

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

	<u>AdvaMed Code of Ethics on Interactions with U.S. Health Care Professionals</u>	<u>AdvaMed Code of Ethics on Interactions with Health Care Professionals in China</u>	<u>MedTech Europe Code of Ethical Business Practice</u>	<u>APACMed Code of Ethical Conduct for Interactions with Health Care Professionals</u>
	Effective July 1, 2009	Effective January 1, 2016	Becomes Effective January 2017	Effective as of 1 January 2016
			Note: The MedTech Europe Code of Ethical Business Practice also contains the Procedural Framework, the Dispute Resolution Principles and the Disclosure Guidelines. These principles discuss trade association rules and anti-trust principles and as such are not included in this analysis.	
Preamble Language, Purpose, Scope	<p>I. Preamble</p> <p>Defines the following terms:</p> <ol style="list-style-type: none"> Medical Technologies – Medical products, technologies and related services and therapies used to diagnose, treat, monitor, manage and alleviate health conditions and disabilities. The Preamble distinguishes between Medical Technologies that are highly dependent upon “hands on” HCP interaction from beginning to end, and drugs and biologics, which act on the human body by pharmacological, immunological, or metabolic means. Companies – Companies that develop, produce, manufacture, and market Medical Technologies. Health Care Professional (HCP) – Individuals or entities 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 United States. <p>Describes the scope and types of interactions with HCPs:</p>	<p>I. Preamble: Goal and Scope</p> <p>Defines the terms:</p> <ol style="list-style-type: none"> Companies – Companies that develop, produce, manufacture, and market Medical Technologies. AdvaMed China Board – China-based governance group of AdvaMed member companies’ most senior company executives in China Institutional Health Care Professionals – 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 Individual Health Care Professionals – individuals employed by these institutions 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.... Unless otherwise specified, the term “Health Care Professionals” refers to individuals and institutions. 	<p>PART 1: Guidelines on the Interactions with Healthcare Professionals and Healthcare Organisations</p> <p>Chapter 1: General Criteria for Events</p> <p>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.</p> <p>1. Event Programme</p> <p>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 and for third party Events the agenda should be under the sole control and responsibility of the third party organizer. 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.</p> <p>For Third Party Organised Educational Events, Entertainment must be outside of the educational programme schedule and paid for</p>	<p>A. Purpose and Applicability of Code</p> <p>This Code of Ethical Conduct for Interactions with Health Care Professionals (“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 (“HCPs”).</p> <p>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.</p>

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	<ol style="list-style-type: none"> 1. Promote the advancement of Medical Technologies – developing and improving cutting edge Medical Technologies 2. Enhance the safe and effective use of Medical Technologies – appropriate instruction, education, training, service and technical support 3. Encourage research and education – support of bona fide medical research, education, and enhancement of professional skills to improve patient safety and access 4. Foster donations and giving for charitable purposes, patient and public education <p>Elaborates the Purpose of the Code of Ethics – To ensure that collaborative relationships meet high ethical standards, they must be conducted with appropriate transparency and in compliance with applicable laws. AdvaMed recognizes the obligation to facilitate ethical interactions between Companies and HCPs to ensure that medical decisions are based on the best interest of the patient.</p> <p>See FAQs 1-10 for additional details.</p>	<ol style="list-style-type: none"> 5. Medical Technologies – Medical products, technologies and related services and therapies used to diagnose, treat, monitor, manage and alleviate health conditions and disabilities. The Preamble distinguishes between Medical Technologies that are highly dependent upon “hands on” HCP interaction from beginning to end, and drugs and biologics, which act on the human body by pharmacological, immunological, or metabolic means. 6. Interactions with HCPs <ol style="list-style-type: none"> (a) Promote the advancement of Medical Technologies – developing and improving cutting edge Medical Technologies (b) Enhance the safe and effective use of Medical Technologies – appropriate instruction, education, training, service and technical support (c) Encourage research and education – support of bona fide medical research, education, and enhancement of professional skills to improve patient safety and access (d) Foster donations and giving for charitable purposes, patient and public education (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. 7. Interactions with Third Party Sales and Marketing Intermediaries <p>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, e.g., distributors,</p>	<p>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.</p> <p>2. Event Location and Venue 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 several considerations including potential adverse public perceptions of the location, a central location for invited participants, ease of access, proximity to a recognized scientific or business center, and any conflicts with tourist seasons.</p> <p>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.</p> <p>4. Reasonable Hospitality Member Companies may provide reasonable 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.</p>	<p>B. Ethical Principles</p> <p>Collaborative interactions to preserve independent decision-making and public confidence</p> <p>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.</p> <p>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.</p> <p>1.3 All interactions with HCPs must be:</p> <ol style="list-style-type: none"> (a) conducted in compliance with applicable laws and codes of conduct; (b) based on the best interests of the patient; and (c) appropriately documented. <p>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.</p>

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		<p>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”).</p> <p>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.</p> <p>8. Purpose of the Code of Ethics – To ensure that collaborative relationships meet high ethical standards, they must be conducted with appropriate transparency and in compliance with applicable laws. AdvaMed recognizes the obligation to facilitate ethical interactions between Companies and HCPs to ensure that medical decisions are based on the best interest of the patient.</p> <p>9. 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. Code is intended to facilitate ethical behavior but is not legal advice. The Code is not intended to define or create legal rights, standards or obligations. Overriding principle: Companies shall encourage ethical business practices and socially responsible industry conduct and shall not engage in any unlawful inducement.</p>	<p>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. Member Companies may not pay for or reimburse Healthcare Professionals’ lodging expenses at top category or luxury hotels.</p> <p>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.</p> <p>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.</p> <p>Part 3: Glossary and Definitions</p> <p>Defines the terms:</p>	

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			Charitable Donations; Company Events; Conference Vetting System (CVS); Code; Disclosure Guidelines; Demonstration Products (Demos); Educational Grants; Employer Notification; Entertainment; Evaluation; Products; Event; Faculty; Financial Hardship; Grants; Guests; Healthcare Organisation (HCO); Healthcare Professional (HCP); Members; Professional Conference Organiser (PCO); Product and Procedure Training and Education Event; Research Grants; Sales, Promotional, and Other Business Meetings; Samples; Scholarships and Fellowships; Third Party Organised Education Events; Third Party Organised Educational Conferences; Third Party Organised Procedure Training; Transition Period.	
Implementation/Certification	<p>II. Code of Ethics Compliance</p> <p>All Companies are strongly encouraged to adopt the Code and implement effective compliance programs.</p> <ol style="list-style-type: none"> Annual Certification – Companies that adopt the Code are strongly encouraged to submit an annual certification that the Company has adopted the Code and has implemented an effective compliance program. Certification should be signed by the CEO and Chief Compliance Officer. AdvaMed will publish a list of Companies that have certified. Contact Information – AdvaMed member Companies shall, and non-members may, supply contact information for the Company’s Compliance Department or anonymous hotline to facilitate reporting of possible violations of the Code. AdvaMed will publish this information on its website. Elements of an Effective Compliance 	<p>II. Code of Ethics Compliance</p> <p>All Companies are strongly encouraged to adopt the Code and implement effective compliance programs.</p> <ol style="list-style-type: none"> Annual Certification – Companies wishing to certify to the Code must submit to AdvaMed an annual certification signed by the most senior executive responsible for 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. 	<p>Introduction</p> <p>Promoting an Ethical Industry MedTech Europe represents the medical technology industry in Europe and is an alliance of two European medical technology industry associations, European Diagnostic Manufacturers’ Association (EDMA) and Eucomed, founded in October 2012. MedTech Europe’s 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 through compliance with applicable laws, setting minimum standards for ethical interactions among health care professionals and promoting ethical interactions with Third Party Intermediaries.</p> <p>Key Legislation Medical Technology in Europe is subject to national and supranational laws and MedTech Europe underlines compliance with laws and regulations having particular relevance to the medical technology industry, such as Safety, Quality and Performance laws, Advertising and Promotion Laws,</p>	<p>C. Effective Code Implementation</p> <p>In order to ensure effective implementation of these Code principles, each Member shall:</p> <ol style="list-style-type: none"> appoint a senior executive responsible for oversight of the Member’s compliance with this Code; adopt practical, useful, and meaningful policies, guidance, and tools intended to ensure compliance with the Code; provide effective and ongoing training and education on the Code and on ethical conduct for interactions with HCPs; ensure that senior management and the Member’s board of directors or other governing body have expressly committed to support the Code; institute appropriate internal monitoring and auditing mechanisms; create safe mechanisms for, and encourage, employees to raise concerns; and require that third party intermediaries (including consultants, distributors, sales

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	<p>Program – Companies are strongly encouraged to follow the seven elements of an Effective Compliance Program:</p> <ol style="list-style-type: none"> Implementing written policies and procedures; Designating compliance officer and compliance committee; Conducting effective training and education; Developing effective lines of communication (including an anonymous reporting function); Conducting internal monitoring and auditing; Enforcing standards through well-publicized disciplinary guidelines; and Responding promptly to detected problems and undertaking corrective action. <p>4. Certification – Companies adopting the Code shall communicate the principles of the Code to employees, agents, dealers, and distributors with the expectation that they will adhere to the Code. The Code is not intended to provide legal advice or to define or create legal rights, standards or obligations.</p> <p><i>See FAQs 11-15 for additional details.</i></p>	<ol style="list-style-type: none"> 2. Contact Information – AdvaMed member Companies shall, and non-members may, supply contact information for the Company’s Compliance Department or anonymous hotline to facilitate reporting of possible violations of the Code. AdvaMed will publish this information on its website. 3. Elements of an Effective Compliance Program – Companies are strongly encouraged to follow the seven elements of an Effective Compliance Program: <ol style="list-style-type: none"> Implementing written policies and procedures; Designating compliance officer and compliance committee; Conducting effective training and education; Developing effective lines of communication (including an anonymous reporting function); Conducting internal monitoring and auditing; Enforcing standards through well-publicized disciplinary guidelines; and Responding promptly to detected problems and undertaking corrective action. 4. Companies 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. 	<p>Data Protection Laws, Anti-corruption laws, Environmental Health and Safety Laws and Competition Laws. National and European Union (EU) competition legislation applies not only to Members in their business operations, but also to MedTech Europe. Members must make every effort to observe EU and national competition laws in all their interactions.</p> <p>Aims and Principles of the Code 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. The Code aims for the advancement and safe and effective usage of Medical Technologies as well as supporting research and education with a series of underlying Principles.</p> <ul style="list-style-type: none"> • The Principle of Image and Perception • The Principle of Separation • The Principle of Transparency • The Principle of Equivalence • The Principle of Documentation <p>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.</p> <p>Administering the Code The Code operates within a Procedural Framework which includes procedures designed to provide an effective and efficient complaint-handling process 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 the national level. For complaints between Member Companies, mediation should be considered</p>	<p>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.</p>

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			<p>seriously before further pursuit of the matter via any formal complaint handling process.</p> <p>The principles outlined in the Procedural Framework aim at supporting Member Associations and are based on principles of proportionality, speed, due process, fairness and transparency. They have been established under the guidance of the MedTech Europe Compliance Panel, acting independently of MedTech Europe.</p> <p>The <i>Conference Vetting System</i> is an independently-managed system which reviews the compliance of Third Party Organised Educational Events with the Code.</p> <p>The Code and the Procedural Framework shall be reviewed when required and at a minimum every 5 years for the Code and every 2 years for the Procedural Framework.</p> <p>Implementation and Transition Period This edition of the Code comes into force as follows:</p> <ul style="list-style-type: none"> • PART 2: The Dispute Resolution Principles 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. <p>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.</p>	

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<p>Company Training and Education</p>	<p>III. Company-Conducted Product Training and Education</p> <p>Companies have a responsibility to make training and education on their products and Medical Technologies available to HCPs.</p> <p>1. The Code defines the following terms:</p> <p>Training: Training on the safe and effective use of Medical Technologies.</p> <p>Education: communicating information directly concerning or associated with the use of Companies' Medical Technologies, e.g., information about disease states and benefits to certain patient populations.</p> <p>Training and Education programs include, but are not limited to, "hands on" training sessions, cadaver workshops, lectures and presentations, and grand rounds. The FDA mandates training and education to facilitate the safe and effective use of certain Medical Technologies.</p> <p>2. Companies should adhere to the following principles concerning training and education:</p> <p>a) Conducive Setting – Programs should be conducted in a setting conducive to the effective transmission of information. Settings may include clinical, educational or conference sites including hotels and other meeting facilities. They may also include the HCPs site.</p> <p>5. Hands-On Training – Hands-on training programs should be conducted at training facilities, medical institutions or laboratories. Training staff should have the proper qualifications and expertise</p>	<p>III. Company-Conducted Product Training and Education</p> <p>1. Definitions: Equivalent to U.S. code, but references to FDA and grand rounds are omitted</p> <p>2. Principles: Equivalent to U.S. code, but "conducive setting" includes statement that it may be appropriate to deliver training in cooperation with an institutional HCP</p>	<p>Chapter 3: Company Events, 2. Product and Procedure Training and Education Events</p> <p>1. General Principles Member Companies may invite Healthcare Professionals to Company Events. Such events include, as defined in the Glossary:</p> <ul style="list-style-type: none"> • Product and Procedure Training and Education Events • Sales, Promotional and Other Business Meetings <p>Company Events should comply with the principles mentioned above and 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.</p> <p>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.</p> <p>Member Companies shall ensure that personnel conducting the Product and Procedure Training and Education Events have the appropriate expertise to conduct such training.</p>	<p>B4. Member organized or supported medical technology training and education</p> <p>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.</p> <p>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 training and education programs, Members may fund the costs of individual HCPs' reasonable travel, modest accommodation, and incidental, modest meals and refreshments.</p> <p>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 spouse or other guests of participating HCPs.</p>

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	<p>to conduct the training. Sales employees may conduct the training if they have the technical expertise.</p> <p>6. Modest meals and refreshments may be provided if they are modest in value and subordinate in time to the training or education.</p> <p>7. Travel and Lodging – Where there are objective reasons to support the need for out-of-town travel to efficiently deliver Training and Education, Companies may pay for reasonable travel and modest lodging costs of the attending HCPs.</p> <p>8. Guests – It is only appropriate for Companies to pay for the meals, refreshments, travel, or other expenses for guests of HCPs or for any other person who does not have a <i>bona fide</i> professional interest in the information being shared at the meeting.</p> <p><i>See FAQs 16-17 for additional details.</i></p>			
Third Party Conferences	<p>IV. Supporting Third-Party Educational Conferences</p> <p><i>Bona fide</i> independent, education, scientific and policymaking conferences including educational conferences sponsored by national, regional, or specialty medical associations and conferences sponsored by accredited continuing medical education providers.</p> <p>Companies may support these through:</p> <p>Conference Grants – Grants must be provided to the conference sponsor to</p>	<p>IV. Supporting Third-Party Educational Conferences</p> <p>Conference Grants – Grants must be provided to the conference sponsor to reduce conference costs, or to training institutions to allow attendance by medical students, residents, fellows and other HCPs in training.</p> <p>Grants may be provided when:</p> <ol style="list-style-type: none"> a. The gathering is primarily dedicated to promoting objective scientific and educational activities, and 	<p>Chapter 2: Third Party Organised Educational Events</p> <p>1. Third Party Organised Educational Conferences</p> <p>Member Companies may support in cash and/or in kind Third Party Organised Educational Conferences which comply with general criteria for events and, where applicable, has approval via the Conference Vetting System. This may be done through grants and other types of funding such as:</p> <ul style="list-style-type: none"> • Educational Grants • Promotional Activity • Satellite Symposia 	<p>B3. Member support of third party educational conferences</p> <p>Member support of HCPs’ education through grants to, or other support of, third party educational programs shall preserve the independence of medical education. Members may support conferences organized by national, regional, or specialty medical associations or institutes or by bona fide medical education providers. Members may purchase advertisements and lease booth space for company displays at such conferences. Conferences must primarily be dedicated to promoting objective medical,</p>

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	<p>reduce conference costs, or to training institutions to allow attendance by medical students, residents, fellows and other HCPs in training.</p> <p>Grants may be provided when:</p> <ol style="list-style-type: none"> The gathering is primarily dedicated to promoting objective scientific and educational activities, and The training institution or conference sponsor selects the attending HCPs in training. <p>Grants should be paid ONLY to organizations with a genuine educational function.</p> <p>The funds may be used to reimburse legitimate expenses for <i>bona fide</i> educational activities.</p> <p>The conference sponsor controls the selection of program content, faculty, methods and materials.</p> <p>Conference Meals and Refreshments – Companies may provide:</p> <ul style="list-style-type: none"> Funding to conference sponsors to support the provision of meals and refreshments to conference attendees Meals and refreshments themselves if they are provided: (1) to all HCP attendees (note exception below) and (2) consistent with applicable standards established by the conference sponsor and any accrediting body. <p>Meals and refreshments provided to fewer than all HCP attendees must meet all the principles stated in Section VIII of the Code, and must be modest in value, subordinate in time and focus</p>	<ol style="list-style-type: none"> The training institution or conference sponsor selects the attending HCPs in training. <p>Grants should be paid ONLY to organizations with a genuine educational function.</p> <p>The funds may be used to reimburse legitimate expenses for <i>bona fide</i> educational activities.</p> <p>The conference sponsor controls the selection of program content, faculty, methods and materials.</p> <p>Support for Conference Attendance by HCPs. Under the following conditions, Companies may sponsor individual HCPs to attend third-party educational conferences:</p> <ol style="list-style-type: none"> Companies cannot reimburse HCPs' travel expenses directly to the HCP; Companies may recommend the list of HCPs to attend educational meetings, from an educational and scientific perspective, and should develop internal procedures to ensure that company-sponsored attendees are properly qualified; Companies should establish internal controls to evaluate and qualify 3rd party service providers (e.g. logistics/travel agencies), if they want to reimburse 3rd party service providers (e.g. logistics/travel agencies) for meeting related expenses. <p>Conference Meals and Refreshments, Faculty</p>	<p>2. Third Party Organised Procedure Training Member Companies may support Third Party Organised Procedure Training either via Educational 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:</p> <ul style="list-style-type: none"> 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. 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. <p>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 rules listed above.</p> <p>Educational Grants may be used as support for Third Party Organised Educational Events in the</p>	<p>scientific, and educational activities and discourse and must be initiated by the conference organizer. Any Member's decision to support must be based on sufficient information to evaluate the medical, scientific, and educational merit of the conference, as well as the appropriateness of the venue and agenda. Conference support shall not be used as a means of inappropriate inducement, and the nature and conditions of support must be appropriately documented.</p> <p>Support by Members can include funding the reasonable costs associated with:</p> <ol style="list-style-type: none"> bona fide education and training of individual HCPs, including the conference registration fees, where the funding is provided to the conference organizer; individual HCPs' reasonable travel and modest accommodation, where there are objective reasons to support the need for out-of-town travel; and incidental, modest meals and refreshments during the course of the conference, provided the meals and refreshments are modest in value and subordinate in time and focus to the educational and/or training purpose of the conference. <p>Where possible, the costs of travel, accommodation, meals and refreshments should not be reimbursed directly to individual HCPs but paid directly to the conference organizer or qualified and reputable third party service providers.</p> <p>Members should not influence the selection of the program content, faculty, educational methods and materials, and preferably also</p>

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	<p>to the purpose of the conference and separate from the educational portion of the conference.</p> <p>Advertising – Companies may purchase advertisements and lease booth space for Company displays.</p> <p>Faculty Expenses – Grants may be made for reasonable honoraria, travel, lodging and modest meals for <i>bona fide</i> faculty members.</p> <p>See FAQs 18-21 for additional details.</p>	<p>Expenses, Advertising – Companies may provide:</p> <ul style="list-style-type: none"> Funding to conference sponsors to support the provision of meals and refreshments to conference attendees Meals and refreshments themselves if they are provided: (1) to all HCP attendees (note exception below) and (2) consistent with applicable standards established by the conference sponsor and any accrediting body. <p>Meals and refreshments provided to fewer than all HCP attendees must meet all the principles stated in Section VIII of the Code, and must be modest in value, subordinate in time and focus to the purpose of the conference and separate from the educational portion of the conference.</p> <p>Advertising – Companies may purchase advertisements and lease booth space for Company displays.</p> <p>Faculty Expenses – Grants may be made for reasonable honoraria, travel, lodging and modest meals for <i>bona fide</i> faculty members.</p>	<p>payment of faculty honoraria, if any.</p>	<p>not the selection of the HCPs attending the conference.</p> <p>While APACMed remains committed to supporting HCPs’ access to needed medical education, APACMed recommends to its Members to phase out direct payment to individual HCPs of any costs referred to in this section regarding travel, accommodation, meals and refreshments, as well as to phase out the ability to influence the selection of HCPs attending any conference referred to in this section. APACMed will work with its Members to revise this Code accordingly</p>
Sales, Promotional and Other Meetings	<p>V. Sales, Promotional, and Other Business Meetings</p> <p>Companies may conduct sales, promotional, and other business meetings with HCPs, subject to the following:</p> <ol style="list-style-type: none"> Occasional modest meals and refreshments may be provided When necessary (e.g., plant tours or demonstration of non-portable equipment) reasonable travel costs and 	<p>V. Sales, Promotional, and Other Business Meetings</p> <p>Equivalent to US Code, but notes that meetings sometimes occur in other cities within China or in overseas locations.</p>	<p>Chapter 3: Company Events, 3. Sales, Promotional and Other Business Meetings</p> <p>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</p>	

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	<p>lodging may be provided</p> <p>c) Meals, refreshments, travel or lodging may not be provided for guests of HCPs or anyone without a <i>bona fide</i> interest in the information being shared at the meeting.</p> <p><i>See FAQs 22-24 for additional details.</i></p>		<p>Meetings should also comply with the following more stringent requirements:</p> <ul style="list-style-type: none"> 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. 	
Consulting	<p>VI. Consulting Arrangements with Health Care Professionals</p> <p>Consulting Companies may pay HCP consultants fair market value for a wide range of valuable, bona fide consulting services that fulfill a legitimate business need and do not constitute an unlawful inducement. The following standards apply:</p> <ul style="list-style-type: none"> Agreements should be written and describe all the services to be provided. Clinical research services should have a written research protocol. Legitimate need for the services should be identified in advance and documented. Selection should be based on the consultant's qualifications and expertise to meet the defined need. Compensation should be consistent with the fair market value in an arm's length transaction for services provided and not based on past, present or anticipated business. Expenses – A Company may pay for documented, reasonable and actual 	<p>VI. Consulting Arrangements with Health Care Professionals</p> <p>Equivalent to US Code, but adds a new subsection stating: Compensation paid to a consultant should not be paid in cash.</p>	<p>Chapter 5: Arrangements with Consultants</p> <p>1. General Principles</p> <p>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.</p> <p>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 and an independent decision-making/review process should be used.</p> <p>2. Criteria for genuine consulting arrangements</p>	<p>B2. Consultancy agreements</p> <p>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.</p>

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	<p>expenses incurred by a consultant that are necessary to carry out the consulting arrangement, such as costs for travel, modest meals, and lodging.</p> <ul style="list-style-type: none"> • Venue and circumstances of any meetings should be appropriate for the subject of the consultation and conducive to the effective exchange of information. • Meals and refreshments should be modest in value and subordinate in time and focus to the primary purpose of the meeting. Recreation or entertainment should not be provided. • Sales Involvement Sales personnel may provide input about the suitability of proposed consultant, but should not control or unduly influence the selection decision. <p><i>See FAQs 25-35 for additional details.</i></p>		<ol style="list-style-type: none"> 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 or the qualifications, expertise and experience to address the identified need. The volume or value of business generated by a prospective consultant 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 Healthcare h. The venue and other arrangements (e.g. hospitality, travel etc.) for Member Company meetings with consultants shall follow the rules previously set out 	

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			<p>for Events.</p> <p>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 and 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.</p> <p>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.</p> <p>4. Disclosure and Transparency</p> <p>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 as applicable. Where no such national requirements apply, Member Companies shall</p>	

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			<p>nevertheless maintain appropriate transparency by requiring the relevant Employer Notification which shall disclose the purpose and scope of the consultancy arrangement.</p> <p>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.</p>	
Royalties	<p>Provisions on Payment of Royalties</p> <p>Companies should enter into a royalty arrangement only where the HCP makes a novel, significant or innovative contribution to the development of a product, technology, process or method.</p> <p>Calculation of royalties should preserve the objectivity of medical decision-making, avoid the potential for improper influence and should not be conditioned on a requirement to purchase, order or recommend the Company's product or technology or a requirement to market the product or technology upon commercialization.</p> <p>Companies are strongly encouraged to consider the appropriateness and practicality of excluding from the calculation of royalty payments the number of units purchased, used, or ordered by the HCP and/or members of the HCP's practice.</p>	<p>Provisions on Payment of Royalties</p> <p>Companies should enter into a royalty arrangement only where the HCP makes a novel, significant or innovative contribution to the development of a product, technology, process or method.</p> <p>Calculation of royalties should preserve the objectivity of medical decision-making, avoid the potential for improper influence and should not be conditioned on a requirement to purchase, order or recommend the Company's product or technology or a requirement to market the product or technology upon commercialization.</p> <p>Companies are strongly encouraged to consider the appropriateness and practicality of excluding from the calculation of royalty payments the number of units purchased, used, or ordered by the HCP and/or members of the HCP's practice.</p>	<p>Chapter 7: Royalties</p> <p>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.</p> <p>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.</p> <p>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</p>	

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			and/or members of the Healthcare Professional's practice or Healthcare Organisation.	
Entertainment & Recreation	<p>VII. Prohibition on Entertainment and Recreation</p> <p>Interactions with HCPs should be professional in nature and should facilitate the exchange of medical or scientific information that will benefit patient care.</p> <p>To avoid the appearance of impropriety, a Company should not provide or pay for any entertainment or recreational event or activity for any non-employee HCP. This includes, for example, theater, sporting events, golf, skiing, hunting, sporting equipment, and leisure or vacation trips.</p> <p>Such events or items should not be provided regardless of (1) their value, (2) whether the HCP is a speaker or consultant, or (3) whether the entertainment or recreation is secondary to an educational purpose.</p> <p><i>See FAQ 36 for additional details.</i></p>	<p>VII. Prohibition on Entertainment and Recreation</p> <p>Equivalent to US Code, but examples of hunting and sporting equipment are omitted.</p>	<p>Chapter 1: General Criteria for Events</p> <p>1. Event Programme</p> <p>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. <i>Entertainment should not dominate or interfere with the overall scientific content</i> of the programme and must be held during times that do not overlap with a scientific session. <i>The Entertainment should not be the main attraction of the Third Party Organised Educational Event.</i></p>	<p>B5. Prohibition on gift giving and entertainment</p> <p>No gifts may ever be given to an 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, theater, sporting events, golf, skiing, hunting, and leisure or vacation trips. This section is not intended to address the legitimate practice of providing educational support items covered in section 6 and appropriate sample products and opportunities for product evaluation covered in section 7.</p>
Meals	<p>VIII. Modest Meals Associated with Health Care Professional Business Interactions</p> <p>Modest meals may be provided as an occasional business consistent with the provisions of this section of the Code.</p> <p>Purpose – The meal should be incidental to the <i>bona fide</i> presentation of scientific, educational or business information, and provided in a manner conducive to the presentation. It should not be part of an entertainment or recreation event.</p> <p>Setting and Location – Meals should be</p>	<p>VIII. Modest Meals Associated with Health Care Professional Business Interactions</p> <p>Equivalent to US Code but specific reference to “dine and dash” programs is omitted</p>	<p>Chapter 1: General Criteria for Events</p> <p>3. Guests</p> <p>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 <i>bona fide</i> professional interest in the information being shared at the Event.</p> <p>4. Reasonable Hospitality</p> <p>Member Companies may provide reasonable</p>	<p>B3. Member support of third party educational conferences</p> <p>(c) Support for third-party educational conferences can include funding the measurable costs associated with incidental, modest meals and refreshments during the course of the conference, provided the meals and refreshments are modest in value and subordinate in time and focus to the educational and/or training purpose of the conference.</p> <p>Where possible, the costs of travel, accommodation, meals and refreshments should not be reimbursed directly to</p>

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	<p>provided in a setting that is conducive to bona fide scientific, educational, or business discussions. Meals may occur at the HCP'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, scientific, educational, or business discussions. It may be impractical or inappropriate to provide meals at the HCP's place of business, for example, (1) where the Medical Technology cannot easily be transported to the HCP'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.</p> <p>Participants – Meals may be provided only to HCPs who actually attend the meeting, and may not be provided for an entire staff where everyone does not attend the meeting, i.e., no “dine and dash” programs. Meals may not be provided for guests of HCPs or any one not having a <i>bona fide</i> professional interest in the information being shared.</p> <p>Other Principles – Depending upon the type of interaction, additional principles may apply and are described in the following sections of the Code:</p> <ul style="list-style-type: none"> • Section III: Company-Conducted Product Training and Education • Section IV: Supporting Third-Party Educational Conferences • Section V: Sales, Promotional, and Other Business Meetings • Section VI: Consulting Arrangements with Health Care Professionals <p><i>See FAQ 37 for additional details.</i></p>		<p>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.</p> <p>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. Member Companies may not pay for or reimburse Healthcare Professionals’ lodging expenses at top category or luxury hotels.</p>	<p>individual HCPs but paid directly to the conference organizer or qualified and reputable third party service providers.</p>

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<p>Educational Items</p>	<p>IX. Educational items; Prohibition on Gifts</p> <p>A Company may occasionally provide items to HCPs that benefit patients or serve a genuine educational function.</p> <p>Items should have a fair market value of less than \$100, except text books and anatomical models.</p> <p>Items must not be capable of non-educational or non-patient-related uses.</p> <p>Non-educational branded promotional items may not be given to HCPs, even if minimal value and related to the HCPs work or benefit patients. Examples include pens, notepads, mugs, and other items that have a Company’s name, logo, or the name or logo of one of its Medical Technologies.</p> <p>Gifts such as wine, flowers, cookies, gift baskets, holiday gifts, or cash or cash equivalents are not permitted.</p> <p><i>See FAQs 38-42 for additional details.</i></p>	<p>X. Educational items and Branded Promotional Items</p> <p>As permitted by applicable laws and regulations, occasional items to benefit patients or serve genuine educational function can be provided.</p> <p>“Modest fair market value” – not specified.</p> <p>No items capable of use for non-educational, non-patient-related purpose, e.g., smartphone, tablet computer, laptop</p> <p>Permissible to provide branded promotional items of minimal value if related to HCP’s practice, e.g., 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.</p> <p>Not permitted: alcohol, tobacco, cash, gift cards, or other cash equivalents</p>	<p>Chapter 8: Educational Items and Gifts</p> <p>Member Companies exceptionally may provide inexpensive educational items and/or gifts, in accordance with national laws, regulations and industry and professional codes of conduct and may only provide such educational items and/or gifts in accordance of the following principles:</p> <ol style="list-style-type: none"> 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 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 	<p>B6. Educational support items</p> <p>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.</p>

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			<p>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.</p> <p>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.</p> <p>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 the above list.</p>	
Coverage, Reimbursement and Health Economics Information	<p>X. Provision of Coverage, Reimbursement and Health Economics Information</p> <p>Companies may provide accurate and objective coverage, reimbursement, and health economic information regarding their Medical Technologies. A Company may collaborate with HCPs, 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 include, but are not limited to:</p>			

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	<ul style="list-style-type: none"> • Identifying the clinical value of the Company's Medical Technologies and the services and procedures in which they are used • Collaborating with HCPs, their professional organizations, and patient groups to conduct joint advocacy on coverage, reimbursement and health economics issues; supporting HCPs and their professional organizations in developing materials and otherwise providing direct or indirect input into payor coverage and reimbursement policies • Providing accurate and objective information and materials to HCPs 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 revenues and associated costs • Providing information relating to changes in coverage or reimbursement amounts, methodologies and policies and the effects of such changes • Providing accurate and objective information designed to offer technical or other support intended to aid in the 			

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	<p>appropriate and efficient use or installation of the Company's Medical Technologies</p> <ul style="list-style-type: none"> Facilitating patient access to Medical Technologies by providing HCPs with assistance in obtaining patient coverage decisions from payors, including providing information and/or training on payor policies and procedures for obtaining prior authorization, and providing sample letters and information on medical necessity and appeals of denied claims. In addition, at the request of an HCP 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, related to a Company's Medical Technology; however, such assistance should not be provided as an unlawful inducement. <p>Companies may not interfere with HCPs independent clinical decision making or provide information as an unlawful inducement or suggest mechanisms for billing for unnecessary services or fraudulent practices to achieve inappropriate payment.</p> <p><i>See FAQ 43 for additional detail.</i></p>			
Grants and Donations	<p>XI. Research and Educational Grants and Charitable Donations</p> <p>Companies may provide research and educational grants and charitable donations but not as an unlawful inducement.</p> <p>Companies should:</p> <ul style="list-style-type: none"> Adopt objective criteria that exclude the 	<p>XI. Research, Academic and Public Education Grants; Charitable Donations</p> <p>Equivalent to US Code, but adds new section:</p> <p>Companies must ensure donation or grant is (a) handled by the financial department of the Institutional HCP and is used according to the donor or grant agreement for bona fide non-profit</p>	<p>Chapter 4: Grants and Charitable Donations</p> <p>1. General Principles</p> <p>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,</p>	<p>B8. Research and educational grants</p> <p>A Member may provide research and educational grants provided that the Member:</p> <p>(a) adopts objective criteria for providing the grants;</p> <p>(b) implements appropriate procedures to ensure that grants are not conditional on</p>

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	<p>volume or value of purchases made by, or anticipated from, the recipient;</p> <ul style="list-style-type: none"> Implement procedures to ensure such grants are not used as an unlawful inducement; and Ensure that grants and donations are appropriately documented. <p>Companies' sales personnel may provide input about the suitability of a proposed grant or donation recipient or program but should not control or unduly influence grant and donation decisions or recipient selection.</p> <p>Research Grants may be provided to support independent medical research with scientific merit; such activities should have well-defined objectives and milestones and may not be linked to purchases of Medical Technologies</p> <p>Educational Grants may be provided for legitimate purposes; such grants can be made to conference sponsors or training institutions but not to individual HCPs. Examples of legitimate purposes of educational grants include but are not limited to:</p> <ul style="list-style-type: none"> Advancement of Medical Education – Companies may make grants to support genuine education of medical students, residents and fellows participating in fellowship programs that are charitable or have an academic affiliation, or other medical personal (See also Section IV) Public Education – Companies may make grants to support patient or public education on health care topics <p>Charitable Donations – Companies may make monetary or Medical Technology donations for</p>	<p>activities; (b) accepted by the legal entity of the Institutional HCP, not internal departments or individual HCP; and (c) not conditioned on buying products or services or otherwise linked to other conditions that might affect fair competition.</p> <p>Research Grants Equivalent to US Code</p> <p>Academic and Public Education Grants. Academic and public information grants may be provided for legitimate purposes, including, but not limited to, the examples below, but are not permitted for Individual HCPs or to Individual HCPs in training.</p> <p><i>Academic Grants.</i> 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.</p> <p><i>Public Education Grants.</i> A Company may make grants for the purpose of supporting education of patients or the public about important health care topics.</p> <p>Charitable Donations Equivalent to US Code but omits reference to charitable missions</p>	<p>supply or procurement of the Member Company's products or services.</p> <p>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 organisation or entity and submits the request in writing on behalf of the qualifying organisation or entity.</p> <p>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 organisation and shall be paid directly to the organisation. A Member Company 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.</p> <p>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.</p> <p>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</p>	<p>the use, recommendation, purchase, or prescription of the Member's products and services; and</p> <p>(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.</p> <p>Research grants may only be used to support independent medical research with scientific 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.</p> <p>B9. Charitable donations</p> <p>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.</p>

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	<p>charitable purposes, such as supporting indigent care, or patient and public education, or the sponsorship of events where the proceeds are intended for charitable purposes; charitable donations should only be made to bona fide charitable organizations or, in rare instances, to individuals engaged in genuine charitable activities for the support of a bona fide charitable mission.</p> <p><i>See FAQs 44-51 for additional details.</i></p>		<p>of any such associated risks and of the relevant information concerning the intended recipient organisation or entity.</p> <p>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.</p> <p>g. This section of the Code (Chapter 4: Grants and Charitable Donations) is not intended to address the legitimate 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.</p> <p>2. Charitable Donations</p> <p>Member Companies may make unrestricted Charitable Donations for genuinely charitable or other philanthropic purposes which means that Member Companies shall have no control over the final use of funds they provide as Charitable Donations beyond general restrictions to ensure that the funds are applied for charitable and/or philanthropic</p>	

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			<p>purposes.</p> <p>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.</p> <p>3. Educational Grants</p> <p>Member Companies may provide restricted Educational Grants for the advancement of genuine medical education. Member Companies shall specify the intended purpose of the Educational Grant in the Grant agreement with the right to verify that the Grant is in fact used for the agreed intended purpose.</p> <p>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.</p> <p>Member Companies may provide Educational Grants for the following (non-exhaustive) purposes:</p> <ul style="list-style-type: none"> a. Support for Third Party Organised Educational Events b. Scholarships and Fellowships c. Grants for Public Awareness Campaigns <p>4. Research Grants</p> <p>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</p>	

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			<p>product(s) for the 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.</p> <p>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.</p> <p>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.</p> <p>Chapter 6: Research</p> <p>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</p>	

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			(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.	
Evaluation and Demonstration Products and Samples	<p>XII. Evaluation and Demonstration Products</p> <p>Under certain circumstances, a Company can provide reasonable quantities of products to HCPs at no charge for evaluation and demonstration purposes to allow HCPs 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.</p> <p>Single Use / Consumable / Disposables may be provided at no charge; should not exceed the amount reasonably necessary for the adequate evaluation of the products under the circumstances.</p> <p>Multiple Use / Capital Equipment may be provided without transfer of title for evaluation purposes only for a period of time that is reasonable to allow an adequate evaluation. The terms of such evaluation should be set forth in advance in writing. Companies should retain title to the product and should have a process in place for promptly removing the products from the HCP's location at the conclusion of the evaluation period.</p> <p>Demonstration Products are typically unsterilized single use products or mock-ups used for HCP and patient awareness, education, and training; not expected to be used in patient care; typically identified as not intended for patient use and typically designated as "Sample," or "Not for</p>	<p>XII. Evaluation and Demonstration Products</p> <p>Evaluation Products: Equivalent to US Code introductory sections, but adds:</p> <p>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.</p> <p><i>Single Use/Consumable/Disposable-</i> Equivalent to US Code but adds that terms of an evaluation of single-use devices should be disclosed in writing to the HCP; . applicable laws, regulations or institutional rules may also require disclosure to a different body</p> <p><i>Multiple Use/Capital-</i> Equivalent to US Code but adds that terms of evaluation of such multiple use products should be set in advance and in writing with the Institutional HCP, not internal departments or individual HCPs.</p> <p>Demonstration Products:</p> <p>Equivalent to US Code but adds in the documentation section that disclosure to a different body may be required by applicable laws, regulations or institutional rules</p>	<p>Chapter 9: Demonstration Products and Samples</p> <p>1. General Principles</p> <p>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.</p> <p>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.</p> <p>Provision of Demonstration Products and/or Samples must not improperly reward, induce and/or encourage Health Care Professionals to purchase, lease,</p>	<p>B7. Evaluation/sample/demonstration products</p> <p>A Member may provide medical technology products to HCPs free of charge for evaluation and demonstration purposes, provided that:</p> <p>(a) they are not given or intended as an improper inducement;</p> <p>(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;</p> <p>(c) they are only provided in quantities and/or for a duration that is reasonably determined to enable adequate evaluation by the HCP;</p> <p>(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</p> <p>(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</p>

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	<p>Human Use,” on the packaging and/or other documentation that accompanies the product.</p> <p>Companies should provide HCPs with documentation disclosing the no-charge status of evaluation and demonstration products.</p> <p><i>See FAQs 52-54 for additional details.</i></p>		<p>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.</p> <p>2. Demonstration Products (Demos)</p> <p>Member Companies may provide examples of their products to Healthcare Professionals and/or Healthcare Organisations in the form of mock-ups that are used for Healthcare Professionals and patient awareness, education and training provided that demonstration products are not intended for clinical use in any patient care nor are they intended for on-sale or other transfer.</p> <p>Member Companies shall clearly record and disclose the no-charge basis and other conditions applicable for the supply of such products no later than the time of the supply, preferably in writing.</p> <p>3. Samples</p> <p>Member Companies may provide a reasonable number of Samples at no charge for Health Care Professionals to familiarise themselves with the products, 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. The quantity of single use items provided for purposes of familiarisation must not exceed the amount reasonably necessary to acquire adequate experience in dealing with the products. Multi use products must have their title retained and</p>	<p>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.</p>

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			have a process in place for removing these items at the conclusion of the familiarization period.	
		<p>XIII. Third Party SMI Relationships</p> <p>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:</p> <ul style="list-style-type: none"> A. Written Policy/Procedure. B. Risk Assessment. C. Due Diligence Program. D. Written Contract. E. Training and Education. F. Monitor/Audit. G. Appropriate Corrective Action. 		
		<p>IX. Travel Associated with Health Care Professional Business Interactions</p> <p>A Company's interactions as outlined in Sections III, IV, V and VI may require Individual HCPs to travel within China or internationally. Companies may provide reasonable travel expenses for Individual HCP travel consistent with this section. Additional principles apply when Companies provide travel expenses for Individual Health Care Professional travel to Third Party Educational Conferences. These additional principles are described in Section IV of this Code of Ethics.</p> <ul style="list-style-type: none"> A. <i>Purpose.</i> There must be a bona fide scientific, educational, or business purpose to provide travel to an Individual HCP 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 		

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		<p>not support the bona fide professional interest of the travel.</p> <p>B. <i>Location.</i> Companies should adopt objective criteria to select locations and venues. Local alternatives should be considered before sponsoring travel for Individual HCPs. Further, Companies are encouraged to consider China-based alternatives before sponsoring international travel for Individual HCPs.</p> <p>C. <i>Reasonable Expenses.</i> Companies may provide for reasonable flights, hotels, meal and incidental expenses for Individual HCP travel.</p> <p>D. <i>Participants.</i> 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.</p> <p>E. <i>Reimbursement.</i> Companies are encouraged to pay for flights/hotels directly where practical. Reimbursement of travel-related expenses over RMB 500 should not be made in cash.</p>		