Area to handle support for Healthcare Professionals attending Events held in the MedTech Europe Geographic Area.	
	<u>The Value of Interactions with Health Care Professionals</u> Health Care Professionals' 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. • Companies and Health Care Professionals 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	5. <u>Interactions with Health Care Professionals</u> The scope of beneficial interactions between Health Care Professionals and Companies is broad and includes interactions intended to: A. *Enhance the Safe and Effective Use of Medical Technologies*. The safe and effective use of sophisticated electronic, in vitro diagnostic, surgical, or other Medical Technologies often requires Companies to provide Health Care Professionals appropriate instruction, education and training. Regulators often require this type of training as a condition of product approval. B. *Promote the Advancement of Medical Technologies*. Developing and improving cutting edge Medical Technologies are collaborative processes between Companies and Health Care Professionals. Innovation and creativity are essential to the development and evolution of Medical Technologies that better serve patients. C. *Encourage Research and Education*. Companies' support of bona fide medical research, education, and enhancement of		

	improve patient care • Companies promote charitable giving and public awareness of medical and health conditions through grants and donations in support of indigent care and patient education	professional skills improves patient safety and increases access to Medical Technologies. D. *Foster Charitable Donations and Giving*. Companies make monetary and Medical Technology donations for charitable purposes, such as supporting indigent care, as well as patient and public education. This increases access to—as well as the quality of—care and treatment in patient populations that may not otherwise be reached. E. *Support Appropriate and Efficient Use*. Providing service, technical or other support intended to aid in the appropriate and efficient use or installation of the Company's Medical Technologies. 6. <u>Interactions with Third Party Sales and Marketing Intermediaries</u> To ensure and improve ongoing patient and clinician access to innovative, reliable and effective Medical Technologies, it is often necessary for Companies to engage third party intermediaries to assist in the marketing, sale and/or distribution of the Companies' products or services. The form of, and terminology used by Companies to describe relationships with these third party sales and marketing intermediaries varies, but may include distributors, wholesalers, distribution or sales agents, marketing agents, brokers, commissionary commercial agents and independent sales representatives with which the Company has a direct contractual relationship ("Third Party SMIs"). It is essential that Companies' interactions with Third Party SMIs, as well as Third Party SMIs' behavior on a Company's behalf (including Third Party SMI interactions with Health Care Professionals and governmental officials) are conducted pursuant to all applicable legal and ethical principles.		
	<u>The Purpose of the AdvaMed Code & Its</u>	7. <u>The Purpose of the Code of Ethics</u>	**Aims and Principles of the Code**	**B. ETHICAL PRINCIPLES**

	Cornerstone Values The AdvaMed 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 & 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. The Code is intended to help Companies make reasonable and appropriate decisions that align with the Code's values. Companies and their employees and agents should be mindful of their interactions and the	AdvaMed recognizes that Health Care Professionals' first duty is to act in the best interests of patients. Companies can serve the interests of patients through beneficial collaborations with Health Care Professionals. To ensure that these collaborative relationships meet high ethical standards, they must be conducted with appropriate transparency and in compliance with applicable laws, regulations and government guidance. AdvaMed recognizes the obligation to facilitate ethical interactions between Companies and Health Care Professionals in order to ensure that medical decisions are based on the best interests of the patient. The ethical principles that govern these interactions are the subject of this Code of Ethics.	The interaction between Members and Healthcare Professionals and Healthcare Organisations is an important feature in achieving MedTech Europe's mission to make safe, innovative and reliable technology and related services available to more people. For example: • Advancement of Medical Technologies The development of innovative medical devices, technologies and in vitro diagnostics and the improvement of existing products require collaboration between Member Companies and Healthcare Professionals and Healthcare Organisations. Innovation and creativity are essential to the development and evolution of medical technologies and/or related services. • Safe and Effective Use of Medical Technology The safe and effective use of medical technology and related services requires Member Companies to offer Healthcare Professionals and Healthcare Organisations appropriate instruction, education, training, service and technical support. • Research and Education Member Companies' support of bona fide medical research and education, serves to enhance Healthcare Professionals' clinical skills and thereby contribute to patient safety and increase access to new technologies and/or related services. In each such interaction Member Companies must continue to respect the obligation of Healthcare Professionals to make independent decisions regarding treatment and safeguard the environment in which the interaction takes place to ensure the integrity of the industry. To achieve this aim, the Code provides guidance on the interactions of Member Companies with both Healthcare Professionals and Healthcare Organisations, based upon the following underlying principles:	**1. Collaborative Interactions to preserve independent decision-making and public confidence** 1.1 APACMed recognizes that collaborative interactions between Members and HCPs are essential to advancing medical technology and ensuring the safe and effective use of Members' products and services. Ultimately, such interactions are to the benefit of patients. 1.2 APACMed is committed to ensuring that these interactions meet the highest ethical standards, preserve HCPs' independent decision-making, and reinforce public confidence in the integrity of patient care, treatment, and product and service selection. 1.3 All interactions with HCPs must be: (a) conducted in compliance with applicable laws and codes of conduct; (b) based on the best interests of the patient; and (c) appropriately documented. 1.4 In promoting or advertising their products and services to HCPs, Members must ensure that they comply with applicable laws and codes of conduct. All statements must be true, accurate, and substantiated.

	perception of their interactions with Health Care Professionals. **Q1 – Why does AdvaMed have a Code of Ethics that differs from codes that govern pharmaceutical or biologics companies?** Drugs and biologics act on the human body by chemical means and can often be administered by the patient alone without the direct supervision of a Health Care Professional or the involvement of a Company representative to instruct on their safe and effective use. Medical Technology, on the other hand, often consists of complex tools, devices, and technology requiring highly dependent "hands on" interactions with Health Care Professionals from beginning to end. Health Care Professionals require training on and an understanding of how to use these products in a safe and effective way. We have developed the AdvaMed Code to address interactions with Health Care Professionals that are specific to the Medical Technology industry.		• **The Principle of Image and Perception:** Member Companies should, at all times, consider the image and perception of the medical technology industry that will be projected to the public when interacting with Healthcare Professionals and Healthcare Organisations. • **The Principle of Separation:** Interaction between industry and Healthcare Professionals / Healthcare Organisations must not be misused to influence through undue or improper advantages, purchasing decisions, nor should such interaction be contingent upon sales transactions or use or recommendation of Member Companies' products. • **The Principle of Transparency:** Interaction between industry and Healthcare Professionals/ Healthcare Organisations must be transparent and comply with national and local laws, regulations or professional codes of conduct. In countries where specific provision is not made, Member Companies shall nevertheless maintain appropriate transparency by requiring prior written notification to the hospital administration, the Healthcare Professional's superior or other locally-designated competent authority, fully disclosing the purpose and scope of the interaction. • **The Principle of Equivalence:** Where Healthcare Professionals are engaged by a Member Company to perform a service for or on behalf of a Member Company, the remuneration paid by the Member Company must be commensurate with, and represent a fair market value for, the services performed by the Healthcare Professional. • **The Principle of Documentation:** For interactions between a Member Company and a Healthcare Professional, such as where	

			services are performed by a Healthcare Professional for or on behalf of a Member Company, there must be a written agreement setting out, inter alia, the purpose of the interaction, the services to be performed, the method for reimbursement of expenses as well as the remuneration to be paid by the Member Company. The activities envisaged by the agreement must be substantiated and evidenced by activity reports and the like. Adequate documentation such as the agreement, related reports, invoices etc. must be retained by the Member Company for a reasonable period of time to support the need for, and materiality of, the services as well as the reasonableness of the remuneration paid. **Q1: Does the definition of Healthcare Professional include purchasing professionals employed in the retail sector, such as a purchasing professional employed by a supermarket chain?** A1: No, the definition of Healthcare Professional does not include a purchasing professional employed in the retail sector unless that individual purchaser arranges for the purchase of Member Companies' medical devices for or on behalf of medical or clinical personnel. For example, if a Member Company's medical devices are sold as part of the common merchandise of the retail outlet, interactions between the Member Company and the purchasing professional do not fall under the Code. However, where the Member Company's medical devices are sold in a retail pharmacy (even if this is located within a supermarket unit), interactions between the Member Company and the responsible purchasing professional will fall under the Code. Q2: Must a Member Company require Employer Notification to be given whenever Company personnel meet HCPs at an HCO? (added in November 2016) A2: No. Unless the Member Company's interaction with an HCP entails a	

			transfer of value or raises a potential conflict of interest there is no requirement for Employer Notification. However, Member Companies must comply with any access requirements imposed by HCOs to visiting Member Company personnel.	
	Scope & 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 U.S. Health Care Professionals, whether occurring inside or outside the United States (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' and agents' interactions with U.S. Health Care Professionals, even if an employee or agent pays for the interaction himself/herself • **Representatives:** A Company adopting the Code is required to communicate the Code's provisions to its employees, agents, dealers, and distributors, 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 their businesses. The AdvaMed Code applies to Companies' interactions linked to Medical Technology. • **Combination Products:** The Code applies to all interactions with U.S. 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),	8. Local Laws, Regulations and Government Guidance Shall Prevail All Companies have an independent obligation to ensure that their interactions with Health Care Professionals comply with all applicable laws, regulations and government guidance within the jurisdictions that they operate. Applicable laws, regulations or government guidance may provide more specificity than this Code, and Companies should seek counsel to address any additional questions. This Code of Ethics is intended to facilitate ethical behavior, and is not intended to be, nor should it be, construed as legal advice. The Code is not intended to define or create legal rights, standards or obligations. Any interpretation of the provisions of this Code, as well as Companies' interactions with Health Care Professionals not specifically addressed in this Code, should be made in light of the following principle: Companies shall encourage ethical business practices and socially responsible industry conduct and shall not engage in any unlawful inducement. **Q1 My Company's policies and procedures apply standards that are more stringent than those described in the AdvaMed Code of Ethics on Interactions with Health Care Professionals in China ("AdvaMed China Code" or "Code"). How does this impact my Company's ability to certify as to compliance with the Code?** The AdvaMed China Code provides Medical Technology Companies with a set of practical principles that Medical Technology Companies may follow in order to form the foundation of a compliance program in China. In order to certify to the Code, Companies must adopt and implement policies that incorporate the Code's	**Key Legislation** The medical technology industry in Europe, in common with other industries, is subject to national and supranational laws which govern many aspects of their business operations. MedTech Europe underlines compliance with the following laws and regulations as having particular relevance to the medical technology industry: • Safety, Quality and Performance Laws; • Advertising and Promotion Laws; • Data Protection Laws; • Anti-corruption Laws; • Environmental Health and Safety Laws; • Competition Laws. National and European Union (EU) competition legislation applies not only to Members in their business operations, but also to MedTech Europe, each of the alliance's working groups and any sub-group within the associations, irrespective of size and name. Liability under competition laws may be strict and a Member may become liable for the infringement of such laws by other Members of an association group in which it participates. Accordingly, Members must make every effort to observe EU and national competition laws in all their interactions.	

	which may also be subject to other trade association codes. **No Unlawful Inducements.** Throughout, the Code refers to the concept of an **"unlawful inducement"** to reflect the prohibitions found in the U.S. Federal Anti-Kickback Statute. The Anti-Kickback Statute prohibits the knowing and willful payment (or offer to pay) or receipt (or solicitation to receive) of anything of value to induce or reward referrals or the generation of business that is payable under a Federal health care program, such as Medicare. **Q1a – To which Company employees, agents, dealers, or distributors does the AdvaMed Code apply?** The AdvaMed Code is intended to apply to all bona fide employees and agents of a Company when acting on the Company's behalf, regardless of the individual's job function or position. The AdvaMed Code is also intended to apply to all dealers, distributors, and resellers – including sub-dealers and sub-distributors – that provide sales and marketing support for the Company and that interact with U.S. Health Care Professionals (as defined in the Glossary) on the Company's behalf.	principles. To the extent that a Company implements policies that address all of the topics covered by the Code but that applies a higher standard than the principles found in the Code, a Company would be considered to be in compliance with the Code and can certify as such. More broadly, if a provision of law or another code of conduct applicable to a Company is more restrictive than a corresponding provision in the China Code, the Company should adhere to the more restrictive provision in the law or other code of conduct. Conversely, if a provision in the AdvaMed China Code is more restrictive than the corresponding provision of law or other code of conduct applicable to a Company, the Company should adhere to the AdvaMed China Code. **Q2 Section I of the AdvaMed China Code notes that Companies' interactions with Third Party Sales and Marketing Intermediaries ("SMIs") are conducted pursuant to all applicable legal and ethical principles. My Company engages distributors in China. Must my Company's distributors comply with the requirements of the AdvaMed China Code?** Yes. In order to comply with the AdvaMed China Code, Companies must require Third Party SMIs with which they engage to comply with Company policies that implement the AdvaMed China Code. This includes Section IV of the AdvaMed China Code, which phases out Direct Sponsorships to individual HCPs to attend Third-Party Educational Conferences, starting January 1, 2018.		
	<u>Complying with the AdvaMed Code</u> The AdvaMed Code does not replace any laws, regulations, or codes that may contain stricter requirements (for example, government ethics rules or state marketing laws). The AdvaMed 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	**II. Code of Ethics Compliance** All Companies doing business in China are strongly encouraged to adopt and certify to this Code and to implement an effective compliance program - one which includes policies and procedures that foster compliance with the Code with respect to their interactions with Health Care Professionals related to Medical Technologies in China.	**Interpreting the Code** The use of capital letters indicates that a word or expression is a defined term, the meaning of which is set out in the Glossary. Any phrase introduced by the terms: including, include, in particular, or any similar expression shall be interpreted as illustrative and shall not limit the sense of the words preceding those terms **Administering the Code**	**C. EFFECTIVE CODE IMPLEMENTATION** In order to ensure effective implementation of these Code principles, each Member shall: (a) appoint a senior executive responsible for oversight of the Member's compliance with this Code;

	(1) promoting an organizational culture that encourages ethical practices and a commitment to comply with the law and (2) preventing and detecting inappropriate conduct. Programs should be **appropriately tailored** for each Company. **"Appropriately tailored"** means that each Company's implementation of an effective compliance program differs depending on a variety of factors (such as size, resources, work force, and business line, among others). Given the wide diversity within the Medical Technology industry, there is no single best compliance program. Companies should develop and implement compliance controls that address the specific types of risks that apply to their operations. 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 (for example, the U.S. Federal Sentencing Guidelines and materials from the U.S. Department of Justice and the U.S. Department of Health and Human Services Office of Inspector General). Elements of an effective compliance program can include: ***(See "Elements of an Effective Compliance Program" Infographic)*** A Company that adopts the Code is **strongly encouraged to submit to AdvaMed an annual certification** stating that the Company has adopted the Code and has implemented an effective compliance program. AdvaMed member Companies must, and non-member Companies may, 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.	1. A Company that wishes to certify to the Code is required to submit to AdvaMed an annual 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 China. For Companies headquartered in China, this would be the Chief Executive Officer or individual with equivalent responsibility within the certifying company. For Companies headquartered outside of China, this would be the most senior representative of the certifying Company's Medical Technology operation in China. This certification must additionally be signed by the Company's Chief Compliance Officer for China or individual with equivalent responsibilities within the certifying Company. AdvaMed will publish on its website a list of those Companies that have submitted this annual certification. 2. Companies that are AdvaMed members shall, and Companies that are non-members may, supply contact information for the Company's Compliance Department 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 such Company. 3. Companies are strongly encouraged to follow the following seven elements of an effective compliance program, appropriately tailored for each Company, namely: (1) implementing written policies and procedures; (2) designating a compliance officer and compliance committee; (3) conducting effective training and education; (4) developing effective lines of communication (including an anonymous reporting function); (5) conducting internal monitoring and auditing; (6) enforcing standards through well publicized disciplinary guidelines; and (7)	The Code operates within a Procedural Framework which includes procedures designed to provide an effective and efficient complaint-handling process, at national and European level, to ensure compliance with the Code. MedTech Europe's dispute handling system is based on the principle that disputes are generally national in nature and are therefore best resolved at national level. For complaints between Member Companies, mediation should be considered seriously before further pursuit of the matter via any formal complaint handling process, either at national or MedTech Europe level. The principles outlined in the Procedural Framework aim at supporting Member Associations when setting up or amending their national dispute-resolution mechanisms. They are based on principles of proportionality, speed, due process, fairness and transparency and have been established under the guidance of the MedTech Europe Compliance Panel, acting independently of MedTech Europe. The Conference Vetting System is an independently - managed system which reviews the compliance of Third Party Organised Educational Events with the Code. The Code and the Procedural Framework shall be reviewed when required and at a minimum every five (5) years for the Code and every two (2) years for the Procedural Framework, in accordance with the governance rules of MedTech Europe. **Q3: What is the Conference Vetting System (CVS) and, is CVS approval required for all Third Party Organised Educational Events before a Member Company can provide support to these events? (added in November 2016)** A3: The Conference Vetting System (see the Glossary) has been established as the online, binding and centralised decision-making process to help Member Companies review the compliance of relevant Third Party Organised Educational Events with the Code. It is managed	(b) adopt practical, useful, and meaningful policies, guidance, and tools intended to ensure compliance with the Code; (c) provide effective and ongoing training and education on the Code and on ethical conduct for interactions with HCPs; (d) ensure that senior management and the Member's board of directors or other governing body have expressly committed to support the Code; (e) institute appropriate internal monitoring and auditing mechanisms; (f) create safe mechanisms for, and encourage, employees to raise concerns; and (g) require that third party intermediaries (including consultants, distributors, sales agents, and brokers) appointed by the Member who may interact with HCPs in connection with the Member's medical technologies agree to conduct their interactions in accordance with applicable laws and ethical principles at least as restrictive as those contained in this Code.

		responding promptly to detected problems and undertaking corrective action. 4. Companies are strongly encouraged to ensure that interactions with individual Health Care Professionals (or to individual units within an Institutional Health Care Professional) are appropriately disclosed to the institution or employer. If applicable laws, regulations or institutional rules specifically require disclosure to a different body, then disclosure should be made in accordance with the applicable laws, regulations or rules. **Q3 The China Code indicates in several places that Companies must document certain arrangements with health care professionals (specifically Section IV ("Supporting Third-Party Educational Conferences"), Section XI ("Research, Academic and Public Education Grants; Charitable Donations") and Section XII ("Evaluation and Demonstration Products")). What guidelines are recommended for Companies to document such transactions?** Section I of the China Code states that Companies "have an independent obligation to ensure that their interactions with Health Care Professionals comply with all applicable laws, regulations and government guidance within the jurisdictions that they operate." Companies are encouraged to consult with legal counsel to assess any applicable legal requirements, including any laws, provisional rules, or government-issued guidance. This might include how certain interactions are documented and entering into written agreements with the recipients of grants, donations, sponsorships, or no-charge evaluation and demonstration product. Companies should ensure that written agreements include appropriate references, such as the parties involved, the parties' roles and responsibilities, the terms of the arrangement, a description of the funds and/or no-charge product provided, and a breakdown of the budget and disclosure of grants and donations, among other standard	independently of the MedTech Europe Secretariat and Members and is under the supervision of the MedTech Europe Compliance Panel. CVS approval is only required for Third Party Organised Educational Events which fall within its scope, as provided here. Where there is a CVS decision in relation to a specific Third Party Organised Educational Event, this decision is binding upon all Member Companies. **Q3bis: What is a Virtual Third Party Organised Educational Event ("Virtual Event") (added in June 2019)** A3bis: A [stand-alone] Virtual Third Party Organised Educational Event ("Virtual Event") consists of the filming of presentations, panel discussions or live clinical procedures (e.g. hands-on sessions, surgery simulations, live surgeries, etc.) and their broadcasting (whether immediate or deferred) to an audience which is not physically in attendance. A Virtual Event is delineated by the lack of Healthcare Professional ("HCP") attendees, as the only HCPs physically present at a Virtual Event are those involved in its creation, i.e. presentation. As a result, a Virtual Event will not be connected in any way with a physical Third Party Organised Educational Event. Conversely, the filming of presentations, discussions, etc. made during a Third Party Organised Educational Event ("Broadcasted Event"), and its broadcasting to audiences not present at the physically attended Event—whether contemporaneously or after the Event—do not qualify as a Virtual Event. For avoidance of doubt, Member Companies may provide financial and/ or in-kind support (e.g. Member Company products) to Virtual Events in accordance with the rules of the Chapter 2 of the Code. **Q3ter: Are Virtual Events subject to the MedTech**	

		contract terms. Additional requirements for written agreements with health care professionals serving as consultants on behalf of a Company are described in Section VI of the China Code. In addition, with respect to grants and sponsorships supporting third-party educational conferences (See Section IV of the China Code), Companies are encouraged to review their policies and internal controls against applicable laws, provisional rules, and government-issued guidance. **Q4 The AdvaMed China Code strongly encourages Companies "to ensure that interactions with individual Health Care Professionals (or to individuals units within an Institutional Health Care Professional) are appropriately disclosed to the institution or employer." How should a Company handle this requirement in those cases in which disclosure might be impractical?** Companies should develop internal controls and procedures that help to ensure that all interactions with HCPs are appropriately documented and disclosed, where necessary. This might include, for example, procedures describing situations in which institutional disclosure or approval may be necessary. There may be instances, however, where such disclosure is impractical or unnecessary (e.g., the HCP serves as the head of a public hospital). Companies are encouraged to develop internal standards for identifying and documenting such instances and should apply these standards consistently.	**Europe Conference Vetting System (CVS)? (added in June 2019)** A3ter: Virtual Events are not subject to CVS. Third Party Organised Educational Events as well as their broadcasting, falling in the scope the MedTech Europe CVS, are subject to CVS. Both Virtual and Broadcasted Third Party Organised Educational Events are subject to the rules of the MedTech Europe Code of Ethical Business Practice. **Implementation and Transition Period** This edition of the Code comes into force as follows: • PART 2: The Dispute Resolution Principles3 shall enter into force on 1 January 2016; and • The balance of the Code [i.e. Introduction, PART 1 and PART 3] shall enter into force on 1 January 2017. For the avoidance of doubt, during the transposition period 1 January 2016 to 31 December 2016, no material or activity will be regarded as being in breach of the Code if it fails to comply with its provisions only because of requirements which this edition of the Code newly introduces. **Transition Period to phase out direct support for HCP attendance at Third Party Organised Educational Events and for HCP speakers at satellite symposia** After the end of the Transition Period (see the Glossary) on 31 December 2017, Member Companies shall no longer provide financial or in kind support directly to individual Healthcare Professionals to cover costs of their attendance at Third Party Organised Educational Events with the exception of Third Party Organised Procedure Training meetings or pursuant to a consulting agreement with a Healthcare Professional speaker	

			engaged by a Member Company to speak at a satellite symposium. This means that support of individual Healthcare Professionals to attend Third Party Organised Educational Events (as provided for at Chapter 2, Section 3) shall no longer be permitted under the Code. After the Transition Period, Member Companies may provide financial or in kind support to Third Party Organised Educational Events only through Educational Grants or other types of funding in accordance with the rules of Chapter 2: Third Party Organised Educational Events and Chapter 4: Charitable Donations and Grants. **Q4: What is the difference between the Transposition period and the Transition Period as defined in the Glossary? (added in November 2016)** A4: Transposition means the process of incorporating the Code within the Member Company's own policy and procedures. This process must be completed by 1 January 2017. Transition Period means the period between 1 January 2016 and 31 December 2017 by the end of which Member Companies must have ceased all financial or in kind direct support to Healthcare Professionals to attend Third Party Organised Educational Conferences. Any exceptions to this rule are outlined in the Code **Q4-bis: How does the Code apply to members with company structures that include different business units e.g., medical devices, pharmaceuticals, research only products? How can educational grants be applied in such organizational structures? (amended in April 2018)** A4-bis: The Code applies to all Member Companies regarding their interactions linked to Medical Technologies. Ensuring compliance with the Code may be more challenging for companies with structures combining different business units, however Member Companies are required	

			to comply with the Code as a minimum standard for all interactions linked to Medical Technologies independent of their organizational set up. For example, if a member were to have Medical Devices or In Vitro Diagnostics marketed under or linked to their pharmaceutical business unit, the interactions with Healthcare Professionals and Healthcare Organisations in relation to these medical technologies would be governed by the Code irrespective of the business unit that pays for or manages the interaction. In this respect, the Member Company cannot circumvent the Code's requirements by using its pharmaceutical business/affiliate to directly support a Healthcare Professional to attend a medical technology-related Third Party Organised Educational Conference as this would amount to a violation of the Code. For the avoidance of doubt, the Code will not apply to Member Companies' interactions linked exclusively to non- Medical Technology products or services such as medicinal products or research only products, without any link to Medical Technology products. However, this does not mean that different business units can be used to circumvent Code requirements as explained above. In case an interaction or activity is linked in part to Medical Technology products, the Code shall apply	
	Glossary • **Commercial Sponsorship:** A payment or in-kind support provided to a third party in exchange for advertising or promotional opportunities for the Company (for example, a Company exhibit at a Third-Party Program). • **Company:** A company that develops, produces, manufactures, and markets Medical Technology. • **Educational Grant:** A payment or in-kind support to a third-party entity (for example, a Third-Party Program Organizer or a training institution) to reduce the costs of	4. Medical Technologies *(found in section I)* Medical Technologies are often highly dependent upon "hands on" Health Care Professional interaction from beginning to end—unlike drugs and biologics, which act on the human body by pharmacological, immunological or metabolic means. For example, implantable Medical Technologies are often placed in the human body to replace or strengthen a body part. Surgical Medical Technologies often serve as extensions of a physician's hands. In other circumstances, Medical Technologies are noninvasive reagents, instrumentation and/or software to aid in the diagnosis, monitoring and treatment decisions made by Health Care Professionals. Some Medical Technologies work synergistically with other	Glossary and Definitions **Charitable Donations:** means provision of cash, equipment, company product or relevant Third Party product, for exclusive use for charitable or philanthropic purposes and/or to benefit a charitable or philanthropic cause. Charitable Donations may only be made on an unrestricted basis and to bona fide charities or other non-profit entities or bodies whose main objects are genuine charitable or philanthropic purposes. **Company Events:** means activities of any type that are planned, budgeted, managed and executed in whole or in part by or on behalf of Member Companies to fulfil a legitimate, documented business need of the Member	***Terms Defined in Footnotes:*** **Third Party Educational Event** is a conference or meeting that is of a medical, scientific, and/or educational nature, intended to promote scientific knowledge, medical advancement, and/or the delivery of effective health care, and organized by a Professional Association, Health Care Institution, or by a bona fide medical or other professional education provider. **Health Care Institution** is a body or legal entity that is a health care, medical, or scientific organization which may have direct or indirect influence on the purchase or acquisition of medical technology.

	providing education. An Educational Grant is not offered for Commercial Sponsorship opportunities. • **Health Care Professionals or HCPs:** A Health Care Professional is any person or entity (a) authorized or licensed in the United States 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 the United States. 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 (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. For purposes of the AdvaMed Code, a "Health Care Professional" is not necessarily limited to a licensed clinician. Whether an individual qualifies as a Health Care Professional may vary based on the facts and circumstances. • **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;	technologies, or are paired with other products that deploy devices in the safest and most effective manner. Many Medical Technologies require technical support during and after deployment.	Company, including but not limited to a legitimate business need to interact with customers including Healthcare Professionals and/or Healthcare Organisations. **Conference Vetting System (CVS):** means the centralised decision-making process which reviews the compliance of Third Party Organised Educational Events with the Code and which is managed independently of MedTech Europe under the supervision of the MedTech Europe Compliance Panel. For more information see: http://www.ethicalmedtech.eu. **Code:** means this MedTech Europe Code of Ethical Business Practice (including the incorporated Questions and Answers), the Disclosure Guidelines, the Procedural Framework and the Dispute Resolution Principles. For the avoidance of doubt the Dispute Resolution Principles shall be replaced by the Procedural Framework and shall cease to have effect once the MedTech Europe Board approves the Procedural Framework. **Disclosure Guidelines:** means the Code provisions setting out the public disclosure requirements under the Code. **Demonstration Products (Demos):** means either single-use or multiple-use products provided free of charge by or on behalf of a Member Company to HCOs or HCPs, who are equipped and qualified to use them. Demos are supplied solely for the purpose of demonstrating safe and effective use and appropriate functionality of a product and are not intended for clinical use. Demos do not include the following: • Samples; • Evaluation Products; • Products provided at no charge as part of a Charitable Donation or as part of a Research or Educational Grant; or	**Professional Association** is a regional, national, or specialty clinical or other professional body representing HCPs.

	○ 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, but may differ depending on regional differences. • **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.		• Products provided at no additional charge as part of the overall purchase price in a commercial supply arrangement, e.g. as part of an agreed discount arrangement, or as substitute products provided pursuant to a warranty agreement. **Educational Grants:** means provision of funding, Member Company or third party products or other in kind support to a Healthcare Organisation by or on behalf of a Member Company on a restricted basis for use solely for the support and the advancement of genuine medical education of Healthcare Professionals, patients and/or the public on clinical, scientific and/or healthcare topics relevant to the therapeutic areas in which the Member Company is interested and/or involved. **Employer Notification:** means the prior written notification provided to a Healthcare Organisation (e.g. hospital administration), a Healthcare Professional's superior or other locally-designated competent authority of any interaction, collaboration or other matter concerning any Member Company and any Healthcare Professional, the purpose and/or scope of which requires notification under this Code. **Entertainment:** Entertainment includes, but is not limited to, dancing or arrangements where live music is the main attraction, sight-seeing trips, theatre excursions, sporting events (e.g. skiing, golf or football match) and other leisure arrangements. For the avoidance of doubt, incidental, background music shall not constitute Entertainment. **Evaluation Products:** means either single-use or multiple-use products and/or equipment provided free of charge to a healthcare institution by or on behalf of a Member Company for purposes of obtaining defined, evaluative user feedback over a defined period of use when used	

	• **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, and association, medical trust fund, continuing medical education provider, or hospital or other health care entity. The AdvaMed Code's history spans several decades. The Code originally appeared as the Health Industry Manufacturers Association Code in 1993. It was later updated and relaunched as the AdvaMed Code in 2003. The last revision and restatement of the Code became effective in 2009. This version of the AdvaMed Code of Ethics on Interactions with Health Care Professionals in the United States, upon its effective date, supersedes and replaces all previous versions of the AdvaMed Code.		within the scope of their intended purpose, as per the authorisation in the country where the supply occurs. Evaluation Products do not include the following: • Demos; • Samples; • Products provided at no charge as part of a Charitable Donation or as part of a Research or Educational Grant; or • Products provided at no additional charge as part of the overall purchase price in a commercial supply arrangement, e.g. as part of an agreed discount arrangement, or as substitute products provided pursuant to a warranty agreement. **Event:** means either a Company Event or Third Party Organised Educational Event. **Faculty:** means a podium speaker, moderator and/or chair, who presents during a Third Party Organised Educational Event. Poster- and abstract-presenters are not considered to be Faculty. **Financial Hardship:** means in relation to a Healthcare Organisation extreme and unavoidable financial distress resulting from matters outside the Healthcare Organisation's control where the Healthcare Organisation is unable to operate and where patient care is consequently jeopardised. Financial distress resulting in whole or in part from mismanagement of the Healthcare Organisation's funds or other matters within its control is not considered to be financial hardship. Financial Hardship must be documented and objectively substantiated. **Grants:** means either an Educational Grant or a Research Grant, or both.	

			Guests: means spouses, partners, family or guests of Healthcare Professionals, or any other person who does not have a bona fide professional interest in the information being shared at an Event. **Healthcare Organisation (HCO):** means any legal entity or body (irrespective of its legal or organisational form) that is a healthcare, medical or scientific association or organisation which may have a direct or indirect influence on the prescription, recommendation, purchase, order, supply, utilisation, sale or lease of medical technologies or related services such as a hospital or group purchasing organisation, clinic, laboratory, pharmacy, research institution, foundation, university or other teaching institution or learned or professional society (except for patient organisations); or through which one or more Healthcare Professionals provide services. **Healthcare Professional (HCP):** means any individual (with a clinical or non-clinical role; whether a government official, or employee or representative of a government agency or other public or private sector organisation; including but not limited to, physicians, nurses, technicians, laboratory scientists, researchers, research co-ordinators or procurement professionals) that in the course of their professional activities may directly or indirectly purchase, lease, recommend, administer, use, supply, procure or determine the purchase or lease of, or who may prescribe medical technologies or related services. **Members:** means all full and associate corporate members ("Member Companies") of Eucomed and/or EDMA (or as applicable MedTech Europe) as well as full and associate national association members of Eucomed and/or EDMA (or as applicable MedTech Europe) ("Member Associations"), as defined in the respective Eucomed, EDMA or MedTech Europe statutes, as applicable and as amended from time to time.	

			Professional Conference Organiser (PCO): a for-profit company or organisation which specialises in the management of congresses, conferences, seminars and similar events. **Product and Procedure Training and Education Event:** means a type of Company Event that is primarily intended to provide Healthcare Professionals with genuine education, including information and/or training on: • The safe and effective use of medical technologies, therapies and/or related services, and/or • The safe and effective performance of clinical procedures, and/or • Related disease areas. In all cases the information and/or training directly concern a Member Company's medical technologies, therapies and/or related services. **Research Grants:** means the provision by or on behalf of a Member Company of funding, products/equipment and/or in kind services to any organisation that conducts research which is made for the sole, restrictive purpose of supporting the development or furtherance of bona fide, scientifically valid and legitimate research by the recipient the purpose of which is to advance medical, scientific and healthcare knowledge, medical technologies and/or clinical techniques designed to improve patient outcomes. **Sales, Promotional and Other Business Meetings:** means any type of Company Event the objective of which is to effect the sale and/or promotion of a Members Company's medical technologies and/or related services, including meetings to discuss product features, benefits and use and/or commercial terms of supply.	

			Samples: means single-use or multiple-use products provided free of charge by or on behalf of a Member Company to HCOs or HCPs who are equipped and qualified to use them in order to enable HCPs to familiarise themselves with the products in clinical use. Samples do not include the following: • Demos; • Evaluation Products; • products provided at no charge as part of a Charitable Donation or as part of a Research or Educational Grant; or • products provided at no additional charge as part of the overall purchase price in a commercial supply arrangement, e.g. as part of an agreed discount arrangement, or as substitute products provided pursuant to a warranty agreement. **Scholarships and Fellowships:** means Educational Grants provided to a Healthcare Organisation by or on behalf of a Member Company to support fellowships or scholarships offered by the Healthcare Organisation. Scholarships in this context means an Educational Grant provided to support a medical school undergraduate whereas a fellowship is a period of intensive training for post-graduate physicians in a chosen clinical sub-specialty (e.g. medical training after a residency). "Scholars" and "Fellows" shall be understood accordingly. **Third Party Organised Educational Events:** means activities of any type that are planned, budgeted, managed and executed in whole or in part by or on behalf of a person or entity other than a Member Company to fulfil Healthcare Professional medical educational needs. **Third Party Organised Educational Conferences:** means a type of Third Party Organised Educational Event that is a genuine, independent,	

			educational, scientific, or policy-making conference organised to promote scientific knowledge, medical advancement and/or the delivery of effective healthcare and are consistent with relevant guidelines established by professional societies or organisations for such educational meetings. These typically include conferences organised by national, regional, or specialty medical associations / societies, hospitals, Professional Conference Organisers (PCOs), patients organisations or accredited continuing medical education providers. **Third Party Organised Procedure Training:** means a type of Third Party Organised Educational Event that is primarily intended to provide Healthcare Professionals with information and training on the safe and effective performance of one or more clinical procedures in circumstances where the information and training concern: • Specific therapeutic, diagnostic or rehabilitative procedures, namely clinical courses of action, methods or techniques (rather than the use of medical technologies); and • Practical demonstrations and/or training for HCPs, where the majority of the training programme is delivered in a clinical environment. • For the avoidance of doubt, proctorship and preceptorship are not considered to constitute Third Party Organised Procedure Training. **Transition Period:** means the period from 1 January 2016 up to and including 31 December 2017, following which Member Companies shall no longer provide financial or in kind support direct to Healthcare Professionals to cover costs of their attendance at Third Party Organised Educational Events with the exception of Third Party Organised Procedure Training meetings or	

			pursuant to a consulting agreement with a Healthcare Professional speaker engaged by a Member Company to speak at a satellite symposium.	
Consulting Arrangements with Health Care Professionals	**Section II – Consulting Arrangements with Health Care Professionals** **Key Concepts:** ✓ Companies rely on Health Care Professionals' expertise in a variety of important ways, such as training on the safe and effective use of Medical Technology, conducting research, and developing product advancements that lead to safer and more effective treatments for patients. ✓ Based on legitimate need, Companies engage Health Care Professionals through written contracts that document the Health Care Professional's services and any fair market value compensation for those services. ✓	**VI. Consulting Arrangements with Health Care Professionals** 1. Companies engage Health Care Professionals to provide a wide-range of valuable, bona fide consulting services through various types of arrangements, such as contracts for research, product development, development and/or transfer of intellectual property, participation on advisory boards, presentations at Company-sponsored training and other services. Companies may pay consultants fair market value compensation for performing these types of services, provided that they are intended to fulfill a legitimate business need and do not constitute an unlawful inducement.	**Chapter 5: Arrangements with Consultants** **1. General Principles** Member Companies may engage Healthcare Professionals as consultants and advisors to provide bona fide consulting and other services, including but not limited to research, participation on advisory boards, presentations at Company Events and product development. Member Companies may pay Healthcare Professionals reasonable remuneration for performing these services. In all cases, consulting arrangements must be permitted under the laws and regulations of the country where the Healthcare Professional is licensed to practise and be consistent with applicable professional codes of conduct in that country. The principles in this chapter are applicable to all consulting arrangements between Healthcare Professionals and Member Companies including where a consultant Healthcare Professional declines a fee for provision of their services. Consulting arrangements shall not be contingent in any way on the prospective consultant's past, present or potential future purchase, lease, recommendation, prescription, use, supply or procurement of the Member Company's products or services. When selecting consultants, Member Companies shall implement an independent decision-making /review process to identify, prevent and mitigate against potential bribery and corruption risks arising in connection with use of consultants. This process shall include a documented, prior evaluation of any such associated risks and of the relevant background information concerning each prospective consultant.	**2. Consultancy agreements** Members may engage HCPs to provide *bona fide* services to the Member or on behalf of the Member, examples of which include clinical research, research and development, participation on advisory boards, and training and education of other HCPs on the safe and effective use of the Member's products and services or associated procedures. The selection of HCPs shall be based on relevant expertise, and shall not be used to induce a HCP to use, recommend, purchase, or prescribe the Member's products and services. HCPs shall be compensated at not more than fair market value for the services provided in the jurisdiction in which the HCP regularly conducts its practice, irrespective of where the consulting service takes place. Any expenses paid or benefits provided to a HCP shall be reasonable and appropriately documented in a written consultancy agreement specifying all services to be provided under the engagement.

	A. <u>Engaging a Health Care Professional to Provide Consulting Services</u> 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, proctoring and preceptorships, 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.** A Company should enter a consulting arrangement with a Health Care Professional only if it has identified a **legitimate need** for the Health Care Professional's services in advance. A **legitimate need** arises when a Company requires the services of a Health Care Professional to achieve a specific objective, such as the need to train Health Care Professionals on the technical components of safely and effectively using a product; the need for clinical expertise in conducting product research and development; or the need for a physician's expert judgment on clinical issues associated with a product. Designing or creating an arrangement to generate business or to reward referrals from the contracted Health Care Professional (or anyone affiliated with the Health Care Professional) are not legitimate needs for a consulting arrangement.	Companies should comply with the following standards in connection with consulting arrangements with Health Care Professionals: A. Consulting agreements should be written and describe all services to be provided When a Company contracts with a consultant to conduct clinical research services, there should also be a written research protocol. B. Consulting arrangements should be entered into only where a legitimate need for the services is identified in advance and documented. C. Selection of a consultant should be made on the basis of the consultant's qualifications and expertise to meet the defined need. D. Compensation paid to a consultant should be consistent with fair market value in an arm's length transaction for the services provided and should not be based on the volume or value of the consultant's past, present or anticipated business. E. Compensation paid to a consultant should not be paid in cash. F. A Company may pay for documented, reasonable and actual expenses incurred by a consultant that are necessary to carry out the consulting arrangement, such as reasonable costs for travel, lodging, local transportation and modest meals. G. The venue and circumstances for Company meetings with consultants should be appropriate to the subject matter of the consultation. These meetings should be conducted in clinical, educational, conference, or other settings, including hotel or other commercially available meeting facilities,	**2. Criteria for genuine consulting arrangements** In addition to the general principles above, the arrangements which cover genuine consultancy or other services must, to the extent relevant to the particular arrangement, fulfil all the following criteria: a. Consulting arrangements must be entered into only where a legitimate business need for the services is identified in advance. b. The number of consultants retained must not be greater than the number reasonably necessary to achieve the identified need. c. Selection of consultants must be based on criteria directly related to the identified business need and the relevance of the consultant's qualifications, expertise and experience to address the identified need. The volume or value of business generated by a prospective consultant or the Healthcare Organisation where s/he performs her/his professional activity is not a relevant criterion d. Consulting arrangements with Healthcare Professionals must be documented in a written agreement, signed by the parties in advance of the commencement of the services, which must specify the nature of the services to be provided and the basis for payment for those services. e. The hiring of the consultant must not be an inducement to purchase, lease, recommend, prescribe, use, supply or procure the Member Company's products or services. f. The remuneration for the services rendered must be reasonable and reflect the fair market value of the services provided. g. Member Companies must maintain records of the services, and associated work products, provided by the consultant	

	• **Consultant Selection.** A Company 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. A Company may not select or compensate consultants as a reward for past usage or as an unlawful inducement for future purchases. A Company should implement safeguards so that consultants are not selected based in whole or in part on sales considerations. • **Number of Consultants.** A Company should engage only as many consultants as are necessary to fulfill the Company's requirements for the bona fide services. • **Fair Market Value Compensation.** A Company should compensate a consultant consistent with the fair market value in an arm's length transaction of the services provided. A Company should not base compensation on the volume or value of the consultant's past, present or anticipated business. A Company should confirm the services performed by the Health Care Professional in accordance with the agreement. • **Expenses.** A Company may pay for documented, reasonable, and actual expenses incurred by a consultant that are necessary to carry out the consulting arrangement, such as costs for travel, lodging, and modest meals. See Sections VI	conducive to the effective exchange of information. H. Company-sponsored meals and refreshments provided in conjunction with a consultant meeting should be modest in value and should be subordinate in time and focus to the primary purpose of the meeting. Companies should not provide recreation or entertainment in conjunction with these meetings. I. A Company's sales personnel may provide input about the suitability of a proposed consultant, but sales personnel should not control or unduly influence the decision to engage a particular Health Care Professional as a consultant. Companies should consider implementing appropriate procedures to monitor compliance with this section.	Healthcare Professionals and of the use made of those services by the Member Company. h. The venue and other arrangements (e.g. hospitality, travel etc.) for Member Company meetings with consultants shall follow the rules for Events set out in Chapter 1: General Criteria for Events. **3. Remuneration and Fair Market Value** The remuneration paid to Healthcare Professionals engaged as consultants by Member Companies shall reflect fair-market-value for the services provided. It shall not be in any way contingent upon the value of products or services which consultants may purchase, lease, recommend, prescribe, use, supply or procure in the course of their own professional practice or that may be purchased, leased, recommended, prescribed, used, supplied or procured by HCOs where they carry on their professional activities. All payments made for services must comply with all applicable tax and other legal requirements. Member Companies may pay for expenses reasonably incurred by consultants in providing the services which are the subject of the consulting agreement including reasonable travel, meals and accommodation expenses incurred by consultants if attending meetings with, or on behalf of Member Companies. The written consulting agreement must detail which expenses can be claimed by the consultant in relation to the provision of the services and the basis for payment of these by the Member Company. **Q44 What is meant by fair market value (FMV) in the context of consulting arrangements?** A44 Fair-market-value is the value of the specified consultancy services which would be paid by the Member Company to the consultant, each dealing at arm's length in an open and unrestricted market, and when neither party is	

	and VII of the Code for information on providing travel, lodging, and meals to Health Care Professionals. • **Written Agreement.** A Company should enter into written agreements that describe all consulting services to be provided and the compensation to be paid in exchange for the services. 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. A Company's sales personnel may provide input about the qualifications of a proposed consultant. A Company should consider implementing appropriate controls to promote compliance with this section. **Q1b – When determining whether a Health Care Professional is qualified to serve as a consultant, is it appropriate to consider the Health Care Professional's subjective abilities, for example his or her recognition as an expert or thought leader on the specific topic?** Yes. There is no single appropriate method of evaluating a Health Care Professional's qualifications to serve as a consultant. A Company may take into account objective factors, such as number of years of practice, familiarity with the Company's products, educational and training background, or geographic location, among others. A Company may also take into account subjective factors, such as recognition as a thought leader or the ability to effectively deliver training content. A Company may weigh these factors differently in making consultant selections, depending upon the type of consultant the Company needs and the type of services to be delivered. For example, a Company may consider educational		under any compulsion to buy or sell, and both parties have reasonable knowledge of the relevant facts. **Q45 How should Member Companies determine FMV for a service?** A45 A Member Company must be able to demonstrate internal methodology to determine fair market value. Amongst other matters this shall take account of the consultant's qualifications, expertise and experience as well as the actual services to be provided to the Member Company **4. Disclosure and Transparency** Member Companies shall ensure they fully comply with all applicable national laws, regulations and professional codes of conduct requiring any publication, disclosure or approval in connection with the use by Member Companies of Healthcare Professionals as consultants. All required consents and approvals shall be obtained, including from the hospital or other Healthcare Organisation administration or from the Healthcare Professional's superior (or locally-designated competent authority), as applicable. Where no such national requirements apply, Member Companies shall nevertheless maintain appropriate transparency by requiring the relevant Employer Notification which shall disclose the purpose and scope of the consultancy arrangement. Member Companies shall also include appropriate obligations on the consultant to ensure that the consultant's status as a consultant for the Member Company and his/her involvement in the research for, or the preparation of, material for scientific publication is disclosed at the time of any publication or presentation.	

	background and clinical experience to be important factors when engaging an HCP to perform clinical research. Or, a Company may consider recognition as a thought leader as a critical factor for some types of HCP consulting services. **Q2 – How can a Company establish "fair market value" for goods or services?** There are different valuation methods that may be used to establish fair market value. For example, many third-party vendors or other experts can assist a Company in developing an approach to assessing fair market value compensation. In all instances, a Company should use a method that incorporates objective criteria – for example, a Health Care Professional's specialty, years and type of experience, geographic location, practice setting, the type of services performed, etc. A Company is encouraged to document its method(s) for evaluating whether compensation reflects the fair market value of the services provided. **Q3 – Why does the AdvaMed Code restrict the involvement of sales in selecting consultants?** The Code requires this separation to avoid the perception that a Company has entered a contract with a Health Care Professional to secure or reward the Health Care Professional for purchasing, using, or recommending the Company's Medical Technology or other sales considerations. **Q4 – What should Companies know about Health Care Professionals' potential conflicts of interest?** Health Care Professionals' interactions with Companies may potentially create conflicts of interest. For example, in addition to his/her industry interactions, a physician could also hold a leadership role in a medical society,			

	serve as a conference planning chair, or act as a medical journal editor. A physician's professional interest in advancing objective, clinical information may compete with his or her industry relationship. Companies should be aware that Health Care Professionals may have these conflicts. Companies should also be mindful of steps that may need to be taken to address these conflicts, including, for example, recusal from decisions that implicate the conflict.			
	B. <u>Royalties</u> Arrangements involving the payment of royalties to a Health Care Professional 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. A Company 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 product, technology, 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. A Company should base the calculation of royalties payable to a Health Care Professional in exchange for Intellectual Property on factors that preserve the objectivity 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 purchase, order or	2. **Provisions on Payment of Royalties.** Arrangements involving the payment of royalties to a Health Care Professional should meet the contractual standards set forth above. Health Care Professionals, acting individually or as part of a group in which they are an active participant, often make valuable contributions that improve products or Medical Technologies. They may develop intellectual property, for example, patents, trade secrets, or know-how, under a product or technology development or intellectual property licensing agreement. A. A Company should enter into a royalty arrangement with a Health Care Professional only where the Health Care Professional is expected to make or has made a novel, significant, or innovative contribution to, for example, the development of a product, technology, process, or method. A significant contribution by an individual or group, if it is the basis for compensation, should be appropriately documented. B. The calculation of royalties payable to a Health Care Professional in exchange for Intellectual Property should be based on factors that preserve the objectivity of medical decision-making and avoid the potential for improper influence. For example, royalties paid in exchange for Intellectual Property should not be conditioned on: (1) a requirement that the Health Care Professional purchase, order or	**Chapter 7: Royalties** Healthcare Professionals, acting individually or as part of a group in which they are an active participant, 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. A royalty arrangement between a Member Company and a Healthcare Professional should be entered into only where the Healthcare Professional is expected to make or has made a novel, significant, or innovative contribution to, for example, the development of a product, technology, process, or method, such that the Healthcare Professional would be considered to be the sole or joint owner of such intellectual property under applicable laws and regulations. The foregoing is without prejudice to Member Companies' obligations to comply with any applicable obligations to pay royalties which may arise under applicable laws and regulations in some countries. Arrangements involving the payment of royalties by or on behalf of Member Companies to a Healthcare Professional must be set out in a written agreement providing appropriate and reasonable remuneration in accordance with applicable laws and regulations. For example, royalties paid in exchange for intellectual property should not be conditional on:	

	recommend any product or Medical Technology of the Company or any product or technology produced as a result of the development project; or (2) a requirement to market the product or 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 Health Care Professional and/or members of the Health Care Professional's practice.	recommend any product or medical technology of the Company or any product or technology produced as a result of the development project; or (2) a requirement to market the product or medical technology upon commercialization. Companies are strongly encouraged to consider whether it is appropriate and practicable to exclude from the calculation of royalties the number of units purchased, used, or ordered by the Health Care Professional and/or members of the Health Care Professional's practice	• A requirement that the Healthcare Professional purchase, order or recommend any product, services or medical technology of the Member Company or any product or technology produced as a result of the development project; or • A requirement to market the product or medical technology upon commercialisation. Subject to national regulations and requirements, Member Companies should exclude from the calculation of royalties the number of units purchased, prescribed, used, or ordered by the Healthcare Professional and/or members of the Healthcare Professional's practice or Healthcare Organisation.	
	C. <u>Clinical Studies & Research Agreements</u> 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. 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, it may be appropriate to enter a separate consulting arrangement with that		**Chapter 6: Research** **1. Member Company-Initiated Research** Where there is a legitimate business need to do so, Member Companies may initiate, conduct, manage and finance scientifically valid research to generate data, whether pre- or post-market. In this context, legitimate business needs for data include medical needs, including patient safety; research and development; scientific purposes (e.g. performance indicators, comparing objective scientific parameters); regulatory, including post-market surveillance (PMS) and post-market clinical follow up (PMCF), vigilance, safety, or reimbursement and health economic, including clinical and cost-effectiveness and outcomes data relevant to health technology assessments (HTA) and reimbursement decision-making. Where a Member Company uses a Healthcare Professional as a consultant, for example to lead a study on the Member Company's behalf (i.e. act as Principal Investigator), the Member Company shall ensure that such consulting arrangements comply fully with Chapter 5: Arrangements with Consultants.	

	individual Health Care Professional.		In accordance with the Documentation Principle, any arrangements made by a Member Company to procure research-related services shall be set out in a written agreement which shall reference a written research protocol; written schedule of work and provide for all required consents, approvals and authorisations to be obtained prior to the commencement of the study. Member Companies must ensure that their research activities comply with all applicable national laws, regulations and researchers' own professional codes of conduct, as well as with applicable Good Clinical Practice guidelines, if relevant. In accordance with the Principles set out in the Introduction: Aims and Principles of the Code, Member Companies shall also ensure appropriate clinical trial transparency in relation to their research activities and results. This shall include appropriate disclosure of information about Member Companies' clinical trials, for example in external public registries and peer-reviewed journals. Where Member Companies engage third party intermediaries for research (e.g. contract research organisations (CROs)), they shall ensure that the research conducted by these third parties on behalf of the Member Company is carried out in accordance with all applicable legal and ethical requirements, including the applicable requirements of the Code. **Q46 What is an example of an external public registry for clinical trial transparency?** A46 Examples of an external public register for clinical trial transparency are www.clinicaltrials.gov or www.who.org **2. Member Company Post-Market Product Evaluation** Where there is a legitimate business need to do	

			so, Member Companies may initiate, post-market third party evaluation of their products, therapies and/or related services and may therefore provide Evaluation Products under a written contract for services in order to obtain defined user evaluation by Healthcare Organisations in relation to the Evaluation Products. Evaluation Products may be provided on a no charge basis in return for the requested user feedback from Healthcare Professionals at the Healthcare Organisation, which shall be formally described in a written protocol or questionnaire forming part of the contract. Where the Evaluation Products are multiple-use Evaluation Products the defined period of time necessary for the evaluation and feedback to occur will depend on the frequency of anticipated use; the nature of the user evaluation feedback requested; the duration of any required training and similar considerations. Member Companies shall in all cases ensure that they retain title to multiple-use Evaluation Products and that they have a process in place for promptly removing such multiple use Evaluation Products and/or any unused single-use Evaluation Products from the Healthcare Organisation's location at the conclusion of the evaluation period unless these are purchased by the Healthcare Organisation. Provision of Evaluation Products and/or related services must not improperly reward, induce and/or encourage Healthcare Professionals and/or Healthcare Organisations to purchase, lease, recommend, prescribe, use, supply or procure Member Companies' products or services. Any offer and/or supply of Evaluation Products shall always be done in full compliance with applicable national laws, regulations and industry and professional codes of conduct. **3. Third Party-Initiated Research** Please refer to Chapter 4: Charitable Donations and Grants: Research Grants.	

Company-Conducted Programs & Meetings With Health Care Professionals	**Section III – Company-Conducted Programs & Meetings with Health Care Professionals** **Key Concepts:** ✓ Companies have a legitimate need to provide important training and education to Health Care Professionals about the safe, effective, and efficient use of Medical Technologies. ✓ Companies may also have a legitimate need to conduct other business meetings with Health Care Professionals (for example, a manufacturing facility tour, a product development meeting, or meetings to discuss service offerings or sales terms). ✓ All Company-conducted programs and meetings with Health Care Professionals should be conducted in a manner conducive to the exchange of information, and all attendees must have a legitimate need to attend the program or meeting. 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. This section of the Code provides Companies with guidelines for organizing and conducting these meetings and programs. This section of the Code applies to Company-conducted training, education, or other business meetings. For a discussion of programs or meetings conducted by a third party (for example, thirdparty educational conferences), see Section IV of the Code.		**Chapter 1: General Criteria for Events** Member Companies may invite Healthcare Professionals to Company Events and Third Party Organised Educational Events. The principles and criteria set out in this Chapter 1 shall apply to all such Events supported in any way by Member Companies, irrespective of who organises the Event. **1. Event Programme** The Event programme should directly relate to the specialty and/or medical practice of the Healthcare Professionals who will attend the Event or be sufficiently relevant to justify the attendance of the Healthcare Professionals. For Third Party Organised Educational Events, the agenda should be under the sole control and responsibility of the third party organiser. A Member Company shall not organise Events which include social, sporting and/or leisure activities or other forms of Entertainment, nor support such elements where part of Third Party Organised Educational Events. For Third Party Organised Educational Events, Entertainment must be outside of the educational programme schedule and paid for separately by the Healthcare Professionals. Entertainment should not dominate or interfere with the overall scientific content of the programme and must be held during times that do not overlap with a scientific session. The Entertainment should not be the main attraction of the Third Party Organised Educational Event. **Q5: What is meant by "legitimate" or "genuine" as used in the definitions of 'Company Event' and 'Third Party Organised Educational Conferences'?** A5: Any Event should be relevant to the Healthcare Professional attendees; the detailed programme should be available sufficient time prior to the Event; present a clear schedule with	

			no gaps during the sessions, (e.g., the minimum duration for a full day Event should be 6 hours or 3 hours for a half day Event including refreshment breaks). If it is a Third Party Organised Educational Event the Faculty must be identified. It is also important that all supporting materials (e.g. flyers, brochures and website) are consistent with the scientific or promotional nature of the programme content, as the case may be. **3 Guests** Member Companies are not permitted to facilitate or pay for meals, travel, accommodation or other expenses for Guests of Healthcare Professionals, or for any other person who does not have a bona fide professional interest in the information being shared at the Event. **Q9: What does the term "facilitate" mean where used in connection with the Guest expenses?** A9: The term "facilitate" refers to the prior arrangement, organisation or booking of meals, travel or accommodation by or on behalf of a Member Company on behalf of the Guest of a Healthcare Professional participant. Such organisation or booking is not permitted unless the individual qualifies as a participant in his/her own right, irrespective of who pays. Such actions are open to misinterpretation. If Healthcare Professionals attending the Event wish to be accompanied by a Guest who does not have a professional interest in the information being shared, the Healthcare Professional must take sole responsibility for the payment and organisation of the Guest's expenses. **Q10: In the event that a Healthcare Professional is accompanied by a Guest at the Event, may this Guest be admitted to any Company Event, or Third Party Organised Educational Events?** A10: It is not appropriate for a Guest of a Healthcare Professional to attend either	

			Company Events (including Satellite Symposia) or Third Party Organised Educational Events (unless the individual qualifies as a participant in their own right), nor is it appropriate, in the interest of maintaining the scientific exchange, for a Guest to participate in related hospitality during such Events (for example, lunches and coffee breaks) even when the Healthcare Professional pays for the Guest's expenses. Member Companies, however, may financially support Third Party Organised Educational Events which offer extra-curricular programmes/ activities beyond the scientific, educational or training sessions for Guests of Healthcare Professionals (such as touristic activities and hospitality), always provided that such an extra-curricular programme/activity (including attendance of the conference dinner or a cocktail reception) is subject to a separate charge which must not be paid for, facilitated or reimbursed by, a Member Company **6. Transparency** Member Companies must ensure full compliance with national laws with regard to the disclosure or approval requirements associated with such financial support and where no such requirements are prescribed, shall nevertheless maintain appropriate transparency, as a minimum, by requiring Employer Notification (as defined in the Glossary) is made prior to the Event.	
	A. <u>Company-Conducted Training & Education</u> 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 related information: ✓ Medical Technology may involve complex equipment, devices, and/or sophisticated software platforms that require technical instruction.	**III. Company-Conducted Product Training and Education** 1. Companies have a responsibility to make training and education on their products and Medical Technologies available to Health Care Professionals. "Training" means training on the safe and effective use of Medical Technologies. "Education" means communicating information directly concerning or associated with the use of Companies' Medical Technologies, e.g.,	**Chapter 3: Company Events** **1. General Principles** Member Companies may invite Healthcare Professionals to Company Events. Such events include, as defined in the Glossary: • Product and Procedure Training and Education Events • Sales, Promotional and Other Business	

	✓ 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. In fact, the U.S. Food and Drug Administration (FDA) often mandates this training and education. 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 settings that are conducive to the effective transmission of information. These may include clinical, educational, conference, or other settings, such as hotels or other commercially available meeting facilities. 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	information about disease states and the benefits of Medical Technologies to certain patient populations. 2. Training and Education programs include, but are not limited to, "hands on" training sessions, cadaver workshops, lectures and presentations. In fact, many medical device regulatory agencies encourage – or even mandate – companies to conduct training and education to facilitate the safe and effective use of certain Medical Technologies. 3. Companies should adhere to the following principles when conducting training and education programs concerning Medical Technologies for Health Care Professionals: A. Programs and events should be conducted in settings that are conducive to the effective transmission of information. These may include clinical, educational, conference, or other settings, such as hotels or other commercially available meeting facilities. In some cases, it may be appropriate for a Company representative to provide training and education at the Health Care Professional's location and/or to deliver training in cooperation with an institutional Health Care Professional. B. Programs providing "hands on" training on Medical Technologies should be held at training facilities, medical institutions, laboratories, or other appropriate facilities. The training staff used by the Company should have the proper qualifications and expertise to conduct such training. Training staff may include qualified field sales employees who have the technical expertise necessary to perform the training. C. Companies may provide Health Care Professional attendees with modest meals and refreshments in connection	Meetings Company Events should comply with the principles mentioned in Chapter 1: General Criteria for Events. Where there is a legitimate business purpose, Company Events may include or take place in Member Company's manufacturing plant or Healthcare Organisations, used by the Member Company as reference centres. **Q22 Is it appropriate for Member Companies to invite Healthcare Professionals on company plant or factory tours where the Healthcare Professionals reside outside the country of location of the plant or factory?** A22 Yes, it is appropriate for Member Companies to invite Healthcare Professionals to plant or factory tours in countries outside their country of residence if there is a legitimate business purpose and the tour complies with the Code in all respects **2. Product and Procedure Training and Education Events** Where appropriate, in order to facilitate the safe and effective use of medical technologies, therapies and/or services, Member Companies should make product and procedure training and education available to relevant Healthcare Professionals. Member Companies shall ensure that personnel conducting the Product and Procedure Training and Education Events have the appropriate expertise to conduct such training. **Q23 Can Member Companies directly support travel and/or accommodation or other expenses of individual Healthcare Professionals for attendance as delegates at Company Organised Events, happening during or around a Third-Party Organised Educational Event? (Amended**	

	have the technical expertise and experience necessary to perform the training. See Section II of the AdvaMed Code for guidelines on engaging Health Care Professionals to provide consulting services on behalf of a Company, such as **serving as faculty** at a Company conducted training and education program. • **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.	with these programs. Any such meals and refreshments should be modest in value and subordinate in time and focus to the training and/or educational purpose of the meeting. D. Where there are objective reasons to support the need for out-of-town travel to efficiently deliver Training and Education on Medical Technologies, Companies may pay for reasonable travel and modest lodging costs of the attending Health Care Professionals. It is not appropriate for Companies to pay for the meals, refreshments, travel, or other expenses for guests of Health Care Professionals or for any other person who does not have a bona fide professional interest in the information being shared at the meeting.	**in November 2018)** A23: No, as of 1 January 2018, Member Companies cannot directly support travel and/or accommodation or other expenses of individual Healthcare Professionals participating as delegates in Company Organised Events which take place during, around, or at the same time and in the same approximate location as a Third-Party Organised Event. However, company Organised Events—including fee-for-service arrangements like Advisory Boards and Clinical Investigator meetings—may be organised at or around a Third Party Organised Educational Event for reasons of convenience and efficiency, given the attendance of Healthcare Professionals at that Third-Party Organised Educational Event. If such an event overlap occurs, the Member Company may only pay for the contractual remuneration and expenses agreed for the provision of the services by the Healthcare Professional at the Company Organised Education Event itself. Under no circumstances may a Member Company pay for incremental costs relating to the Healthcare Professional's attendance at the Third Party Organised Educational Event, such as registration costs, hospitality, additional travel or accommodation. Member Companies may provide flexibility in the Healthcare Professionals' travel arrangements—provided there is no additional or incremental cost involved (i.e. registration, hospitality, additional accommodation or travel). Moreover, the Healthcare Professionals must have an active role at such a Company Organized Event, rather than being mere passive attendees. [E.g. no support shall be provided by Member Companies to Healthcare Professionals attending a Company Organised Educational Event as a delegate or trainee where this is organised at or around a Third Party Organised Educational Event.] Specific examples of support which can and cannot be provided could include the following:	

			• For an advisory board or a clinical investigator meeting organized at or around a Third-Party Organised Educational Event: ▫ the registration fee of the Healthcare Professional to the Third-Party Organised Educational Event shall in no circumstances be covered by the Member Companies - as this would not be related to the services to be provided. ▫ the flight and accommodation costs can be covered pursuant to the services provided, with the flexibility caveat noted above. • For a satellite symposium or a booth speaker engagement taking place during the Third-Party Organised Educational Event (i.e. as part of that Third-Party Organised Educational Event): ▫ the Healthcare Professional's registration fee for the Third-Party Organised Educational Event may be covered only if the Healthcare Professional's access to the satellite symposium or booth at the Third-Party Organised Educational Event is conditional upon the payment of the registration fee. Where this does apply, the registration fee must, where possible, be prorated to the actual attendance required in order to deliver the required services. E.g. if the satellite symposium is held on a single day of the three-day event, and it is possible to choose a one-day registration, that option should be selected. ▫ the flight and accommodation costs can only be covered if the Healthcare Professional is not already benefiting from an educational grant covering his/her attendance to the event. **Q24 Under the Code, Chapter 3, Point 2, what is meant by "Company Organised Educational Event"? (added in November 2016)** A24 "Company Organised Educational Event" is a Company Event as defined in the Glossary, whose	

			objective is genuine and bona fide medical education, and the enhancement of professional skills. “Educational” means communicating information directly concerning or associated with the use of Member Companies’ medical technologies, e.g., information about disease states and the benefits of medical technologies to certain patient populations. In all cases the information and/or training must directly concern a Member Company’s medical technologies, therapies and/or related services. This means that a Member Company must meet the following tests when organizing such an Event in order to be compliant with the MedTech Europe Code: The entire Event must comply with the criteria of Chapters 1 and 3; a) The programme must be rigorous from a scientific and/or educational point of view. This means that its content must include current scientific information of a nature and quality which is appropriate to the Healthcare Professionals who are attendees at the Event. b) The programme must be genuine and bona fide educational, and therefore cannot have a primary sales and marketing objective. This means that the Education part must fill most of the Program. c) Information on the programme, clearly indicating the name of the Company organising the Event, should be made available sufficiently in advance in order for invited Healthcare Professionals to be able to make a reasoned judgment as to the rigor and quality of the programme, provided however that subsequent changes, deletions and additions to the programme are acceptable to the extent that such changes, deletions and additions are reasonable and do not significantly modify the quality or nature of the programme. d) The programme should in principle involve full	

			days, with the majority of the morning and afternoon parts dedicated to scientific and/or educational sessions, unless the Event is a half day event, commences or ends on a mid-day or lasts less than half a day. Such half-day or less sessions are permissible, but there should not be any non-scientific or non- educational events or activities organized for the other part of the day. Furthermore, there should be no significant gaps in the programme which would permit Healthcare Professionals to engage in non-scientific or non-educational activities. For example, early morning sessions should not be followed by late afternoon or evening sessions with large blocks of free time in between. **Q25 Are cruise ships or golf clubs appropriate venues for Product and Procedure Training and Education Events?** A25 No. Cruise ships, golf clubs or health spas and venues renowned for their entertainment facilities are not appropriate venues and should not be used. Appropriate examples include hospital, clinic or surgical centre laboratory, educational, conference, or other appropriate settings, including Member Companies' own premises or commercially available meeting facilities, that are conducive to effective transmission of knowledge and any required "hands on" training	
	B. <u>Company Business Meetings</u> 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, 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.	**V. Sales, Promotional, and Other Business Meetings** Companies may conduct sales, promotional and other business meetings with Health Care Professionals to discuss, for example, Medical Technology features, sales terms, or contracts. Often, these meetings occur close to the Health Care Professional's place of business but they may occur in other cities within China or in overseas locations. It is appropriate to pay for reasonable travel costs of attendees when necessary (e.g., for plant tours or demonstrations of non-portable equipment and/or to provide occasional modest	**3. Sales, Promotional and Other Business Meetings** Where it is appropriate, Member Companies may organise Sales, Promotional and Other Business Meetings where the objective is to discuss product and related services features and benefits, conduct contract negotiations, or discuss sales terms. In addition to the principles laid down in the Chapter 3, Section 1, Sales, Promotional and Other Business Meetings should also comply with the following more stringent requirements:	

	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 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 meals and refreshments to Health Care Professionals attending a Company's business meeting.	meals and refreshments in connection with such meetings). However, it is not appropriate to pay any expenses (including meals, refreshments, travel, or lodging) of guests of Health Care Professionals or any other person who does not have a *bona fide* professional interest in the information being shared at the meeting. See Section VIII for additional principles related to the provision of meals associated with Health Care Professional business interactions.	• Such meetings should, as a general rule, occur at or close to the Healthcare Professional's place of business; • It is not appropriate for travel or accommodation support to be provided to Healthcare Professionals by Member Companies, except where demonstrations of non-portable equipment are necessary. **Q26 What criteria should a Member Company apply when considering the country location of Product and Procedure Training and Education Events?** A26 If the participants are primarily of one country, the venue should be in the specific country involved. If the participants are from multiple countries in Europe, then a European country affording ease of access for participants should be chosen. It is expected that the country selected is the residence of at least some of the participants of the Product and Procedure Training and Education Event. **Q27 Can a Member Company use a meeting venue outside Europe?** A27 Yes, provided the participants are from multiple countries outside Europe. If the participants are primarily from within Europe, the venue should be in Europe. It is expected that the country selected (and the state, if the location is in the United States) is the residence of at least some of the participants of the Product and Procedure Training and Education Event. **Q28 Can Member Companies directly support travel and/or accommodation of individual Healthcare Professionals at Company Events, which include new product launches, even if only portable equipment or solutions are being demonstrated? (Added June 2017)** A28 Member Companies can pay for travel and/or accommodation of individual Healthcare	

			Professionals to attend Company Events which include product launches provided that such Events fall within the scope of Chapter 3, Section2, of the Code ("Product and Procedure Training and Educational Events").	
Educational & Research Grants, Charitable Donations, and Commercial Sponsorships	**Section IV – Educational & Research Grants, Charitable Donations, and Commercial Sponsorships** **Key Concepts:** ✓ Medical Technology Companies – together with other organizations – play an important role in educating Health Care Professionals and patients, providing charitable support to the community, and supporting life-changing research. ✓ Medical Technology Companies may support third-party educational, charitable, and research programs through monetary, in-kind, and other contributions. ✓ Medical Technology Companies should establish processes and guidelines so that decisions to support Third-Party Programs are made objectively and not used as unlawful inducements to Health Care Professionals. Companies provide monetary, in-kind, and other contributions to third parties in support of their educational, 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. **Documentation.** A Company should document grants, donations, and sponsorships in writing as		**Chapter 4: Grants and Charitable Donations** **1. General Principles** a. Grants and Charitable Donations (see the Glossary) shall not be contingent in any way on past, present or potential future purchase, lease, recommendation, prescription, use, supply or procurement of the Member Company's products or services. It is important that support of charitable and/or philanthropic programmes and activities by Member Companies is not viewed as a price concession, reward to favoured customers or as an inducement to purchase, lease, recommend, prescribe, use, supply or procure Member Companies' products or services. b. A Member Company shall not provide Grants or Charitable Donations to individual Healthcare Professionals. Grants and Charitable Donations must be provided directly to the qualifying organisation or entity, as the case may be. Grants and Charitable Donations shall not be provided in response to requests made by Healthcare Professionals unless the Healthcare Professional is an employee or officer of the qualifying organization or entity and submits the request in writing on behalf of the qualifying organisation or entity. c. The payment (or provision of other support) by way of any Grant or Charitable Donation shall always be made out in the name of the recipient organization and shall be paid directly to the organisation. A Member Company	**3. Member support of Third Party Educational Events** 3.1 Member support of a Third Party Educational Event[1] shall at all times preserve the independence of medical and scientific education. A Third Party Educational Event must primarily be dedicated to promoting medical, scientific, and educational activities and discourse, and must be initiated by the Third Party Educational Event organizer. 3.2 Member's decision to support a Third Party Educational Event must be based on sufficient information to enable the Member to evaluate the medical, scientific, and educational merit of the Third Party Educational Event, as well as the appropriateness of the venue and agenda. Members should not seek to inappropriately influence the program content, selection of faculty, educational methods, or materials at the Third Party Educational Event. 3.3 Under no circumstances shall a Member's support of a Third Party Educational Event be to induce an HCP to use, recommend, purchase, or prescribe the Member's products and/or services. The nature of and the conditions attaching to a Member's support of a Third Party Educational Event must be properly documented in writing. 3.4 Subject to Section 8 (Research and educational grants), a Member may provide an educational grant to: (a) the organizer of the Third Party Educational Event to defray the costs of running the Third Party Educational

	appropriate based on the program and type of support provided. This could include, for example, a written agreement. **Funding Requests.** Companies may receive requests to support Third-Party Programs that include requests for both Educational Grants and Commercial Sponsorship. Sometimes these requests can be co-mingled.]\		shall not provide Grants or Charitable Donations in the name of any Healthcare Professional. In addition, all Grants and Charitable Donations shall identify the Member Company as the provider of the Grant or Charitable Donation. d. It must in all cases be lawful under applicable national laws and regulations for the Grant or Charitable Donation recipient to receive and benefit from the particular type of Grant / Charitable Donation. e. Member Companies shall implement an independent decision-making / review process to identify, prevent and mitigate against potential bribery and corruption risks arising in connection with the provision of a Grant or a Charitable Donation to a specific prospective recipient. This process shall include a documented, prior evaluation of any such associated risks and of the relevant information concerning the intended recipient organisation or entity. f. All Grants and Charitable Donations must be appropriately documented by the Member Company. Moreover, Grants and Charitable Donations shall only be provided in response to a written request submitted by the requesting organisation or documented initiative from a Member Company containing sufficient information to permit an objective evaluation of the request to be carried out by the Member Company. No Grant or Charitable Donation shall be provided until a written agreement documenting the terms of this is signed by both parties. g. This section of the Code (Chapter 4: Grants and Charitable Donations) is not intended to address the legitimate	Event and/or to support attendance of HCPs at the Third Party Educational Event; (b) a Health Care Institution to support attendance of HCPs at the Third Party Educational Event; and/or (c) a Professional Association to support attendance of HCPs at the Third Party Educational Event. 3.5 Without limiting Section 3.4, Member support of Third Party Educational Events shall be limited to funding: (a) the purchase of advertising and leasing of booth space for displays and promotional activities at the Third Party Educational Event; (b) the holding of satellite symposia at the Third Party Educational Event; (c) registration fees to the Third Party Educational Event; (d) reasonable travel to, and modest accommodation at, the Third Party Educational Event where out-of-town travel is required; and (e) incidental meals and refreshments, provided the meals and refreshments are modest in value and are subordinate in time and focus to the educational purpose of the Third Party Educational Event. 3.6 Members shall neither: (a) arrange, pay for, offer to pay for, or otherwise reimburse the expenses of any individual HCP to attend or speak at a Third Party Educational Event; nor

			practice by Member Companies of providing appropriate rebates, additional product and/or service offerings, including free of charge, or other comparable pricing incentive mechanisms ("value adds") which are included in competitive and transparent centralised purchasing arrangements, such as, for example, tenders. **Q29 Under the General Principles in Chapter 4. Grants and Charitable Donations, what is meant by an "independent decision-making/review process"?** A29 In accordance with the Principle of Separation, an "independent decision-making/review process", is a process where the decision-making criteria are not primarily sales-driven and where the Member Company's sales function does not decide upon and/or approve a decision to provide a Grant or Charitable Donation. For example, such a process could be led by a Member Company's legal, finance or compliance functions, operating within a robust governance framework and according to clear, consistent and transparent criteria for review and decision-making. **Q30 Under the Code, what is meant by "prior evaluation of any associated risks and of the relevant information" relating to a Grant or a Charitable Donation?** A30 Prior to deciding to provide a Grant or a Charitable Donation, the Member Company must evaluate the appropriateness of the award of the proposed Grant or Charitable Donation to the proposed recipient. Such an evaluation shall consider all the circumstances including, but not limited to, consideration of the legal status and structure of the requesting (i.e. prospective recipient) organisation as well as of the nature and scope of its activities and the terms and conditions to which the Grant or Charitable Donation will be subject. The evaluation shall be	(b) select, or influence the selection of, any HCP to attend a Third Party Educational Event, whether as a delegate or as faculty. In accordance with Section 8 (Research and educational grants), Members may only support attendance of HCP speakers and delegates at Third Party Educational Events through provision of educational grants under Section 3.4, provided the recipient of the grant makes an independent decision on selection of the attending HCPs. 3.7 Nothing in this Section 3 applies to Section 4 (Member organized or supported medical technology training and education).

			documented and shall be based on information available to the Member Company, such as information or documentation available from public sources. For Educational Grants provided in relation to Third Party Organised Educational Events, this may also include information of how the funds have been applied by the recipient in relation to previous equivalent Events and whether funds have been spent in accordance with the terms and conditions of any previous Grant **Q31 What does "sufficient information" mean where used in connection with documentation of Grants and Charitable Donations?** A31 The written request by a requesting organisation should include as a minimum a detailed description of the scope and purpose of the programme, activity or other project, which is the object of the Grant or Charitable Donation. It shall also contain a description of the proposed recipient, its legal status and structure, and where relevant, a budget.	
	A. <u>Supporting Third-Party Programs through Educational Grants and Commercial Sponsorship</u> 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 advertise and promote their products and services. 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:** A Company may provide an Educational Grant in support of a Third-Party Program directly to the	**IV. Supporting Third-Party Educational Conferences** **1.** "Third-Party Educational Conferences" are *bona fide* independent, educational, scientific, and policymaking conferences promoting scientific knowledge, medical advancement and the delivery of effective health care. These typically include conferences organized by national, regional, or specialty medical societies, institutions, and associations; medical trust funds; continuing medical education providers; and hospitals and other Institutional Health Care Professionals (collectively, "Third-Party Conference Organizers"). **2.** Company Support for Third-Party Educational Conferences. Companies may support Third-Party Educational Conferences as follows:	**3. Educational Grants** Member Companies may provide restricted Educational Grants (see the Glossary) for the advancement of genuine medical education. "Restricted" in this context means that Member Companies shall specify the intended purpose of the Educational Grant in the Grant agreement. A Member Company shall also ensure that the Educational Grant agreement with the recipient organization includes rights to enable it to verify that the Grant is in fact used for the agreed intended purpose. Member Companies shall document and publicly disclose all Educational Grants in accordance with the Code's Disclosure Guidelines, and publication shall commence no later than the end of the Transition Period. Member Companies may provide Educational	**8. Research and educational grants** A Member may provide research and educational grants provided that the Member: (a) adopts objective criteria for providing the grants; (b) implements appropriate procedures to ensure that grants are not conditional on the use, recommendation, purchase, or prescription of the Member's products and services; and (c) ensures that the recipient of the grant makes an independent decision on application of the grant and/or selection of any beneficiary of the grant. Research grants may only be used to support independent medical research with scientific

	Third- Party Program Organizer or, in some instances, to a training institution 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: ✓ 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. A Company's sales personnel may provide input about the proposed Educational Grant recipient or program. When Companies provide Commercial Sponsorship in support of a Third-Party Program, the level of Commercial Sponsorship should reflect a commercially reasonable fee in exchange for the marketing and promotional benefits received by the Company, such as	A. *Educational Grants/Donations.* Companies may provide a grant or donation of funds to a Third-Party Conference Organizer or other appropriate third party (such as a training institution, hospital, medical or other professional association, educational foundation, or similar entity that supports the training and education of Health Care Professionals) to reduce or defray conference costs ("Educational Grant/Donation"). Companies may only provide Educational Grants/Donations to support Third-Party Educational Conferences that are primarily dedicated to promoting objective scientific and educational activities and discourse. The Third-Party Conference Organizer should independently control and be responsible for the selection of program content, faculty, educational methods, and materials. Educational Grants/Donations may only be provided to support a genuine, independent educational function and may only be used for legitimate expenses associated with bona fide educational activities. B. When an Educational Grant/Donation is requested by a Third-Party Conference Organizer or other appropriate third-party (as described in Section IV-2-A above), only the Third-Party Conference Organizer or, if different, the Educational Grant/Donation recipient may select and invite the individual Health Care Professionals who will receive support to attend the Third-Party Educational Conference. A Company cannot participate in or attempt to influence the selection of individual Health Care Professionals that benefit from the Educational Grant / Donation.	Grants for the following (non-exhaustive) purposes: a. **Support for Third Party Organised Educational Events:** As a general principle, any Third Party Organised Educational Event supported by way of an Educational Grant from a Member Company to a Healthcare Organisation must: • Comply with Chapter 1. General Criteria for Events; and • Where applicable, have approval via the Conference Vetting System (see the Glossary) **Q36 Can a small sized Healthcare Organisation (HCO) receive Educational Grants to support Healthcare Professionals participation at Third Party Organised Educational Events? (added in November 2016)** A36 Yes, in principle. There are no size limits for HCOs to receive Educational Grants; however, Member Companies must ensure that the final beneficiaries of the Educational Grant cannot be identified beforehand. For example, HCOs composed of a single Healthcare Professional will in practice not be allowed to receive Educational Grants to support Healthcare Professionals participation at Third Party Organised Educational Events, as the final beneficiary is known upfront. **Q36-bis Can an Educational Grant or funds earmarked for education be provided to a specific hospital or department or specify individual hospital or department as criteria for HCOs and/or PCOs? (added January 2018)** A36-bis One of the guiding principles in the Code is that companies should not receive or be able to determine the names of the ultimate HCP beneficiaries and the inclusion of a criterion specifying an individual hospital or hospital	merit or health care policy development, provided that such activities have well-defined objectives and milestones. Educational grants may only be made to advance patient care, for medical education of medical students, residents, fellows participating in fellowship programs, or other medical personnel, or for educating the public on health care issues.

	advertising, signage, display/exhibit space, or other promotional opportunities. A Company 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.** A Company 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.* If permitted by applicable standards, a Company can (a) recommend a knowledgeable faculty or appropriate categories of attendees; or (b) select and send faculty to the Third-Party Program to speak on the Company's behalf, provided that the Company contracts with the faculty subject to the provisions of Section II of the Code and an appropriate disclosure is made to the Program attendees that the faculty is presenting on behalf of and paid by the Company. *Each Third-Party Program may vary in terms of the accreditation standards that apply (for example, ACCME standards) and the Third-Party Program Organizer's own internal rules and requirements. ***Review Processes*** Companies are encouraged to adopt controls for reviewing requests to support Third-Party Programs. Companies should consider the	A Company may not provide Educational Grants/Donations as a quid pro quo or with the intention to influence the recipient's decision to purchase, order, recommend, or market any product or medical technology, nor can a Company condition a grant / donation on a requirement to purchase, order, recommend, or market any product or medical technology. Companies should ensure that all support for Third-Party Educational Conferences is appropriately documented. Upon the completion of the Third-Party Educational Conference, a Company should consider requesting that a Third-Party Conference Organizer provide a report or accounting of how it has used the Company's Educational Grant/Donation funds. When making such a request, a Company should not request a Third-Party Conference Organizer to provide a list of specific Health Care Professionals who have benefited from the Company's Educational Grant/Donation, except as necessary to conduct a bona fide compliance audit, monitoring exercise, or investigation. B. *Conference Meals and Refreshments.* Companies may provide funding to the ThirdParty Conference Organizer to support the provision of meals and refreshments to conference attendees. Companies may also provide meals and refreshments for Health Care Professional attendees if such meals and refreshments are provided: (1) to all Health Care Professional attendees (with the limited exception noted below), and (2) in a manner that is consistent with applicable standards established by the conference organizer and the body accrediting the educational activity. Meals and refreshments may be provided to fewer than all Health Care Professional	department is not prohibited under the Code. However, companies should bear in mind that the smaller the hospital or department the greater will be the risk that companies will be able to make such a determination making the use of such a criterion inappropriate under the Code. In addition, companies should be mindful of any proximate or ongoing tender proceedings with that specific hospital, as such tenders may raise additional red flags. **1) Support for HCP Participation at Third Party Organised Educational Events:** Where the Educational Grant is provided for the purpose of supporting Healthcare Professionals' attendance at Third Party Organised Educational Events, the Healthcare Organisation receiving the Grant shall be solely responsible for selection of participants and this shall be expressly reflected in the written Grant agreement. **Q37 How can Member Companies in practice ensure that Educational Grants made available for Third Party Organised Educational Events which are subject to the Conference Vetting System, are positively reviewed by CVS?** A37 It is the responsibility of Member Companies to individually ensure compliance with this Code obligation. For example, Member Companies may themselves consider submitting relevant Third Party Organised Educational Events for CVS review or they may decide to include appropriate contractual obligations making it a pre-condition for an Educational Grant that the Third Party Organised Educational Event be submitted and positively assessed via the CVS, for example by the prospective Grant recipient or by a third party. **Q37-bis Can Member Companies give criteria for HCOs and/or PCOs to allocate their Educational funds? (added in January 2018)**	

	following questions when reviewing such requests: ✓ Is the request for funding reasonable and reflective of the educational purpose of the program? ✓ Do the topics, faculty, attendees, and educational materials reflect an objective, legitimate, educational purpose? ✓ Are the venue and setting conducive to the exchange of educational information? ✓ Does the agenda reflect the legitimate educational, medical, scientific, or policymaking purpose of the meeting? ✓ Do any of the meals or refreshments, recreational activities, or free time provided detract from the primary purpose of the Third-Party Program? ✓ Does the Third-Party Program appear to primarily promote the medical services of a specific provider (for example, a program focused on highlighting a particular physician practice group's medical services vs. appropriate educational topics)? **Q5 – As part of my Company's financial support of a third party's program, the organizer has offered several sponsorship benefits, including a golf foursome and several additional badges to secure entry into the conference. Can my Company invite a Health Care Professional to join the golf foursome? Can we give one of the badges to a Health Care Professional?** No. A Company should not pass along to a Health Care Professional any benefits that the Company receives in exchange for its financial support, including for educational and charitable programs. **Q6 – Does the Code permit my Company to**	attendees if the Company providing such meals and refreshments satisfies all other principles related to meals set forth in Section VIII. Any meals and refreshments should be modest in value, subordinate in time and focus to the purpose of the conference, and clearly separate from the continuing medical education portion of the conference. C. *Faculty Expenses.* Companies may make Educational Grants / Donations to the Third Party Conference Organizer for reasonable honoraria, travel, lodging, and modest meals for Health Care Professionals who are bona fide conference faculty members (i.e. they are listed as faculty in the conference program and have meaningful speaking/presentation roles during the program); provided, however, that Companies cannot select or unduly influence the selection of faculty at such conferences or direct Third-Party Conference Organizers to use Educational Grant/Donation funds to compensate specific faculty members. D. *Advertisements and Demonstration.* Companies may purchase advertisements and lease booth space for Company displays. E. *Phase-Out of Direct Sponsorship.* i. For purposes of the AdvaMed China Code, "Direct Sponsorship" means those arrangements in which a Company (i) pays for a specific Health Care Professional's attendance at a Third-Party Educational Conference, (ii) selects or influences the selection of a specific Health Care Professional, or (iii) has been provided with advance knowledge of the identity of a specific Health Care Professional	A37-bis Yes, objective criteria for a HCOs and/or PCOs to select HCPs to benefit from Educational funds may be given as long as such selection criteria are relevant to the HCPs' educational needs and are not so specific that it would effectively select individual HCPs. Examples of criteria for selecting Educational Grant Recipients are Healthcare Professionals' specialty, years of practice, country, city/region of practice and/ or academic criteria such as number of publications, participation in clinical trials in a given pathology. **2) Support for Third Party Organised Educational Events:** Where the prospective beneficiary of an Educational Grant is the organiser of the Third Party Organised Educational Event and is also a Healthcare Organisation, the recipient Healthcare Organisation shall be solely responsible for: • The programme content; • The selection of Faculty; and • The payment of Faculty honoraria, if any. Member Companies shall not have any detailed involvement in determining the content of the educational programme for selection of Faculty (see Glossary) and this shall be reflected in the written Grant agreement. If expressly requested to do so, Member Companies may recommend speakers or comment on the programme. **Q38 Is it appropriate for a Member Company that has provided an Educational Grant to support Healthcare Professional attendance at a Third Party Organised Educational Event to receive the names of the Healthcare Professionals benefiting from the Educational Grant? (Added in June 2017)**	

	host a Satellite Symposium? Yes. The opportunity to host a Satellite Symposium may be offered to Companies who provide a Commercial Sponsorship in support of a Third-Party Program. Although the Company is responsible for the content of the Satellite Symposium, these programs may be subject to the Third-Party Organizer's application and approval process. While Satellite Symposia are generally included on the Third-Party Program's agenda and promotional materials, these are Company-conducted events. Companies should be transparent in promoting these as such. **Q7 – Can my Company pay for the travel, lodging, or registration expenses of a Health Care Professional who serves as faculty or attends a Satellite Symposium?** • *If a Health Care Professional serves as faculty at the Satellite Symposium:* Yes. A Company may engage a Health Care Professional to serve as a bona fide faculty member on its behalf, including at a Satellite Symposium, subject to the requirements in Section II of the Code. This includes covering the Health Care Professional's relevant registration fees (limited, as appropriate, to the time necessary to speak at the Satellite Symposium) as well as modest and reasonable travel and lodging expenses, subject to Section VI of the Code. • *If a Health Care Professional is only attending the Satellite Symposium:* No. A Company generally draws its audience for Satellite Symposium from the attendees of the related Third-Party Program. The Code prohibits Companies from directly paying for the travel, lodging, or registration fees for Health Care Professionals to attend a ThirdParty Program, including Satellite Symposia held at Third-Party Programs. This prohibition does not preclude a Company	who would benefit directly from the Company's funding. Direct Sponsorship usually involves direct payment by the Company to the Health Care Professional, the Health Care Professional's institution, or a third-party vendor for a specific Health Care Professional's travel, lodging, meals, other transportation expenses, and conference registration fees, among other costs. ii. For Third-Party Educational Conferences occurring before January 1, 2018, Companies may engage in Direct Sponsorship of individual Health Care Professionals to attend Third-Party Educational Conferences, provided that the following criteria are met: a. Companies cannot reimburse Health Care Professionals' travel expenses directly to the Health Care Professional; b. Companies may recommend the list of Health Care Professionals to attend Third-Party Educational Conferences, from an educational and scientific perspective, and should develop internal procedures to ensure that company-sponsored attendees are properly qualified; and c. Companies should establish internal controls to evaluate and qualify third-party service providers (e.g., logistics / travel agencies), if they want to reimburse third-party service providers (e.g., logistics/travel agencies) for meeting related expenses.	A38 A Member Company should not proactively seek to receive the names of the Healthcare Professionals benefiting from its Educational Grant. Generally, when a Third Party Organised Educational Event is supported by more than one company, all companies should receive the same attendance list, from which it should not be possible to identify which Healthcare Professionals have benefited from a particular Member Company's Educational Grant. However, where required by law, a Member Company may, in accordance with the applicable legal requirements, request and obtain the names of the Healthcare Professionals participating in the Event, who are benefiting from that Company's Educational Grant. For purposes of auditing, compliance and monitoring by relevant Company functions, it may be necessary for a Member Company to request and receive the names of the Healthcare Professionals who have benefited from the Educational Grant provided by the Member Company after the Event has taken place. In either of the above cases, unless required by law, such Healthcare Professional names should never be received by the Member Company until the Educational Grant agreement has been signed and the independent selection process of the Healthcare Professionals has been completed. **Q38-bis Can a Member Company provide funds to a commercial organisation where the commercial organisation will be responsible for the management of the Educational Grant (i.e., selection of HCPs, arrangement of conference attendance, travel and accommodation) but is not the organiser of the event (or all of the events) in question? (Amended in November 2018)** A38-bis In principle yes, however Member Companies must bear in mind that certain compliance risks may rise from working with intermediary companies for the management of Educational Grants, and must also take all	

	from paying for a Health Care Professional's modest and reasonable travel and lodging expenses to attend a separate, unrelated Company-organized training or educational session or Company-conducted consultant meeting (for example, an advisory board), as described in Sections II and III of the Code. **Q7a – In evaluating Educational Grant requests or requests for Commercial Sponsorship in support of a Third-Party Program, how should Companies assess the venue of the Third-Party Program?** A Company may give varying weight to different factors when assessing whether to support a Third-Party Program through an Educational Grant and/or Commercial Sponsorship. For those programs with venues that may be considered luxury, resort, or "getaway" locations, a Company may want to consider other factors about the program to determine if, on the whole, the program is appropriate, such as a robust agenda; whether there are significant gaps in the agenda; whether there are entertainment or recreational activities associated with the program; whether the Third-Party Organizer promotes the luxury or resort nature of the venue in its promotional materials; whether the venue maintains appropriate and adequate conference facilities; whether the audience is composed of mostly local physicians; among many other factors. Reviewing Educational Grant requests and Commercial Sponsorship requests requires the Company to look at all of the facts and circumstances surrounding the program to determine whether to fund, partially fund, or deny the request. **Q7b– What are examples of giveaways or other benefits that a Third-Party Program Organizer cannot use Educational Grant funds to support under the Code?** Section IV of the AdvaMed Code lists the appropriate uses of a Company's Educational	iii. For Third-Party Educational Conferences occurring on or after January 1, 2018, Companies can no longer engage in Direct Sponsorship of individual Health Care Professionals to attend Third-Party Educational Conferences. **Q6 What is a Third-Party Educational Conference?** A Third-Party Educational Conference is a *bona fide* independent, educational, scientific, and policymaking conference promoting scientific knowledge, medical advancement, and the delivery of effective health care. A Third-Party Educational Conference typically includes conferences organized by national, regional, or specialty medical societies, institutions, and associations; medical trust funds; continuing medical education providers; and hospitals and other institutional health care providers. **Q7 What is the impact of the AdvaMed China Code revisions?** For Third-Party Educational Conferences that occur on or after 1 January 2018, Companies will no longer be permitted to (i) pay for, offer to pay for, or otherwise reimburse the expenses of individual HCPs to attend a Third-Party Educational Conference, (ii) select –or influence the selection of – any individual HCP to attend a Third-Party Educational Conference or (iii) has been provided with advance knowledge of the identity of a specific Health Care Professional who would benefit directly from the Company's funding. **Q8 What is the rationale for the AdvaMed China Code revisions relating to direct sponsorship?** The revisions to the AdvaMed China Code align with international best practices to foster transparency and to reduce the potential for conflicts of interest while preserving and enhancing meaningful scientific exchange,	necessary actions to mitigate them. In particular, Member Companies must ensure that any company receiving funds for the management of Educational Grants manages those funds in accordance with the Code. To the extent the managing company will select particular HCPs to benefit from the grant, the Member Company must ensure that the managing company has the experience and expertise sufficient to make an appropriate selection. Additionally, Member Companies must include appropriate and specific compliance-related criteria in all contractual arrangements relating to management of Educational Grants, to ensure that the funds are used appropriately and in accordance with ethical standards and local rules and regulations. The contractual arrangements should include appropriate provisions to provide the Member Companies the right to monitor and audit the activity of the companies managing the Educational Grants. However, Member Companies may not provide an Educational Grant or Educational funds to a Third Party Travel Agency directly. For the avoidance of doubt, a Member Company may provide an Educational Grant to a Healthcare Organisation (HCO) or funds earmarked for education to a Professional Conference Organizer (PCO) which is structured so that payments for travel, accommodation [and registration] are remitted directly by the Member Company to a third party travel agency on behalf of the HCO / PCO, which is the recipient of the Educational Grant or the funds earmarked for education. In these circumstances the Member Company may choose to establish a tri-partite contract, with the HCO/ PCO and the third party travel agency. Such a third party travel agency could in principle include a third party travel agency also used by the Member Company for its own internal travel arrangements provided this is not a Company-internal function or Company-owned entity. In any event, where a Member Company decides to use any such arrangement involving funding for, or payments to, a third party travel agency to arrange travel, accommodation [and/or registration] it is	

	Grant. This includes providing HCPs with items of value "permissible under the Code, such as modest meals, refreshments, and educational items." The AdvaMed Code permits a Third-Party Program Organizer to use Educational Grant funds to provide items to HCPs attending the Third-Party Program that are permissible under the Code. Some examples of prohibited items include gift baskets, entertainment or recreational activities, and branded, non-educational promotional items, among others. **Q7c – When can a Company send an HCP to speak at a Third-Party Program?** The following flowchart is intended to help Companies determine whether it is appropriate under the AdvaMed Code for a Company to send an HCP to speak on its behalf at a Third-Party Program. ***(See "Elements of an Effective Compliance Program" Infographic)*** **Q7d – Can a Company sponsor a luncheon during a Third-Party Program through the Third-Party Program Organizer?** A Company can provide a meal to an HCP directly under the AdvaMed Code (see Section VII). The AdvaMed Code also permits a Company to provide an Educational Grant to a Third-Party Program Organizer, which can in turn provide a meal to the HCP attendees of a Third-Party Program. In both instances, a meal must be modest; subordinate in time and focus to a *bona fide* discussion of scientific, educational, or business information; and offered in a setting that is conducive to such discussion. **Q7e – Can a Company sponsor a meal with entertainment during a Third-Party Program (for example, live music)?** No. Section IX of the AdvaMed Code prohibits providing or paying for any entertainment or recreational events. Further, Section VII of the	training and education of HCPs on medical technologies. Direct sponsorship of individual HCPs to attend Third-Party Educational Conferences is not permitted in many countries around the world and will no longer be permitted by several other industry associations' codes of ethics, also effective 1 January 2018. **Q10 What alternative means are available for Companies to support HCP education during Third-Party Educational Conferences?** The main impact of the AdvaMed China Code revisions is to prohibit Companies' ability to select and directly sponsor individual HCPs to attend a Third-Party Educational Conference. But, Companies can continue to support HCP education in other ways, including: (a) providing educational grants/donations to a Third-Party Conference Organizer or other health care institution to defray the costs of operating the program and/or to support the attendance of HCPs; (b) purchasing advertising and leasing booth space for exhibits, displays, and promotional activities; (c) organizing satellite symposia; and (d) supporting Third-Party Organized Procedure Training. Companies can provide educational grants/donations to the Third-Party Conference Organizer or other appropriate third party (such as a training institution, hospital, medical or other professional association, educational foundation, or similar entity that supports the training and education of Health Care Professionals) to cover the costs of HCPs' attendance at Third-Party Educational Conferences, provided that a Company does not select or influence the selection of the specific HCP who would benefit from such funds. **Q11 Can Companies propose or recommend individual HCPs to serve as faculty at or to participate as attendees at a Third-Party Educational Conference?** Companies can make recommendations to a Third-Party Conference Organizer for individual HCPs to serve as faculty at a Third-Party	important that the Member Company carries out appropriate, prior due diligence on a country-by-country and case-by-case basis in order to evaluate and mitigate the particular compliance risks and practicalities where such an arrangement is considered.Additionally, the Member Company must include in all of the contractual arrangements appropriate and specific compliance-related criteria and conditions for the HCO/ PCO to outsource travel arrangements to a third party travel agency, which should include appropriate provisions to allow the monitoring and controlling the activity of the third party travel agency **Q39 Does Chapter 4: Donations and Grants – Educational Grants of the Code apply to requests received by Member Companies in the context of public procurement processes for educational support for Third Party Organised Educational Events from Healthcare Organisations and purchasing bodies?** A39 No. Such requests and any subsequent financial or other support provided by a Member Company are not considered to be Educational Grants for the purpose of the Code. Such arrangements are commercial in nature and not philanthropic and should be documented in a written commercial agreement in accordance with normal business practice. **Q40 In the event that a commercial organisation, such as a Professional Conference Organiser (PCO), organises a Third Party Organised Educational Event independently of any Healthcare Organisation (HCO), is it appropriate for Member Companies to sponsor such events and what rules shall apply? (modified in November 2016)** A40 Member Companies may enter into a commercial sponsorship arrangement with a Professional Conference Organiser organising a Third Party Organised Educational Event independently of any Healthcare Organisation.	

	Code requires all Company meals to be subordinate in time and focus to a bona fide discussion of scientific, educational, or business information and "should not be part of an entertainment or recreational event." Accordingly, a Company cannot sponsor a meal with entertainment, even if held in connection with a Third-Party Program. **Q7f – Is a "journal club" considered a "Third-Party Program" under the AdvaMed Code?** Yes. A "journal club" is a group of HCPs who meet regularly to review and evaluate academic literature on a core medical or clinical topic. Companies should evaluate requests for journal club support based on all of the facts and circumstances of the proposed arrangements. The AdvaMed Code permits Companies to support journal clubs as Third-Party Programs, and Companies can provide such support as outlined under Section IV of the Code. First, a Company can provide an Educational Grant to the journal club organizer, subject to the requirements of Section IV. The journal club organizer can use a Company's Educational Grant funding to defray the costs of putting on the program (ex: AV needs and space rental) and to provide Code-permissible items to participants (ex: a modest meal). Second, a Company could provide Commercial Sponsorship to the journal club organizer in exchange for marketing and promotional benefits, such as advertising, signage, or display space.	Educational Conference, if requested by the Third-Party Conference Organizer. Companies may also make recommendations as to the general categories of HCPs who should participate as attendees at a Third-Party Educational Conference; however, Companies cannot provide recommendations for specific HCP attendees or recommendations that are so detailed or granular in nature as to, in essence, indicate which individual HCPs should benefit from a Company's grant funding or other support for the conference. **Q13 Can my Company pay for HCP attendees' travel, lodging, and registration fees if we arrange to co-organize an educational program with a Third-Party Conference Organizer?** There may be circumstances in which a Company works with a third party (for example, a hospital or medical society) to jointly organize an educational program or product training for HCPs. In these cases, a Company should analyze the facts and circumstances of each such 21 jointly organized program to determine whether it is most appropriately considered a Third-Party Educational Conference or a Company-Conducted Product Training and Education Program: • If the Third-Party Conference Organizer has control over and is responsible for the selection of program content, faculty, educational methods, and materials, the program is most appropriately considered a Third-Party Educational Conference and the prohibition on direct sponsorship applies. A Company cannot circumvent the prohibition on direct sponsorship by simply serving as a co-organizer of a program with a Third-Party Conference Organizer. • If the Company has control over and is responsible for the selection of program content, faculty, educational methods, and materials, the program is most appropriately considered a Company-Conducted Product Training and Education Programs, and the	However, such arrangements do not fall within the definition of Educational Grant as Professional Conference Organiser are for-profit organisations. Sponsorship arrangements are therefore commercial in nature and Member Companies should consequently document these in a written commercial agreement in accordance with normal business practice and the requirements of the Code (Chapter 2: Third Party Organised Educational Events). In addition, where a Member Company provides funds earmarked for the advancement of genuine educational purposes to a Professional Conference Organiser, acting independently of any Healthcare Organisation, , all the Code provisions governing Educational Grants shall also apply. For example, if a Member Company provides funding to a Professional Conference Organiser to fund Healthcare Professional delegate places and expenses at a Third Party Organised Educational Conference, such Event, where applicable, must have CVS approval and the Member Company shall publicly disclose such funding in accordance with the Code's Disclosure Guidelines. **b. Scholarships and Fellowships** Member Companies may provide Educational Grants on a restricted basis in the form of Grants for Scholarships and Fellowships to support advancement of genuine medical education of Healthcare Professionals (see the Glossary). Only Healthcare Organisations where Healthcare Professionals are in training shall be eligible to request and/or receive such Educational Grants. A Member Company shall not provide Educational Grants to support Scholarships and Fellowships upon request of individual Healthcare Professionals. Similarly, the Member Company shall not have any involvement in any way in the selection of the HCPs who will benefit from the Educational	

		Company can pay for HCP attendees' travel, lodging, and other fees incurred to attend the program, subject to Section III of the AdvaMed China Code. • If the program has been set up as a Satellite Symposium, the Company should confer with Section IV of the AdvaMed China Code and the relevant FAQs on Satellite Symposia. • If both parties have some form of control over program content, faculty, educational methods, or materials, a Company cannot pay for HCP attendees' travel, lodging, or other fees incurred to attend the program. Companies should analyze all HCP training and educational programs (Company-Conducted Product Training and Education, Satellite Symposia, and Third-Party Educational Conferences) in light of the phase-out of direct sponsorship found in Section IV of the AdvaMed China Code. A Company cannot structure its programs or support programs designed to circumvent the prohibition on direct sponsorship. **Q14 My Company is planning to host a Satellite Symposium in connection with an upcoming Third-Party Educational Conference of Chinese cardiologists. Can my Company compensate a physician who serves as faculty at my Company's Satellite Symposium?** Yes. A "Satellite Symposium" is a Company-organized program held in connection with a ThirdParty Educational Conference. While a Company may pay a fee to a Third-Party Conference Organizer in exchange for the opportunity to host the Satellite Symposium in connection with the conference, a Satellite Symposium is considered a Company-organized event. Accordingly, a Company can compensate a physician for the fair market value of his/her faculty services at 22 the Satellite Symposium, provided that the arrangement meets the requirements listed in Section VI of the Code. In general, a Company may also be able to cover a	Grant and this shall be reflected in the written Grant agreement between the Member Company and the recipient HCO. **Q41 Can a Member Company pay for or reimburse travel costs to a Third Party Organised Educational Event for a Scholar or Fellow?** A41 No, a Member Company cannot additionally pay for, or reimburse, the travel or other participation costs incurred by a Scholar or Fellow attending a Third Party Organised Educational Event. Such costs shall be included in the Educational Grant supporting the Scholarship or Fellowship if it is intended that the Grant should extend to such attendance. **Q42 Can Member Companies support professional training of Healthcare Professionals on general medical education topics, such as courses on health economics/health technology appraisal, good laboratory practice or similar topics that promote patient care? (Added in June 2017)** A42 Member Companies can support genuine medical education for Healthcare Professionals on general healthcare-related topics through Educational Grants in accordance with Chapter 4 of the Code. Member Companies can also support genuine medical training on general healthcare-related topics through company-organised "Product and Procedure Training and Education Events" as long as the information directly concerns the Member Company's medical technologies, therapies, and/or related services. The Event must be conducted in accordance with, and meet the other requirements of, Chapter 3, Section 2 of the Code. **c. Grants for Public Awareness Campaigns** Member Companies may also provide Educational Grants on a restricted basis to	

		Satellite Symposium faculty member's other costs, including travel, lodging, and registration fees, associated with providing faculty services at the Satellite Symposium; however, a Company cannot structure a Satellite Symposium or arrange to cover for HCP faculty costs in such a way that circumvents the phase-out of direct sponsorship. For example: • If a Satellite Symposium faculty member had planned to attend the Third-Party Educational Conference independently, the Company conducting the Satellite Symposium may pay for the faculty member's incremental costs of adding him or her as faculty of the Satellite Symposium (for example, this might include covering one additional day of lodging costs or the additional costs to change travel reservations). • If a Satellite Symposium faculty member was not planning to attend the Third-Party Educational Conference, the Company conducting the Satellite Symposium should not pay for the faculty member's incremental costs if he or she decides later to attend the Third-Party Educational Conference. Rather, the faculty member is responsible for covering incremental costs incurred to attend the Third-Party Educational Conference (for example, additional lodging costs or costs to change travel reservations) himself or herself. Further, for HCPs who attend the Satellite Symposium as non-faculty, the AdvaMed China Code would not permit a Company to pay for these HCPs' travel or lodging expenses. Finally, a Company cannot deem an unreasonable number of faculty members at a satellite program in a way that undermines the phase-out of direct sponsorship. For example, Companies could not designate all attendees at a Satellite Symposium to be faculty by creating programs whereby all attendees serve on speaker panels. Companies should establish internal controls and policies for how to set up Satellite Symposia and for who can serve as faculty at such programs consistent with	Healthcare Organisations for the legitimate purpose of providing information, promoting awareness and/or educating patients, carers or the general public about relevant healthcare topics or medical conditions or diseases in therapeutic areas in which the Member Company is interested and/or involved. **Q43 What are examples of relevant disease awareness and health education for patients, carers and the general public for which a Member Company may legitimately provide an Educational Grant?** A43 A Member Company may provide an Educational Grant to support the provision of high quality information to patients and the public about health and disease provided there is an objective patient or public need for such information and the topics covered are linked to the therapeutic areas in which the Member Company is interested and/or involved. Such disease awareness campaigns must not, however, promote the use of particular therapies, services or promote specific HCOs, nor may they aim to stimulate demand by the public for specific therapies or for specific Healthcare Organisations	

		the purposed of the ban on direct sponsorship as described in section IV and the associated FAQs. **Q15 What factors should Companies consider when evaluating whether to support a Third-Party Educational Conference with an Educational Grant/Donation pursuant to Section IV of the AdvaMed China Code?** Companies are encouraged to adopt policies and procedures that evaluate the legitimacy of a Third-Party Conference Organizer or Third-Party Educational Conference in determining whether to provide an Educational Grant/Donation. Companies should consider analyzing and maintaining appropriate documentation regarding their review of relevant factors, including, for example: • Whether the Third-Party Conference Organizer operates independently from an individual HCP or whether it is affiliated with an individual HCP; • Whether the Third-Party Conference Organizer maintains the hallmarks of an independent entity (ex: a separate bank account); • Whether the Third-Party Conference Organizer has a history of bribery/corruption charges; • Whether the Third-Party Conference Organizer has been subject to an official government audit and, if so, the results of such audit; • Whether the Third-Party Conference Organizer is willing to submit to an audit of its books and records upon request; • Whether the Third-Party Conference Organizer has provided documentation of official government registration, corporate		

		certification, or other necessary qualifications and approvals; • Whether the Third-Party Conference Organizer appears on a list of industry-approved conference organizers (if available); • The size of the Third-Party Conference Organizer; • The date of the Third-Party Conference Organizer's formation; • The educational quality of the program agenda and educational materials; • The caliber of the faculty selected to speak at the program; and • The appropriateness of the venue. **Q16 My Company has provided an Educational Grant/Donation to a Third-Party Conference Organizer in support of an upcoming ThirdParty Educational Conference. At the event, Health Care Professional attendees will be able to participate in a contest. The winner of the contest will have all of his or her registration fees covered to attend a future international Third-Party Educational Conference. Is this a Direct Sponsorship under Section IV of the Code?** This arrangement would not be considered a Direct Sponsorship provided that (a) the winner is selected based upon objective criteria and the winner's meeting these criteria is well-documented; (b) the winner is not selected in an effort to influence his or her decisions to use a particular product; and (c) the prize is paid in accordance with applicable laws and regulations. **Q17 My Company has provided an Educational Grant/Donation to a Third-Party Conference Organizer in support of a Third-Party Educational Conference. The Conference Organizer has provided my Company with several free**		

		registrations for individuals to attend. Can I provide these free registrations to HCPs? No. Covering the registration fee for an HCP to attend a Third-Party Educational Conference would be considered a Direct Sponsorship. The AdvaMed China Code phases out Direct Sponsorships to individual HCPs to attend Third-Party Educational Conferences, starting January 1, 2018. Accordingly, free registrations cannot be provided to HCPs after this date. **Q18 In order to facilitate the training of Health Care Professionals, my Company would like to engage several Health Care Professionals as consultants to attend an upcoming Third-Party Educational Conference (including covering their travel, lodging, meals, and registration fees). These consultants would learn the content presented during the program, collect educational materials from the program, and later train other Health Care Professionals on the content on behalf of my Company. Is this permissible under the AdvaMed China Code?** No. Engaging Health Care Professionals as consultants to attend a Third-Party Educational Conference in an effort to learn the content of the meeting and to subsequently train other Health Care Professionals on the content would be considered a Direct Sponsorship and therefore not permitted under the Code, starting January 1, 2018. **Q19 Can my Company pay for the travel and lodging costs of an HCP to attend a Third-Party Educational Conference and present a scientific poster on his/her relevant research during the event?** No. Selecting and covering the travel and lodging costs of an individual HCP to attend and present on a particular research project or study during a Third-Party Educational Conference is the responsibility of the Third-Party Conference Organizer (or other relevant entity).		

	B. <u>Supporting Other Third-Party Programs through Educational Grants</u> A Company 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 educational and training programs and 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), patients, and the public about important health care topics. A Company 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. A Company's sales personnel may provide input about a proposed Third-Party Program.	B. *Academic and Public Education Grants.* Academic and public information grants may be provided for legitimate purposes, including, but not limited to, the examples below. A Company may not make academic or public information grants to Individual Health Care Professionals, or to Individual Heath Care Professionals in training. i. *Academic Grants*. A Company may make grants to support the genuine medical education of medical students, residents, and fellows participating in fellowship programs that are charitable or have an academic affiliation, or other medical personnel. ii. *Public Education Grants*. A Company may make grants for the purpose of supporting education of patients or the public about important health care topics.		
	C. <u>Supporting Independent Third-Party Research</u> 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 treatments, promote improved delivery of health care, and otherwise benefit patients. To help meet these objectives, a Company may provide in-kind or monetary research grants in support of independent research with scientific merit.	**XI. Research, Academic and Public Education Grants; Charitable Donations** 1. Companies may provide research and educational grants and charitable donations to Health Care Professionals, in accordance with applicable laws and regulations. A Company may not provide such grants or donations as an unlawful inducement. Therefore, a Company should: (a) adopt objective criteria for providing such grants and donations that do not take into account the volume or value of purchases made by, or anticipated from, the recipient; (b) implement appropriate procedures to ensure that such	**4. Research Grants** Where permitted by national laws, regulations, national guidelines and professional codes of conduct, Member Companies may provide restricted Research Grants (see the Glossary) to support clearly defined third party-initiated research studies for clinical or non-clinical research programmes in therapeutic areas in which the Member Company is interested and/or involved. Research Grants may include in kind or financial support for legitimate, study-related, documented expenses or services, and/or reasonable quantities of single-use and/or multiple-use free of charge product(s) for the	

	• **Objectives & Milestones.** A Company 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 or research grants should also 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.** A Company should establish controls for reviewing requests for research grants. • **Sales Involvement.** Sales personnel should not control or unduly influence the decision of who will receive support or the amount of the support. A Company's sales personnel may provide input about the proposed research program or recipient. Company-initiated or directed research involving a Company's Medical Technologies (such as clinical study agreements) is addressed separately in Section II of the Code.	grants and donations are not used as an unlawful inducement; and (c) ensure that all such grants and donations are appropriately documented. 2. A Company should ensure, when providing such grants or donations, that the donation or grant is (a) handled by the financial department of the Institutional Health Care Professional and is used according to the donor or grant agreement for bona fide nonprofit activities; (b) accepted by the legal entity of the Institutional Health Care Professional, not internal departments or individual Health Care Professionals; and (c) not conditioned on buying products or services or otherwise linked to other conditions that might affect fair competition. 3. A Company's sales personnel may provide input about the suitability of a proposed grant or charitable donation recipient or program, but sales personnel should not control or unduly influence the decision of whether a particular medical or healthcare institution will receive a grant or donation or the amount of such grant or donation. Companies should consider implementing procedures to monitor compliance with this section. A. *Research Grants.* Research provides valuable scientific and clinical information improves clinical care, leads to promising new treatments, promotes improved delivery of health care, and otherwise benefits patients. In furtherance of these objectives, a Company may provide research grants to support independent medical research with scientific merit. Such activities should have well-defined objectives and milestones and may not be linked directly or indirectly to the purchase of Medical Technologies. Company-initiated or directed research involving a Company's Medical Technologies (such as clinical study	limited duration of the research. Member Companies providing Research Grants shall ensure that they do not influence the research. However, in order to ensure that Research Grants are provided on a "restricted" basis, Member Companies shall clarify the intended research scope and purposes for which the Grant is requested and shall ensure that the written Grant agreement with the recipient organisation includes rights for the Member Company to verify that the Grant is applied solely for the agreed intended research use. Such verification may include a request for study-related documentation, such as a copy of the research protocol, a copy of the ethics committee and/or regulatory approvals or a copy of the study report upon completion or earlier termination of the research. All requests for Research Grants from prospective Grant beneficiaries must be in writing and must detail, as a minimum, the type, nature and objectives of the research activity, the milestones and budget, the approximate duration of the research, and where applicable, the requirements for ethics committee, regulatory and/or other authorisations or approvals. A Member Company may give consideration to a request for a Research Grant prior to ethics committee approval for the specific research project but shall not take any final decision regarding the Grant request unless and until the research receives formal ethics committee approval. Research Grant agreements shall include provisions relating to adverse event reporting where appropriate, and shall require full disclosure of the Member Company and of the Grant by the Grant recipient organisation and the lead-investigator in all oral or written presentations of the results. For guidance on how Member Companies may	

		agreements) is addressed separately in Section VI.	undertake Member Company-initiated research please refer to Chapter 6: Research: Member Company-Initiated Research. **Q43-bis Can Member Companies support the participation of Poster or Abstract Presenters in Third Party Organised Educational Conferences? (Added in March 2019)** A43-bis Poster or Abstract Presenters at Third Party Organised Educational Conferences are not to be considered as Speakers, as defined in the Code ("Glossary'). As such, if Member Companies want to support their participation in the Conference, such support may be provided through an Educational Grant (if it complies with the requirements of the Code, specifically those of Chapter 4). Alternatively, the support can be included in a Research Agreement, whether it relates to Company Initiated or Third Party Initiated Research. However, if the support is included in a Research Agreement, Companies may only support attendance of Poster and Abstract presenters to Third Party Organised Educational Conferences provided the following considerations are met: - The selection of the Poster or Abstract Presenters is done independently by the Third Party Organiser of the Event, - The support envisioned must be specific and detailed in the Research Agreement between the Member Company and the Healthcare Organisation, and - The Company is not directly involved in the selection of the specific investigator who would benefit from the support (for the avoidance of doubt principal investigators with whom a company might have a direct relationship would be eligible to receive support for the dissemination of the research results). Companies should also consider including in the	

			Research Agreement a clause which stipulates that funds will be made available only once the Poster or Abstract Presenter has been selected independently by the Third Party Organiser of the Event.	
	D. <u>Supporting Charitable Programs through Charitable Donations and Commercial Sponsorship</u> A Company may make monetary or in-kind charitable donations of product or equipment for charitable purposes, such as indigent care, patient or public education. A Company may also provide Commercial Sponsorships in support of events where the proceeds are intended for charitable purposes. • **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. A Company 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 state law, and (3) whether the organization has a charitable mission or purpose, among other factors. • **Use of Funds.** A Company must require that any donation is used only towards charitable or philanthropic purposes. • **Indigent Care Donations.** A Company may make charitable donations of product for indigent patients, provided that these donations serve exclusively to benefit patients and are permitted under applicable laws. Companies should consider making product donations for indigent cases contingent upon a hospital's agreement that	C. *Charitable Donations*. A Company may make monetary or Medical Technology donations for charitable purposes, such as supporting indigent care, patient education, public education, or the sponsorship of events where the proceeds are intended for charitable purposes. Donations should be motivated by bona fide charitable purposes and should be made only to bona fide charitable organizations or other organizations with a bona fide charitable purpose. Companies should exercise diligence to ensure the bona fide nature of the charitable organization or charitable mission.	**2. Charitable Donations** Member Companies may make unrestricted Charitable Donations for genuinely charitable or other philanthropic purposes. "Unrestricted" in this context means that Member Companies shall have no control over the final use of funds (or other support) they provide as Charitable Donations beyond general restrictions to ensure that the funds (or other support) are applied for charitable and/or philanthropic purposes. Charitable Donations may be made only to charitable organisations or other non-profit entities which have charitable and/or philanthropic purposes as their main purposes and which are objectively engaged in genuine charitable or philanthropic activities. Charitable Donations shall always be made in accordance with the general principles set out in Chapter 4: Grants and Charitable Donations. Restricted Charitable Donations to non-profit hospitals may be permissible in case of demonstrated Financial Hardship (see Glossary), when Charitable Donations serve exclusively the benefit of the patient, are limited in value, or explicitly permitted by applicable national laws. This section of the Code (Chapter 4: Grants and Charitable Donations–Charitable Donations) is not intended to address legitimate commercial transactions by Member Companies in the form of leasing of stands or booth space at Third Party Organised Educational Events and/or at any conference or event organized by a charity or other philanthropic organisation. Such activity is considered to be part of Member Companies' normal marketing activity. Member Companies	**9. Charitable donations** Members may make donations of money, products, or services for charitable or other philanthropic purposes, or sponsor events where the proceeds are intended for charitable purposes, unless the donations are prohibited under applicable laws and/or codes of conduct. Charitable donations shall be made to bona fide non-profit entities, charitable organizations, missions supporting charitable projects, and to other organizations supporting charitable projects. A charitable donation must not be targeted to HCPs, nor used as encouragement or as a reward for a HCP using, recommending, purchasing, or prescribing a Member's products or services. All charitable donations shall be appropriately documented.

	no third parties will be billed for the donated product. • **Charitable Events.** A Company 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. A Company's sales personnel may provide input about a proposed charitable program or recipient. **Q8 – My Company has been asked to sponsor a local hospital's heart walk to raise money for heart disease research. In exchange for a fee, my Company will receive exhibit space at a health care expo the hospital is holding in connection with the charitable walk. My Company will also receive prominent placement in the relevant advertising. Is this OK?** Yes. A Company may provide a Commercial Sponsorship in support of a charitable fundraiser, separate from a charitable donation. As with Commercial Sponsorship of a Third-Party Program: ✓ The level of Commercial Sponsorship should reflect a commercially reasonable fee in exchange for the marketing and promotional benefits received by the Company, such as advertising, signage, display/exhibit space, or other promotional opportunities; and ✓ The Commercial Sponsorship must comply with applicable laws governing the marketing and promotion of its products.		should, however, always consider the appropriateness of the location, venue and the general arrangements for any such events and the impression that may be created by the arrangements in order not to bring the industry into disrepute. **Q32 Under the Code, can a Member Company make a Charitable Donation to support the general running of hospital or other Healthcare Organisation?** A32 No, a Member Company cannot make available a Charitable Donation to support the general running of a hospital or other Healthcare Organisation. A Charitable Donation shall only be given to a legal entity or body which has charitable and/or philanthropic purposes as its main purposes. For the purpose of the Code and irrespective of their legal status, hospitals and Healthcare Organisations are considered to generally have health functions as their main purposes and accordingly are not generally considered to have charitable and/or philanthropic functions as their main purposes. It is not therefore appropriate to provide Charitable Donations to support their general running. **Q33 Is it permissible for a Member Company to specify restrictions in relation to the final use of a Charitable Donation where a Member Company wishes its Charitable Donation to be applied as part of a specific aid programme or as part of the relief effort following a specific natural disaster, such as a major earthquake in a particular country? (added in November 2016)** A33 Under the Code it is not appropriate for a Member Company to apply conditions or restrictions to the final use of a Charitable Donation which go beyond general restrictions to ensure that the funds (or other support) are applied for charitable and/or philanthropic purposes. Member Companies may therefore impose general restrictions concerning the final use, such as the relief of a specific disaster in a	

			particular country (e.g. for use to aid reconstruction and/or re-equipping of healthcare facilities following the earthquake in that country). However, Member Companies must take care that such general restrictions are not so specific that the Charitable Donation is no longer unrestricted. The Charitable Donation must not be misused or be perceived to influence through undue or improper advantages, purchasing decisions, nor should such Donation be contingent upon sales transactions or use or recommendation of Member Companies' products **Q34 Is it permissible for a Member Company to make a Charitable Donation to a Healthcare Professional's designated charity in instances where the Healthcare Professional has requested the Member Company to do so in lieu of receiving a professional fee for the provision of consultancy or speaking services to the Member Company?** A34 No. Under the Code it is not appropriate for a Member Company to support the favourite charity of a Healthcare Professional in response to a request by that Healthcare Professional irrespective of the underlying reasons. No exception can be made for sport events, such as payment of the registration charge to participate in a charity run. **Q35 Under the Code, may a Member Company make a Charitable Donation such as the purchase of a table of dinner invitations at a fundraising dinner or entries to participate in, or attend at, a fundraising sports or other event?** A35 Yes, Charitable Donations made by Member Companies may take the form of dinner invitations for a fundraising dinner or participating in other recreational events such as a fundraising golf tournament, if arranged by a charitable or other non-profit philanthropic organisation. The Member Company may use some or all of its ticket allotment for its own employees and return any unused portion to the sponsoring charitable or	

			non-profit philanthropic organisation for use as the sponsoring organisation sees fit. However, the Member Company should not invite Healthcare Professionals to attend such an event at the Member Company's expense. Furthermore, the Member Company is not permitted to suggest to the sponsoring organisation, the names of Healthcare Professionals who could be invited to attend the event, irrespective of whether or not the specified Healthcare Professionals will be seated at the Member Company's table.	
Jointly Conducted Education and Marketing Programs	**Section V – Jointly Conducted Education and Marketing Programs** **Key Concepts:** ✓ Companies may partner with Health Care Professionals to conduct joint education and marketing programs designed to highlight both Medical Technology and a Health Care Professional's ability to diagnose or treat medical conditions. ✓ A Company and a Health Care Professional should serve as bona fide partners, and contributions and costs should be shared fairly and equitably between the parties. Medical Technology 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 patients and other 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. These programs could include, for example, an event in which a Company shares information about its Medical Technologies to an audience of Health Care Professionals or patients, and a physician speaks about the medical conditions	F. *Third-Party Organized Procedure Training.* i. For purposes of the AdvaMed China Code, a "Third-Party Organized Procedure Training" is a practical, hands-on training conducted by a third party organization on specific surgical or clinical skills relevant to the performance of particular medical procedures. ii. Venue. A Third-Party Organized Procedure Training must be held in a clinical setting or in an environment suitable for simulating medical procedures. Examples of permissible clinical settings include hospitals, clinics, laboratory, or other spaces appropriate for performing or simulating the performance of a medical procedure. The venue must not be selected because of its entertainment, leisure, or recreational facilities. iii. Educational Grant/Donation Support. Companies may support Third-Party Organized Procedure Training through Educational Grants/Donations to the third-party organizer in accordance with the provisions laid out in Section IV of the AdvaMed China Code. iv. Direct HCP Support. Companies may also support Third-Party Organized	**Chapter 2: Third Party Organised Educational Events** Member Companies may provide financial and/or in kind support (e.g. Member Company products) to Third Party Organised Educational Events in accordance with the rules of this Code. Such Events include: • Third Party Organised Educational Conferences; and • Third Party Organised Procedure Training meetings. **1. Third Party Organised Educational Conferences** Member Companies may support in cash and/or in kind Third Party Organised Educational Conferences (see the Glossary) which comply with: • Chapter 1: General Criteria for Events; and • Where applicable, has approval via the Conference Vetting System (see the Glossary) Where permitted under national laws, regulations and professional codes of conduct, Member Companies may provide financial and/or in kind support to Third Party Organised Educational Conferences (always provided that the Third Party Organised Educational Conference has been approved via the Conference Vetting System,	4. **Member organized for supported medical technology training and education** 4.1 Members may provide or support training and education to HCPs on product-specific technology deployment, use, and application to facilitate the safe and effective use of medical technologies. Members may also provide or support education to HCPs on topics concerning or associated with the use of their medical technologies. Examples of training and education programs include "hands-on" training sessions, workshops, lectures, and product presentations. Training and education shall be conducted by qualified personnel, which may include Member personnel with appropriate technical expertise or personnel of an independent, reputable, professional third party. 4.2 Training and education programs shall be conducted in venues that are conducive to the transmission of education and training and are selected based on their suitability for the proposed program and for the convenience of attendees. Appropriate venues may include the HCP's premises, the Member's premises, or other clinical, laboratory, educational, or conference training facilities (including hotel conference rooms), depending on the nature of the program. The venue must not be selected because of its entertainment, leisure, or recreational facilities. To assist HCPs attending

	that the Medical Technology is intended to treat, the procedures that use the Medical Technology, and the physician's ability to perform these procedures. Companies should apply the following principles: • There must be a bona fide, legitimate need for the Company to engage in the activity for its own educational or marketing benefit. • 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 on providing information related to a product's labeling and guidelines for furnishing appropriate health economics information, among other controls. • Jointly conducted education and marketing programs should be balanced and promote both the Company and its Medical Technologies, and the Health Care Professional and the range of services offered for the diagnosis and treatment of related medical conditions. • The Company and the Health Care Professional should serve as bona fide partners in the program and should make equitable contributions towards the activity and costs (for example, developing content, invitations, space rental, AV needs, and other production costs). • The arrangement should be documented in a written agreement that describes the purpose of the arrangement and the roles, responsibilities, and contributions of each party, including payment of costs.	Procedure Training by covering a Health Care Professional's registration fees to attend the program. Where there are objective, documented reasons to support the need for out-of-town travel to attend a Third-Party Organized Procedure Training, Companies may also pay for reasonable travel and modest lodging costs of the attending Health Care Professionals. It is not appropriate for Companies to pay for the meals, refreshments, travel, or other expenses for guests of Health Care Professionals to attend a Third-Party Organized Procedure Training or for any other person who does not have a bona fide professional interest in the information being shared at the program. No travel- or lodging-related expenditures can be reimbursed directly to the Health Care Professional. Companies can only pay for travel- and lodging-related expenditures for a Health Care Professional's attendance at a Third-Party Organized Procedure Training that is established as a stand-alone event. In other words, Companies cannot directly support Health Care Professionals' attendance at a procedure-based training that is organized in connection with, held immediately prior to or after, or simultaneous to a Third-Party Educational Conference, as defined above. Direct support as described in this Section is exempt from the January 1, 2018 phase-out of Direct	where appropriate) through grants and other types of funding, such as: **a. Educational Grants** Please refer to Chapter 4: Charitable Donations and Grants for guidance on Educational Grants. **b. Promotional Activity** Member Companies may purchase packages that may include promotional and advertising services, for example, advertisement space and booth space for company displays. Member Companies should ensure that the overall image projected by the promotional activity at Third Party Organised Educational Conferences is perceived as professional at all times. It should never bring discredit upon or reduce confidence in the medical technology industry. **c. Satellite Symposia** Member Companies may purchase satellite symposia packages at Third Party Organised Educational Conferences and provide presentations on subjects that are consistent with the overall content of the Third Party Organised Educational Conference. Member Companies may determine the content of these satellite symposia and be responsible for speaker selection. **Q16: What is meant by "in kind support" as used in Chapter 2, Section 1 of the Code in connection with "Third Party Organised Educational Conferences"? (amended in January 2018)** A16: "In kind support" can be provided to the Healthcare Organisation (HCO) and Member Companies should take care to ensure that any such in kind support does not, nor is perceived to, circumvent the prohibition of Member Companies providing direct financial support to identifiable Healthcare Professionals (HCPs) to attend Third	training and education programs, Members may fund the costs of individual HCPs' reasonable travel, modest accommodation, and incidental, modest meals and refreshments. Members shall not provide, pay for, or arrange for recreation or entertainment for participating HCPs, nor shall Members provide, pay for, or arrange for travel, accommodation, meals, or refreshments of spouses or other guests of participating HCPs.

	Q8a – What are examples of the types of programs that fall under Section V? The following are examples of jointly conducted education and marketing programs: • A promotional advertisement that appears in a magazine or periodical, on a billboard, a television or radio spot, an online advertisement or social media, featuring the benefits of the Company's Medical Technology and highlighting the skills and expertise of the HCP to perform procedures that use the Medical Technology. • An educational program for patients or referring physicians during which a Company and an HCP provide clinical information about specific Medical Technology; and an HCP describes what patients should expect when undergoing a procedure, relevant treatment options, and his/her own ability to perform the procedure that uses the Medical Technology. This list is not meant to be exhaustive. There are other types of programs on which Companies and HCPs can collaborate to deliver high-quality, effective educational content to patients, other physicians, or the public. **Q8b – What types of controls should companies implement in connection with jointly conducted programs?** Companies and HCPs engaged in a jointly conducted educational and marketing program may adopt many types of controls. Some examples include appropriate governing policies; periodic assessment of the appropriate business need for the program; focused training; a process for evaluating the fair market value of jointly conducted education and marketing programs; and field-based monitoring, among others.		Sponsorships, as described in Section IV(E) above. Companies should establish internal controls to evaluate and qualify third party service providers (e.g., logistics / travel agencies), if they seek to reimburse such service providers for any travel or lodging expenses associated with an HCP's attendance at a Third-Party Organized Procedure Training. All expenses subject to a Company's direct support must be well documented.	Party Organised Educational Conferences. For example, after the Transition Period, it would not be appropriate for Member Companies to directly handle the conference registration, travel, or accommodation arrangements for individual (and identifiable) HCP delegates at a Third Party Organised Educational Conference. Examples of "in kind support" which Member Companies may provide could include modest secretarial and/or logistical support to assist with meeting arrangements. **Q17: Please provide examples of appropriate booth activities which will be perceived as professional?** A17: Booth activities at Third Party Organised Educational Conferences should aim primarily at displaying Member Companies' products and services and related literature. Therefore, other activities should be limited and reasonable and in principle, only soft drinks and snacks should be served. **Q18: Can a Member Company for example be present via a satellite symposium, rent booth space at a Third Party Organised Educational Conference which was assessed as non-compliant by the Conference Vetting System (CVS)? (Amended in November 2016)** A18: Please refer to Annex I for a detailed visualisation of the scope of CVS and its impact on commercial activities. **Q19: Can Member Companies directly support attendance by Healthcare Professionals engaged to speak only at satellite symposia at Third Party Organised Educational Conferences, e.g. registration fee, travel and/or accommodation? (Amended in June 2017)** A19: Member Companies must ensure all aspects of the arrangement comply with the Code, including entering into a consulting agreement with Healthcare Professionals engaged to speak at	

	• A documented, jointly conducted program between a Company and an HCP should also entail both parties making equitable contributions towards the costs of the program. While costs do not need to be split evenly between the parties (for example, monetary or in-kind contributions of both parties), each party should contribute to the program in a way that is commensurate with the benefits it receives.		satellite symposia. The consulting agreements may provide for payments to be made in respect of travel and/or accommodation for the purpose of delivering the speaker services. Where payment of a registration fee is required in order for speakers to access satellite symposia, Member companies may also pay for the registration fee. **2. Third Party Organised Procedure Training** Member Companies may support Third Party Organised Procedure Training either via Educational Grants (in accordance with Chapter 4: Charitable Donations and Grants) or by providing financial support directly to individual Healthcare Professionals to cover the cost of attendance at Third Party Organised Procedure Training sessions in accordance with the following rules: • Financial support must comply with the criteria provided in Chapter 1: General Criteria for Events. Member Companies may therefore pay travel, hospitality and the registration fee. • Where applicable, the Third Party Organised Procedure Training has approval via the Conference Vetting System (see the Glossary). • For financial support to Third Party Organised Procedure Training meetings Member Companies must apply the requirements governing conduct and attendance at such meetings in the country where the Healthcare Professional carries on their profession and give due consideration to the requirements in the country where the meeting is being hosted. **Q20: What are the main differences between Third Party Organised Educational Conferences and Procedure Trainings? (added in November 2016)** A20: Both Third-Party Organised Educational Conferences (see the Glossary) and Procedure	

			Trainings (see the Glossary) are a type of Third Party Organised Educational Events. Therefore, they must comply with Chapter 1. General Criteria for Events; and, where applicable, are subject to the Conference Vetting System (see the Glossary). However, unlike Third Party Organised Educational Conferences, Third Party Organised Procedure Trainings are not subject to the phase out of direct support for the attendance of HCPs. Nonetheless, for Third Party Organised Procedure Trainings the following three criteria shall apply: • Programme: Unlike Third Party Organised Educational Conferences which are theoretical in nature, Third Party Organised Procedure Trainings consist of practical, hands-on trainings, generally involving more than one provider/manufacturer/sponsor. This must be evident by the programme of the Event. The programme, which is often referred to as a "course", rather than a conference or seminar, must be focused on acquiring specific medical skills relevant to certain medical procedures (rather than products, or medical technologies). Examples may include courses aimed at acquiring or improving the Healthcare Professional's skills in minimally invasive surgery; orthopaedic trauma surgery; or the implantation of cardiac rhythm devices; etc. The programme must also include practical demonstrations (and/or actual live surgeries, where allowed). Examples of practical demonstrations may include surgery simulations where technologies are used on cadavers; skin models; synthetic bones; cath labs; etc. • Venue: Third Party Organised Procedure Trainings are typically organised in a clinical environment, as opposed to, e.g., a classroom setting. For the avoidance of doubts, the adjective "clinical" includes places suitable for the simulation of medical procedures, rather than just the medical treatment of real patients.	

			Examples of clinical environment include hospitals or clinics, where medical treatment on real patients may be given; as well as conference rooms which are appropriately set up to simulate medical procedures, for example with the presence of medical technologies to be used on cadavers; skin models; synthetic bones; etc. • Stand-alone event: Third Party Organised Procedure Trainings must stand-alone. Where the majority of the Training is not given in a clinical environment, for example, where the Training is organised in connection, adjacent to or at the same time as a larger Third Party Organised Educational Conferences, that Training will not qualify as a Third Party Organised Procedure Training, as defined in the Code. **Q21: In the definition of Third Party Organised Procedure Training, what is meant by "Proctorship" and "Preceptorship"? Further, do Proctorships and Preceptorships require CVS approval before they can be provided and/ or supported by a Member Company? (added in November 2016)** A21: For the purpose of the Code both Proctorship and Preceptorship are types of clinician-to-clinician training funded by a Member Company. Proctorship is where the trainee clinician performs a procedure under the supervision of another clinician and where the trainee clinician has primary responsibility for the patient undergoing the procedure. Preceptorship is where the supervising clinician oversees the procedural training of the trainee clinician and the trainee does not have primary responsibility for the patient undergoing the procedure. Such Proctorships and Preceptorships normally take place on HCO premises and are not subject to CVS approval as it is not considered to be either a Third Party Organised Educational Event or a Third Party Organised Procedural Training. **3. Transition Period: Support of Individual Healthcare Professionals to Third Party**	

			Organised Educational Events Member Companies may provide financial support directly to individual Healthcare Professionals to cover the costs of attendance at Third Party Organised Educational Events where this is permitted under national laws, regulations and professional codes of conduct. Such support shall be in accordance with the following rules: • Financial support must comply with the criteria provided in Chapter 1: General Criteria for Events. In addition Member Companies may pay the registration fee. • Where applicable, the Third Party Organised Educational Event has approval via the Conference Vetting System (see the Glossary). • For financial support to Third Party Organised Educational Events Member Companies must apply the requirements governing conduct and attendance at such Third Party Organised Educational Event in the country where the Healthcare Professional carries on their profession and give due consideration to the requirements in the country where the meeting is being hosted.	
Travel & Lodging; Venue	**Section VI – Travel & Lodging; Venue** **Key Concepts:** ✓ Companies may pay for Health Care Professionals' modest and reasonable travel and lodging costs to attend a Company-conducted program or meeting under certain circumstances. ✓ In all instances, there must be objective, legitimate reasons that support the need for travel and lodging for Health Care Professionals. There may be programs or meetings for which a	**IX. Travel Associated with Health Care Professional Business Interactions** A Company's interactions with Health Care Professionals as outlined in Sections III, IV, V and VI of this Code may require Individual Health Care Professionals to travel within China or internationally. Accordingly, Companies may provide reasonable travel expenses for Individual Health Care Professional travel consistent with the limitations in this section and any additional restrictions on the provision of travel to Health Care Professionals as listed in Sections III, IV, V, and VI, as applicable. As described in Section IV above, starting January 1, 2018, Companies can no longer engage in Direct Sponsorship of	**2. Event Location and Venue** *(in Chapter 1: General Criteria for Events)* The Event location and venue should not become the main attraction of the Event. For the location and the venue, Member Companies must take into account at all times the following considerations: • Potential adverse public perceptions of the location and venue for the Event. The perceived image of the location and venue must not be luxury, or tourist/holiday-oriented, or that of an Entertainment venue. • The Event location and venue should be	

	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, 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. **When does the Code permit a Company to pay for a Health Care Professional's travel & lodging?** • To provide consulting services to a Company, if the Health Care Professional is subject to an executed consulting agreement and there is an objective, legitimate reason that supports the Health Care Professional's in-person participation (see Section II) • To attend a Company-conducted training or education program concerning Medical Technologies, if there is an objective, legitimate reason that supports the Health Care Professional's in-person attendance (see Section III) • To speak on a Company's behalf at a Third-Party Program, subject to the conditions described in Section IV • Companies may determine that there are other types of programs or meetings that qualify to cover a Health Care Professional's modest travel and lodging costs to attend. Some examples could include plant tours and	individual Health Care Professionals to attend Third-Party Educational Conferences, including the provision of travel expenses for individual Health Care Professionals to travel to Third-Party Educational Conferences. (Note: Section IV of this Code describes limited circumstances in which Companies can cover reasonable travel costs to support the attendance of Health Care Professionals at Third-Party Organized Procedure Training Courses after the January 1, 2018 phase-out date for Direct Sponsorships.) A. ***Purpose*.** There must be a bona fide scientific, educational, or business purpose to provide travel to an Individual Health Care Professional and the length of the trip must be commensurate with this purpose. Companies must not provide recreational activities, side trips, city tours, or any other activities that do not support the bona fide professional interest of the travel. B. ***Location*.** Companies should adopt objective criteria to select locations and venues. Local alternatives should be considered before sponsoring travel for Individual Health Care Professionals. Further, Companies are encouraged to consider China-based alternatives before sponsoring international travel for Individual Health Care Professionals. C. ***Reasonable Expenses*.** Companies may provide for reasonable flights, hotels, meal and incidental expenses for Individual Health Care Professional travel. D. ***Participants*.** A Company may not provide travel or other expenses for guests of Individual Health Care Professionals, or for any other person who does not have a bona fide professional interest in the activity requiring travel. E. ***Reimbursement*.** Companies are encouraged to pay for flights/hotels directly where practical. Reimbursement of travel-related	centrally located when regard is given to the place of residence of the majority of invited participants. • The need for ease of access for attendees. • The Event location and venue should be in or near a city or town which is a recognised scientific or business centre, suitable for hosting an Event which is conducive to the exchange of ideas and the transmission of knowledge. • Member Companies must take into account the season during which the Event is held. The selected time of year must not be associated with a touristic season for the selected geographic location. **Q6: Can a Member Company organise or support an Event at a hotel or resort that offers significant leisure facilities such as golf, casino or ski/ water sports? (Amended in June 2017)** A6: In principle no. It is not appropriate for a Member Company to organise or support Events at hotels or resorts renowned for their entertainment facilities or centred around recreational or sporting activities such as golf, private beach or ski/water sports. Exceptions might be considered for venues well adapted to business meetings in an otherwise compliant geographic location where there is a compelling need to use the chosen venue, for example, a lack of alternative venues or genuine safety or security issues. In certain circumstances, hotel accommodation separate from the Third-Party Organised Event venue might be required for compliance Where an exception is considered, the Event's promotional material should not feature the on-site leisure aspects of the conference venue as a key attraction and the Event's agenda should be arranged in such a way that attending Healthcare Professionals would not be free to make use of	

	demonstrations of equipment, among others. In all instances, there must be an objective, legitimate reason that supports the Health Care Professional's in-person attendance at the program. **When does the Code prohibit a Company from paying for a Health Care Professional's travel & lodging?** • To attend any Company meeting without an objective, legitimate reason that supports the need for travel • To attend a Third-Party Program (see Section IV) --- • **Modest and Reasonable Travel and Lodging.** 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 establish controls on the timing and location of travel arrangements for Health Care Professionals. • **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. • **Setting.** The setting for a Company-conducted program or meeting of Health	expenses over RMB 500 should not be made in cash. **Q20 Section IX of the Code indicates that Companies can reimburse HCPs for travel-related expenses of RMB500 and under; however, Section IV of the Code (regarding sponsorship of HCPs to attend third-party educational conferences) indicates that Companies cannot reimburse HCPs' travel expenses directly to the HCP. Are these provisions consistent?** Yes, these provisions are consistent. Section IX of the Code is intended to provide general guidance regarding all instances of a Company's payment for HCP travel, but it also notes that additional principles may apply if Companies elect to provide travel expenses for individual HCPs attending third-party educational conferences (outlined in Section IV of the Code). For Third-Party Educational Conferences occurring prior to January 1, 2018, the only travel-related expenses intended to be covered by Section IV's prohibition on direct reimbursement to an HCP attending a third-party educational conference are hotel, airfare, or train expenses. There may be exceptional circumstances where other modest transportation expenses (for example, cab fare to and from the airport to a conference venue or airfare ticket change fees) are incurred by the HCP. These limited transportation expenses are not intended to be covered by Section IV and can be reimbursed, subject to Section IX's RMB500 cap and subject to Companies' internal procedures and controls for reviewing and approving such expenses. For Third-Party Educational Conferences occurring on or after January 1, 2018, Companies can no longer reimburse Health Care Professionals' travel-related expenses to attend Third-Party Educational Conferences.	the leisure and sporting facilities during any significant part of a normal working day. Further, where hotels require additional payment to use the leisure or sporting facilities, Member Companies may not make such payments on behalf of the Healthcare Professionals. For reasons of perception, cruise ships or hotels with on-site casinos are under no circumstances compliant with the Code, either as an Event venue or for accommodation for Healthcare Professionals. **Q7: Under the Code, what is meant by "ease of access" in relation to Event location and venue?** A7: When originating location of the majority of attendees is considered, Event location and venue need to be in close proximity to an airport and / or train station with appropriate international connections, with associated reliable ground transportation infrastructure to the venue. **Q8: Under the Code, how does the "season" impact evaluation of Event location? (Amended in March 2019)** A8: Even assuming a location or venue meets all other applicable requirements under the Code, geographic locations renowned primarily as seasonal vacation or holiday destinations (for example, ski-, island-, or beach resorts) are still not appropriate locations during the season in question. For this purpose, in Europe, the ski season is considered to run from December 20 - March 31 and the summer season from June 15 - September 15. Equivalent, seasonally adjusted dates apply in other regions of the world. Member Companies must not support or organise Events at these locations if they take place during those seasons, even if only in part. **4. Reasonable Hospitality** Member Companies may provide reasonable	

	Care Professionals should always be conducive to the exchange of information and should not be the main attraction of the event. Companies should consider the following principles when choosing a setting: ✓ The setting should be 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 state laws. Ski resorts, island or beach resorts, and other resorts in geographic locations renowned primarily as seasonal vacation destinations may not be appropriate during the season in question. Companies may assess the appropriateness of these venues differently, for example: • If the Company is headquartered or has a significant facility in one of these geographic areas; • If the Company is hosting a strictly local Company-conducted program attended by local Health Care Professionals (for example, a technical training program held in Hawaii for local Hawaiian physicians); or		hospitality to Healthcare Professionals in the context of Company Events and Third Party Organised Educational Events but any hospitality offered must be subordinate in time and focus to the Event purpose. Member Companies must in any event meet the requirements governing hospitality in the country where the Healthcare Professional carries on their profession and give due consideration to the requirements in the country where the Event is being hosted. The Code seeks to find a balance between the courteous and professional treatment of Healthcare Professionals by Member Companies, with the desire to avoid even the appearance that hospitality may be used by Member Companies as a means to induce Healthcare Professionals to purchase, prescribe or recommend Member Companies' products. Accordingly, Member Companies must assess what is "reasonable" in any given situation and regional variations will apply. As a general guideline, "reasonable" should be interpreted as the appropriate standard for the given location and must comply with the national laws, regulations and professional codes of conduct. The term "hospitality" includes meals and accommodation and it is important that Member Companies differentiate between "hospitality" which is permitted and Entertainment which is not. Please refer to the Glossary for the definition of Entertainment. Member Companies may not pay for or reimburse Healthcare Professionals' lodging expenses at top category or luxury hotels. For the avoidance of doubt, if the Event venue is a hotel which complies with the requirements of the Code, it would be acceptable for Member Companies to offer participants meals and accommodation at the same hotel. However, accommodation and/ or other services provided to Healthcare Professionals should not cover a period of stay beyond the official duration of the Event.	

	• If the Company is hosting a meeting held in conjunction with a Third-Party Program. **Q9 – Does the Code permit Companies to pay for travel to attend Company-conducted training or education program?** Yes. The Code contemplates that a Company may bring Health Care Professionals together at a central location to deliver training and education concerning Medical Technologies, which may make out-of-town travel necessary. **Q10 – Does the Code permit a Company to pay for travel to a Company-conducted general educational program not concerning a Medical Technology?** No. It may be appropriate for a Company to conduct a general educational session not concerning a Medical Technology, but it is not the type of program for which Company-supported travel would be appropriate under the Code. **Q10a – What types of controls should Companies consider with respect to limiting Health Care Professionals' travel and lodging costs associated with a Company-conducted meeting?** Companies may consider many types of controls with respect to HCP travel and lodging. Some examples include, among others: limiting the duration of Company-funded travel and lodging to arrangements that are the closest in time and in location to the Company program or meeting for which the Health Care Professional is traveling; applying limits to class of travel and lodging; placing restrictions on how travel and lodging arrangements can be changed, by whom, and whether the Company or the HCP must pay for any related change fees or additional costs.		**Q11: Is it acceptable to offer a cash advance by way of a cheque or bank transfer payable to a Healthcare Professional for a specific amount to cover all or part of the Healthcare Professionals' travel or accommodation expenses for attendance at the Event?** A11: It is not acceptable to make an advance payment to a Healthcare Professional to cover prospective expenses. Payments should generally be made to the supplier/vendor or intermediary agency. Alternatively Member Companies may reimburse individual Healthcare Professional expenses retrospectively against original invoices or receipts. **5. Travel** Member Companies may only pay or reimburse for reasonable and actual travel. Travel provided to Healthcare Professionals should not cover a period of stay beyond the official duration of the Event. For air travel, in principle, this means that Member Companies can only pay or reimburse economy or standard class unless the flight time is of a duration of greater than 5 hours including connection flights, in which case business class can be considered. First class is never appropriate. **Q12: May Member Companies offer to cover the travel and accommodation expenses of Healthcare Professionals for periods that extend beyond the duration of the Event programme attended?** A12: Generally, travel and accommodation support offered by Member Companies to Healthcare Professionals should be tailored to the duration of the Event. Member Companies must always keep in mind the impression which may be created by the arrangements for any meeting.	

Providing Modest Meals and Refreshments To Health Care Professionals	**Section VII – Providing Modest Meals and Refreshments To Health Care Professionals** **Key Concepts:** ✓ Meals and refreshments provided to Health Care Professionals must be provided in a manner and place that are conducive to the presentation of scientific, educational, or business information. ✓ Meals and refreshments should be subordinate in time and in focus to the discussion and presentation of scientific, educational, or business information. A Company occasionally may 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 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 and 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 or an off-site space that is conducive to the discussion, such as a restaurant. • **Participants.** A Company may provide a meal or refreshments only to Health Care Professionals who actually attend and have a bona fide purpose for attending the meeting. A Company may not provide a meal or	**VIII. Modest Meals Associated with Health Care Professional Business Interactions** 1. A Company's business interactions with Health Care Professionals may involve the presentation of scientific, educational, or business information and include, but are not limited to, the different types of interactions described in Sections III through VI of this Code of Ethics. Such exchanges may be productive and efficient when conducted in conjunction with meals. Accordingly, modest meals may be provided as an occasional business courtesy consistent with the limitations in this section. A. ***Purpose*.** The meal should be incidental to the bona fide presentation of scientific, educational, or business information and provided in a manner conducive to the presentation of such information. The meal should not be part of an entertainment or recreational event. B. ***Setting and Location***. Meals should be in a setting that is conducive to bona fide scientific, educational, or business discussions. Meals may occur at the Health Care Professional's place of business. However, in some cases the place of business may be a patient care setting that is not available for, or conducive to, such scientific, educational, or business discussions. In other cases, it may be impractical or inappropriate to provide meals at the Health Care Professional's place of business, for example, (1) where the Medical Technology cannot easily be transported to the Health Care Professional's location, (2) when it is necessary to discuss confidential product development or improvement information, or (3) where a private space cannot be obtained on-site. C. ***Participants*.** A Company may provide a meal only to Health Care Professionals		

	refreshments: ✓ For an entire office staff where everyone does not attend the meeting; ✓ If a Company representative is not present (such as a "dine & dash" program); 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. **ESTABLISHING MEAL POLICIES** Companies are strongly encouraged to develop policies on providing modest and occasional meals to Health Care Professionals. This may include establishing a per meal spending limit for meals and refreshments with a Health Care Professional and whether the amount should vary to account for geographic areas (for example, New York City) that are generally more expensive. **Q10b – For Companies that have chosen to place per-meal spending limits on meals with Health Care Professionals, does AdvaMed recommend a specific dollar value?** No. AdvaMed does not recommend a specific dollar amount for a per-person spending limit on meals with Health Care Professionals. AdvaMed maintains benchmarking and best practices information on its website, and Companies take differing factors into account in establishing their spending limits. The fact that a meal costs less than a Company's spending limit does not mean the meal complies with the Code; rather, all meals and refreshments provided to HCPs must meet all of the requirements of Section VII of the Code.	who actually attend the meeting. A Company may not provide a meal for an entire office staff where everyone does not attend the meeting. A Company also may not provide a meal where its representative is not present. A Company may not pay for meals for guests of Health Care Professionals or for any other person who does not have a bona fide professional interest in the information being shared at the meeting. 2. ***Other principles.*** Depending on the type of business interaction or meeting, additional principles may apply, as described in other sections of this Code of Ethics. Specifically: A. Section III: Company-Conducted Product Training and Education. B. Section IV: Supporting Third-Party Educational Conferences. C. Section V: Sales, Promotional, and Other Business Meetings. D. Section VI: Consulting Arrangements with Health Care Professionals.		

	Q11 – Is a general discussion to build good business relationships an appropriate purpose for providing a meal to a Health Care Professional? No. A meal should only be provided to a Health Care Professional as part of a bona fide business discussion. This includes, for example, discussions on Medical Technology development and improvement, pricing, or contract negotiations, among other legitimate topics. The discussion should account for most of the time spent during the meal. A casual get-together or the development of general goodwill should not be the primary purpose of a meal with a Health Care Professional.			
Educational & Patient Benefit Items; Prohibition on Gifts	**Section VIII – Educational & Patient Benefit Items; Prohibition on Gifts** **Key Concepts:** ✓ Companies may not provide branded, promotional items or "gifts" to Health Care Professionals. ✓ Companies may provide modest, appropriate educational items or patient benefit items to Health Care Professionals. A Company may occasionally provide modest, appropriate educational items to Health Care Professionals that benefit patients or serve a genuine educational function for Health Care Professionals. Companies may not provide gifts to Health Care Professionals. This means that a Company 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,	**X. Educational Items and Branded Promotional Items** 1. As permitted by applicable laws and regulations, a Company occasionally may provide items to Health Care Professionals that benefit patients or serve a genuine educational function for Health Care Professionals. Other than medical textbooks or anatomical models used for educational purposes, any such item should have a modest fair market value. A Company may not provide items that are capable of use for non-educational or non-patient-related purposes, for example, a smartphone, tablet computer, laptop, etc. 2. Companies may provide branded promotional items of minimal value to Health Care Professionals related to the Health Care Professional's practice. Such items could include stationery items, USB drives, mouse pads, and other items bearing a company's logo. Such items should have a value of RMB 200 or less. 3. This section is not intended to address the legitimate practice of providing products for	**Chapter 8: Educational Items and Gifts** Member Companies exceptionally may provide inexpensive educational items and/or gifts, in accordance with national laws, regulations and industry and professional codes of conduct of the country where the Healthcare Professional is licensed to practise. Member Companies may only provide such educational items and/or gifts in accordance of the following principles: a. Educational items and/or gifts may be provided but these must relate to the Healthcare Professional's practice, or benefit patients, or serve a genuine educational function. b. No educational items and/or gifts should be provided in response to requests made by Healthcare Professionals. c. Educational items and/or gifts must not be given in the form of cash or cash equivalents. d. Educational items and/or gifts must be modest in value, and can be branded or non-branded items. e. A Member Company may occasionally	**6. Educational support items** Members must ensure that sales of products and services are never made on the basis of a HCP receiving anything of value from a Member. Members may occasionally provide to HCPs branded or non-branded items of minimal value, in addition to medical textbooks, medical journals, and anatomical models. These items must serve a genuine educational function relating to the HCP's practice or otherwise benefit patients.

	laptop, or other mobile device capable of personal use) ✓ Branded, 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, pens, notepads, mugs, and other items with a Company or product name or logo) ✓ Gifts such as cookies, wine, flowers, chocolates, 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. ✓ A Company may not raffle or give away an item that it could not otherwise give a Health Care Professional under the Code. **Q12 – What are "modest" educational items?** Other than medical textbooks or anatomical models used for educational purposes, any educational item provided to a Health Care Professional should have a fair market value of less than US $100. **Q13 – What is an item for the benefit of patients?** Items considered to be intended for the benefit of patients could include starter kits, and educational brochures, for example. With respect to starter kits, a Company should adopt appropriate safeguards regarding the provision of such kits to ensure they are not offered as an unlawful inducement. **Q14 – May a Company or its representative provide a gift to recognize a life event for a**	evaluation and demonstration purposes, which is addressed in Section XII. 4. Under no circumstances should companies provide the following items to Health Care Professionals: alcohol, tobacco, cash, gift cards, or other cash equivalents. **Q21 Would AdvaMed provide a list of educational items or patient benefit items that are permitted under the Code?** Each Company and each industry sector may have varying educational needs and/or obligations which impact the degree of education Companies must provide to HCPs. Accordingly, it would be difficult for AdvaMed to provide a comprehensive or satisfactory list of all educational items or patient benefit items that are permissible under Section X of the Code. Items appropriate for one sector may not be appropriate for another sector. Companies are encouraged to develop internal procedures for evaluating individual items to assess whether they either serve a genuine educational function for an HCP or benefit patients. Examples of patient benefit items could include educational brochures or kits explaining a disease state or how a particular Medical Technology works. Examples of educational items could include medical textbooks or anatomical models.	provide educational items of greater value to a Healthcare Organisation always provided that the item serves a genuine educational function for the Healthcare Professionals at that Healthcare Organisation and is of benefit to patients. Such items shall not be provided to Healthcare Professionals for their personal use. The item shall also be related to the therapeutic areas in which the Member Company is interested and/or involved. For higher value educational items, Member Companies must maintain appropriate records of their provision of such educational items to Healthcare Organisations. Such items should not be part of the Healthcare Organisation's normal overheads or routine costs of operation. f. Provision of educational items and/or gifts must not improperly reward, incentivise and/or encourage Healthcare Professionals to purchase, lease, recommend, prescribe, use, supply or procure the Member Company's products or services. Member Associations shall provide guidelines on appropriate limits for gifts, in accordance with the principles above. Prize draws and other competitions at Events are permissible if the prize awarded complies with Chapter 8. Educational Items and Gifts. In addition, it must comply with national laws, regulations and industry and professional codes of conduct. This Chapter is not intended to address the legitimate practice of providing appropriate Evaluation Products, Demonstration products or Samples. For guidance on how Member Companies may provide Evaluation Products, Demonstration products or Samples, please refer to Chapter 6: Research and Chapter 9: Demonstration Products and Samples, as applicable.	

	Health Care Professional, such as a wedding, birth, anniversary, or death of a family member? No. A Company or its representative acting on the Company's behalf may only provide items to Health Care Professionals that are intended for the benefit of patients or serve a genuine educational function for the Health Care Professional. Gifts such as flowers, fruit baskets, etc. do not meet this requirement, even if provided to recognize a significant life event. **Q14a – Does the AdvaMed Code include any restrictions on a Company employee or representative accepting a gift from a Health Care Professional?** No. The AdvaMed Code does not address whether a Company employee or representative can 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.		**Q47 Under Chapter 8, what are examples of items of modest value that are "related to the Healthcare Professional's practice or for the benefit of patients".** A47 Stationery items, calendars, diaries, computer accessories for business use and clinical items such as wipes, nail brushes, surgical gloves and tourniquets are examples of modest value items that could be appropriately provided as gifts to Healthcare Professionals provided their value falls within the maximum value prescribed under national laws, regulations and industry and professional codes of conduct. Food, alcohol and items which are primarily for use in the home or car are not appropriate as they are not related to the Healthcare Professional's practice nor are they for the benefit of patients. **Q48 May a Member Company provide a small gift to a Healthcare Professional to mark significant life events such as a marriage, birth, birthday or death?** A48 The Code restricts the types of gift that may be given to a Healthcare Professional and it would not be appropriate to give gifts to mark significant life events such as a marriage, birth or birthday. However, in the case of death, it is for each Member Company to determine the appropriateness of making a tasteful gift as a mark of respect. **Q49 Where Healthcare Professionals engaged by Member Companies as consultants or speakers decline a professional fee for their services, would it be appropriate for the Member Company to show its appreciation by giving the Healthcare Professional a small gift such as a bottle of wine or a bouquet of flowers?** A49 No, it would not be acceptable for the Member Company to make such a gift because to do so could be open to misinterpretation and would be likely to breach the Principle of Image and Perception. Moreover such gifts would not	

			comply with Chapter 8. Educational Items and Gifts as they neither relate to a Healthcare Professional's practice nor serve an educational function. **Q50 Please provide examples of educational items of greater value that can be provided to Healthcare Organisations under the Code?** A50 Examples of educational items of greater value that can be provided may include medical textbooks or anatomical models, but only if those relate to the therapeutic areas in which the Member Company is interested and/or involved.	
Prohibition on Entertainment & Recreation	**Section IX – Prohibition on Entertainment & Recreation** **Key Concept:** ✓ Companies may not provide entertainment or recreation to Health Care Professionals in any form. A Company may not provide or pay for any entertainment or recreational event for a Health Care Professional. Some examples of entertainment and recreational activities include, among others, theater, sporting events, golf, skiing, hunting, 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.	**VII. Prohibition on Entertainment and Recreation** Company interactions with Health Care Professionals should be professional in nature and should facilitate the exchange of medical or scientific information that will benefit patient care. To ensure the appropriate focus on an educational and/or informational exchange and to avoid the appearance of impropriety, a Company should not provide or pay for any entertainment or recreational event or activity for any Health Care Professional. Such activities include, for example, theater, sporting events, skiing, golf, lavish meals and leisure or vacation trips. These activities also include recreational activities such as city tours organized in conjunction with bona fide travel. Such entertainment or recreational events or activities should not be provided, regardless of: (1) their value; (2) whether the Company engages the Health Care Professional as a speaker or consultant; or (3) whether the entertainment or recreation is secondary to an educational purpose.		**5. Prohibition on gift giving and entertainment** No gifts may ever be given to a HCP, directly or indirectly, including gifts of cash, cash equivalents such as gift cards/certificates, tobacco, or alcohol. Members should not provide, nor arrange, entertainment or recreation to, or for, HCPs. Entertainment or recreation includes, for example, theatre, sporting events, golf, skiing, hunting, and leisure or vacation trips. This Section 5 is not intended to address the legitimate practice of providing educational support items covered in Section 6 (Educational support items) and appropriate sample products and opportunities for product evaluation covered in Section 7 (Evaluation/sample/demonstration products).
Communicating for The Safe & Effective Use of Medical Technology	**Section X – Communicating for The Safe & Effective Use Of Medical Technology** **Key Concepts:** ✓ Access to truthful and non-misleading			

	information relating to Medical Technologies is critical to a Health Care Professional's ability to exercise his or her medical judgment, to provide high-quality care, and to safely use available Medical Technology. ✓ Companies are encouraged to apply the principles outlined in this section and develop related controls. Health Care Professionals may use a product for any use that they determine is in the best medical interests of their patients. This includes uses that are contained in the Medical Technology's labeling or otherwise consistent with such labeling, but it could also include uses that are not approved or cleared (i.e. "off-label" uses). As recognized under U.S. law and by the FDA, off-label use of these Medical Technologies can be an important part of medical practice and may even constitute a medically recognized standard of care. Access to truthful and non-misleading information relating to Medical Technologies, including information on both on- and off-label uses, is critical to a Health Care Professional's ability to exercise his or her medical judgment in the best interest of patients, to provide high-quality care, and to safely use available Medical Technology. Industry appropriate communications of such information can include, among other activities: • Proper dissemination of peer-reviewed scientific and medical journal articles, reference texts, and clinical practice guidelines; • Presentations at educational and medical meetings regarding clinical trial results or research and development data for an investigational use (taking care that no claims are made regarding safety and effectiveness); and			

	• Discussions with consultants and Health Care Professionals to obtain advice or feedback relating to topics such as unmet patient needs, product research and development, and the like. The following principles recognize industry's responsibility to communicate about medical and scientific information to assist in achieving positive patient outcomes and support of the public health: 1. Company responses that contain information regarding unapproved or uncleared uses should be provided by authorized personnel. 2. Company communications must be truthful and non- misleading. 3. Information related to unapproved or uncleared uses should be identified as such. Companies are encouraged to develop policies and controls that apply the principles above and that incorporate the requirements of applicable guidance (for example, judicial decisions related to appropriate product communications, guidance from the FDA, and the like).			
Provision of Health Economics & Reimbursement Information	**Section XI – Provision of Health Economics & Reimbursement Information** **Key Concepts:** ✓ Medical Technology Companies may support patients in obtaining access to a Company's Medical Technology by providing Health Care Professionals with timely and complete coverage, reimbursement, and health economics information. ✓ Medical Technology Companies may not, however, interfere with a Health Care Professional's independent clinical decision making or provide coverage, reimbursement			

	and health economics support as an unlawful inducement. As Medical Technologies have become increasingly complex, so have 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: • A Company may provide this information regarding its Medical Technologies if it is accurate and objective. • A Company may also collaborate with Health Care Professionals, patients, 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, 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 Medicare and other			

	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 regarding 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 buy or use 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 • Facilitating patient access to the 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 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. A Company may not interfere with a Health Care Professional's independent clinical decision making or provide coverage, reimbursement, and health economics support as an unlawful inducement. For example, a Company should not provide free services that eliminate an overhead or other expense that a Health Care Professional would otherwise have incurred as part of its business operations. Further, a Company should not suggest mechanisms for billing for services that are not medically necessary, or for engaging in fraudulent practices to achieve inappropriate payment.			
Demonstration, Evaluation, and Consigned Products	**Section XII – Demonstration, Evaluation, and Consigned Products** **Key Concepts:** ✓ Companies may provide reasonable quantities of products to Health Care Professionals at no charge to permit Health Care Professionals to evaluate and assess whether to purchase the product. ✓ Companies may also provide Health Care Professionals with non-sterile demonstration units to use in educating patients about the product and its use.		**Chapter 9: Demonstration Products and Samples** **1. General Principles** Member Companies may provide their own products as Demonstration Products and / or Samples at no charge in order to enable Healthcare Professionals and/or Healthcare Organisations to evaluate and /or familiarise themselves with the safe, effective and appropriate use and functionality of the product and/or related service and to determine whether, or when, to use, order, purchase, prescribe or recommend the product and/or service in the future. Demonstration Products and/or Samples may be either single- or multiple-use products. Member Companies may also provide products from another company in conjunction with those products if those other company's products are required in order to properly and effectively	

			demonstrate, evaluate or use the Member Company's products, e.g. computer hardware and software produced by a company other than the Member Company. Provision of Demonstration Products and / or Samples must not improperly reward, induce and/or encourage Health Care Professionals to purchase, lease, recommend, prescribe, use, supply or procure Member Companies' products or services. Any supply of products shall always be done in full compliance with applicable national laws, regulations and industry and professional codes of conduct with Member Companies maintaining appropriate records in relation to the provision of these products. Member Companies shall in all cases maintain appropriate records in relation to the provision of Demonstration Products and / or Samples to Healthcare Professionals and / or Healthcare Organisations, for example recording proof of delivery for any Demonstration Products and/or Samples provided and receipt of return for multiple-use Demonstration Products and/or Samples. Member Companies shall clearly record in the Member Company's records as well as clearly disclose to Healthcare Professionals and/or Healthcare Organisations the no-charge basis and other conditions applicable for the supply of such Demonstration Products and / or Samples no later than the time of the supply. The disclosure to Healthcare Professionals and Healthcare Organisations shall be in writing. This Chapter is limited to the provision of Demonstration Products and/or Samples and related services at no charge and is not intended to apply to provision of products or related services under any other arrangements, for example (but not limited to) provision within the framework for clinical trials and/or other research or commercial supplies by way of rebates or pricing incentives in a public procurement context.	
	A. <u>Demonstration & Evaluation Products</u>	**XII. Evaluation and Demonstration Products**	**2. Demonstration Products (Demos)**	**6. Evaluation/sample/demonstration products**

	Providing products 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, 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 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 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 amount reasonably necessary for the adequate evaluation of the products under the circumstances. • **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 and consistent with any applicable transparency reporting requirements.	1. Providing products to Health Care Professionals at no charge for evaluation or demonstration purposes can benefit patients in many ways. These benefits include improving patient care, facilitating the safe and effective use of products, improving patient awareness, and educating Health Care Professionals regarding the use of products. Under certain circumstances described below, a Company may provide reasonable quantities of products to Institutional Health Care Professionals at no charge for evaluation and demonstration purposes. 2. Companies should ensure that the provision of evaluation and demonstration products is neither conditioned on buying products or services, nor linked to other conditions that might affect fair competition. 3. This section is limited to providing evaluation and demonstration products only and is not intended to address any other arrangement. 4. Company products that may be provided to Health Care Professionals for evaluation include single use (e.g., consumable or disposable products) and multiple use products (sometimes referred to as "capital equipment"). These products may be provided at no charge to allow Health Care Professionals to assess the appropriate use and functionality of the product and determine whether and when to use, order, purchase, or recommend the product in the future. Company products provided for evaluation are typically expected to be used in patient care. A. *Single Use/Consumables/Disposables.* The number of single use products provided at no charge should not exceed the amount reasonably necessary for the adequate evaluation of the products under the circumstances. The terms of an evaluation of single-use devices should be	Member Companies may provide examples of their products to Healthcare Professionals and / or Healthcare Organisations in the form of mock-ups (such as unsterilised single use products) that are used for Healthcare Professionals and patient awareness, education and training. For example, a Healthcare Professional may use a Demonstration Product to show a patient the type of technology which will be implanted in the patient or may use the Demo to train other Healthcare Professionals in the use of the product. Demonstration Products are not intended for clinical use in any patient care nor are they intended for on-sale or other transfer. Member Companies shall clearly record in the Member Company's records as well as clearly disclose to Healthcare Professionals and/or Healthcare Organisations the no-charge basis and other conditions applicable for the supply of such Demonstration Products no later than the time of the supply. It is recommended that the disclosure to Healthcare Professionals and Healthcare Organisations be in writing. **3. Samples** Member Companies may provide a reasonable number of Samples at no charge to allow Healthcare Professionals and/or Healthcare Organisations to familiarise themselves with the products and/or related services, to acquire experience in dealing with them safely and effectively in clinical use and to determine whether, or when, to use, order, purchase, prescribe or recommend the product and/or service in the future. For Samples, which are single-use products, the quantity provided for purposes of familiarisation must not exceed the amount reasonably necessary for the Healthcare Professionals / Healthcare Organisation to acquire adequate experience in dealing with the products.	A Member may provide medical technology products to HCPs free of charge for evaluation and demonstration purposes, provided that: (a) they are not given or intended as an improper inducement; (b) only reasonable quantities of evaluation products are supplied to HCPs to familiarize them with the products and enable them to gain experience with the products in their practice; (c) they are only provided in quantities and/or for a duration that is reasonably determined to enable adequate evaluation by the HCP; (d) they are appropriately documented and accounted for by the Member, including to minimize any risk of the HCP being able to financially benefit from the products; and (e) if not meant for human use or diagnostics purposes, they are marked "Not for human use" or "Not for diagnostic purposes" or with similar language to indicate that the products are solely for demonstration purposes and that they cannot be sold or used for human clinical studies or routine patient management.

	○ 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 similar considerations. ○ The **terms of an evaluation** of such multiple use products should be set in advance in writing, specifying the length of the evaluation period and addressing products that have not been 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 typically 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. ○ Demonstration products typically are not intended to be used in patient care. ○ Demonstration products typically are identified as not intended for patient use through designations like “Sample” or	disclosed in writing to the Health Care Professional. If applicable laws, regulations or institutional rules specifically require disclosure to a different body, then disclosure should be made in accordance with the applicable laws, regulations or rules. B. *Multiple Use/Capital.* Multiple use products provided without transfer of title for evaluation purposes should be furnished only for a period of time that is reasonable under the circumstances to allow an adequate evaluation. The terms of an evaluation of such multiple use products should be set in advance and in writing with the Institutional Health Care Professional, not internal departments or individual Health Care Professionals. Companies should retain title to such multiple use products during the evaluation period and should have a process in place for promptly removing such multiple use products from the Health Care Professional's location at the conclusion of the evaluation period unless the Health Care Professional purchases or leases the products. C. *Demonstration.* Company demonstration products are typically unsterilized single use products or mock-ups of such products that are used for Health Care Professional and patient awareness, education, and training. For example, a Health Care Professional may use a demonstration product to show a patient the type of device that will be implanted in the patient. Demonstration products typically are not intended to be used in patient care. Demonstration products also are typically identified as not intended for patient use by use of such designations as "Sample," "Not for Human Use," or other suitable designation on the product, the product	For Samples, which are multiple-use products, the specific length of time necessary for a Healthcare Professional to familiarize him / herself with the product will depend on the frequency of anticipated use; the duration of required training; the number of Healthcare Professionals who will need to acquire experience in dealing with the product and similar considerations. Member Companies shall in all cases ensure that they retain title to multiple- use Samples and that they have a process in place for promptly removing such multiple use Samples from the Healthcare Professional’s location at the conclusion of the familiarisation period.	

	"Not for Human Use" on the product, the packaging, or documentation that accompanies the product. **Q15 – What are examples of appropriate reasons for providing single-use or multiple-use evaluation products to a Health Care Professional?** Examples may include the Health Care Professional may have not recently purchased or used the products (i.e. the Health Care Professional is not familiar with the product); or the product may be marketed for a new indication or new surgical technique; among other reasons. **Transparency.** A Company should consider whether federal or state law (for example, the U.S. Physician Payments Sunshine Act) requires reporting the value of evaluation products provided to Health Care Professionals. **Q16 – What additional asset management principles should companies consider adopting?** In addition to the principles outlined in Section XII of the AdvaMed Code, Companies may also want to consider other controls regarding asset management, including product provided at no charge (for example, demonstration and evaluation units, loaned products, inkind grants/donations) or for charge (for example, rental products, placed capital, consignment product). Possible examples of these controls may include the following: • Written policies, procedures and work instructions that govern when assets can be supplied to an HCP, including related auditing and monitoring; • Specialized training and education for Company representatives; and • Clear documentation, recordkeeping, and	packaging, and/or documentation that accompanies the product. 5. Companies should provide Health Care Professionals with documentation and disclosure regarding the no-charge status of evaluation and demonstration products unless applicable laws, regulations or institutional rules specifically require disclosure to a different body, in which case disclosure should be made in accordance with the applicable laws, regulations or rules.		

	asset tracking requirements, including any obligations to compensate or return Medical Technology to the Company, as appropriate.			
	B. <u>Consigned Products</u> 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 space rental terms (if applicable). • 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.			
Company Representatives Providing Technical Support in the Clinical Setting	**Section XII – Company Representatives Providing Technical Support in the Clinical Setting** **Key Concepts:** ✓ Company representatives can play an important role in the clinical setting by providing technical support on Medical Technology. ✓ Companies are encouraged to apply the principles outlined in this section and develop related controls.	**XIII. Third Party SMI Relationships** Companies are encouraged to adopt a Third Party SMI Management Compliance Program in addition to overall compliance program, applicable to all relevant personnel, including a Company's senior leadership. Taking into account a variety of risk-based factors, as well as local applicable laws; such programs may include the following elements: A. Written Policy/Procedure. B. Risk Assessment.		

	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. 3. Company representatives should not interfere 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. A Company's technical support should not eliminate an overhead or other expense that the Health Care Professional should otherwise incur while providing patient care.	C. Due Diligence Program. D. Written Contract. E. Training and Education. F. Monitor/Audit. G. Appropriate Corrective Action.		