

Comparison of the AdvaMed China, AdvaMed U.S., APACMed, Kuala Lumpur, RDPAC, and CAMDI Codes

Topics	<u>AdvaMed Code of Ethics on Interactions with Health Care Professionals in China</u> Available here	<u>AdvaMed Code of Ethics on Interactions with U.S. Health Care Professionals</u> Available here	<u>APACMed Code of Ethical Conduct for Interactions with Health Care Professionals</u> Available here	<u>Kuala Lumpur Principles for Codes of Ethics in the Medical Technology Sector</u> Available here	<u>RDPAC Code of Practice</u> Available here	<u>CAMDI Code of Ethics</u> Available here
Effective Date	Revised; Effective July 1, 2024	Effective June 1, 2023	Effective January 1, 2024	Effective April 2022	Effective April 1, 2023	Effective October 18, 2016
Preamble: Goal and Scope of Code	<p>AdvaMed and the AdvaMed China Board recognize the obligation to facilitate ethical interactions between Companies and institutional Health Care Professionals (HCPs) as well as individual HCPs; benefits of interactions between HCPs and Companies include:</p> <ul style="list-style-type: none"> Enhancing the safe and effective use of Medical Technologies; Promoting the advancement of Medical Technologies; Encouraging research and education; Fostering charitable donations and giving; and Supporting appropriate and efficient use. <p>Companies have an independent obligation to comply with applicable local laws, regulations, and government guidance.</p> <p>Companies' engagement / interactions with Third Party Sales and Marketing Intermediaries (SMIs) should be conducted pursuant to all applicable legal and ethical principles.</p>	<p>No appreciable differences from AdvaMed China, although includes callouts, FAQs, and more detail.</p> <p>AdvaMed's guidance on ethical interactions is based on six cornerstone values:</p> <ul style="list-style-type: none"> Innovation; Education; Integrity; Respect; Responsibility; and Transparency. <p>Also addresses equitable patient access and diversity in the medical technology industry.</p> <p>Code may be silent on certain interactions or may not address all aspects of an interaction with a HCP.</p> <p>Describes Code's scope and applicability as:</p> <ul style="list-style-type: none"> Not providing legal advice or creating legal rights or obligations. Applies to interactions linked to Medical Technology (including combination products that include a Medical Technology component) with U.S. HCPs occurring inside or outside U.S. Requires Companies to communicate Code to representatives. 	<p>No appreciable differences from AdvaMed China.</p> <p>Acknowledges that interactions between Companies and HCPs are "essential" to advancing Medical Technologies and ultimately benefit patients.</p>	<p>No appreciable differences from AdvaMed China, although notes that ethical interactions ensure that business conduct is free of corruption, "which enhances the ability of all companies, especially smaller ones, to compete in a global market."</p> <p>Identifies seven principles for Company-HCP interactions:</p> <ul style="list-style-type: none"> Patients first; Integrity; Independence; Appropriateness; Transparency; Advancement; and Responsibility. 	<p>RDPAC is comprised of 45 leading multinational pharmaceutical companies with R&D capabilities.</p> <p>Describes the "ethos" of the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA).</p> <ul style="list-style-type: none"> Fairness made up of Integrity and Accountability; Respect made up of Education and Privacy; Honesty made up of Transparency and Speaking up; and Care made up of Innovation and Quality. <p>Scope includes interactions with HCPs and "promotion of pharmaceutical products."</p> <p>Identifies those Company activities the Code does not seek to regulate (e.g., promotion of medical devices).</p>	<p>Reflects 2017 AdvaMed China Code.</p>
Code of Ethics Compliance / Effective Code Implementation	<p>Companies that wish to adopt and certify the Code should submit to AdvaMed an annual certification signed by the most senior executive responsible for the Company's Medical Technology operation in China as well as the Company's CCO.</p>	<p>No appreciable differences from AdvaMed China.</p> <p>Emphasizes need for Companies' compliance programs to be "appropriately tailored."</p>	<p>No appreciable differences from AdvaMed China, although does not expressly require Companies to submit an annual certification or contact information for Company's Compliance Department or anonymous</p>	<p>No appreciable differences from AdvaMed China.</p> <p>Focuses additionally on other key stakeholders (medical technology sector, HCPs, and the government) to promote ethical collaborations.</p>	<p>Provides Complaint and Dispute Resolution Procedure whereby Companies may report complaints of Code breaches.</p>	<p>Reflects 2017 AdvaMed China Code.</p>

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	<p>AdvaMed Members should supply contact information for the Company's Compliance Department or anonymous hotline to facilitate reporting of Code violations.</p> <p>Identifies seven elements of effective compliance:</p> <ul style="list-style-type: none"> • Implementing written policies and procedures; • Designating a 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>Companies should ensure interactions with individual HCPs are appropriately disclosed.</p>		<p>hotline to facilitate reporting of Code violations.</p>			
Company-Conducted Product Training and Education	<p>Companies have a responsibility to make training and education (e.g., "hands on" training sessions, cadaver workshops, lectures and presentations) on their products and Medical Technologies available to HCPs.</p> <p>Identifies principles for conducting training and education programs:</p> <ul style="list-style-type: none"> • Setting conducive to the effective transmission of information, including clinical, educational, conference, virtual, or other commercially available meeting facilities; • Appropriate facilities for training; 	<p>No appreciable differences to AdvaMed China.</p> <p>Addresses whether alcohol may be provided at Company-conducted programs and meetings.</p> <p>Acknowledges arrangements to advance value-based care.</p>	<p>No appreciable differences to AdvaMed China.</p>	<p>Similar sentiment to AdvaMed China.</p>	<p>Describes ethical guidance for "medical interaction programs" with HCPs, which broadly covers Company-conducted training and education.</p>	<p>Reflects 2017 AdvaMed China Code.</p>

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	<ul style="list-style-type: none"> Qualified training staff with expertise to conduct training; and Travel, lodging, meals, and refreshments compliant with Code. 					
Supporting Third-Party Educational Conferences	<p>Companies that wish to provide support educational grants/donations should:</p> <ul style="list-style-type: none"> Ensure conferences are primarily dedicated to promoting objective scientific and educational activities and discourse; support is for a genuine, independent educational function; and expenses associated with bona fide educational activities. Not participate in or attempt to influence the selection of individual HCPs that benefit. Not provide 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 condition a grant/donation on a requirement to purchase, order, recommend, or market any product or medical technology; and Document appropriately. <p>Companies that wish to provide conference meals and refreshments should ensure they are provided to all HCP attendees in a manner that is consistent with applicable standards established by the conference organizer and the body accrediting the educational activity.</p> <p>Companies that wish to cover faculty expenses for reasonable honoraria, travel, lodging, and modest meals should ensure HCPs are bona fide conference</p>	<p>Similar sentiment to AdvaMed China, although U.S. Code contains more substantive detail on topic.</p> <p>Company’s 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.</p> <p>Describes review process checklist for handling requests to support Third-Party Programs.</p> <p>Addresses Company-conducted satellite symposiums and journal clubs.</p>	<p>Similar to AdvaMed China, although specifies (1) which recipients a Company may provide an education grant to, (2) what types of funding qualify as permissible support, and (3) limited exceptions to general prohibition against direct sponsorship of HCPs to Third Party Educational Events.</p>	<p>Similar sentiment to AdvaMed China.</p>	<p>Describes ethical guidance for “medical interaction programs” with HCPs, which broadly cover third-party educational conferences.</p> <p>Companies should:</p> <ul style="list-style-type: none"> Have a comprehensive internal recording and filing mechanism to accurately document, with reasonable and clear classifications, expenditures and benefits provided to HCPs that are associated with medical interaction programs; and Have clear separation between expenditures associated with interactions with HCPs and those for internal expenses for employees. <p>Does not expressly refer to any “phase-out of direct sponsorship” rule.</p>	<p>Reflects 2017 AdvaMed China, although refers to “conference grants” and does not expressly refer to any “phase-out of direct sponsorship” rule.</p> <p>Companies can sponsor individual HCPs to attend third-party educational conferences within certain guidelines.</p>

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	<p>faculty members (e.g., speaking role during program).</p> <p>Describes Phase-Out of Direct Sponsorship rules, which states:</p> <ul style="list-style-type: none"> For conferences occurring before January 1, 2018, Companies can engage in Direct Sponsorship of individual HCPs if certain criteria were met. However, for conferences occurring on or after January 1, 2018, Companies cannot engage in Direct Sponsorship of individual HCPs. <p>Companies that wish to support third-party organized procedure training may do so under certain conditions.</p>					
Sales, Promotional, and Other Business Meetings	<p>Companies that wish to conduct sales, promotional and other business meetings with HCPs to discuss, e.g., Medical Technology features, sales terms, or contracts may schedule the meetings to occur close to the HCP's place of business, virtually, in other cities within China, or in overseas locations.</p> <p>Companies can pay for reasonable travel costs of attendees when necessary.</p>	<p>Identifies five principles for Company sales, promotional, and other business meetings:</p> <ul style="list-style-type: none"> Legitimate need to conduct the meeting. Setting conducive to discussion of relevant information. Objective, legitimate need for HCP to attend meeting. Travel, lodging, meals, and refreshments compliant with Code. <p>Acknowledges other types of business meetings with HCPs to discuss Medical Technology features, Sales terms, Company service offerings and their impact on health care delivery, equipment demonstration, product development or clinical testing needs, or value-based solutions, services, or arrangements.</p>	No mention of this topic.	No mention of this topic.	Describes guidance for advisory board meetings.	Reflects 2017 AdvaMed China Code.
Consulting Arrangements with HCPs	Companies that wish to pay consultants fair market value compensation for performing certain types of services (e.g., research, product development, development and/or transfer of	No appreciable differences from AdvaMed China, although China Code specifically references no cash payments.	Similar sentiment to AdvaMed China, although no discussion of HCP arrangements involving payment of royalties.	Similar sentiment to AdvaMed China, although no discussion of HCP arrangements involving payment of royalties.	No appreciable differences from AdvaMed China, although notes Companies should establish caps on service fees to be paid to each HCP (e.g., caps on the	Reflects 2017 AdvaMed China Code.

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	<p>intellectual property, participation on advisory boards, presentations at Company-sponsored training) intended to fulfill a legitimate business need should ensure:</p> <ul style="list-style-type: none"> • Consulting arrangements are: <ul style="list-style-type: none"> ○ Written, describe all services to be provided, and documented appropriately (e.g., when conducting clinical research services, there should also be a written research protocol); and ○ Entered into only where a legitimate need for the services is identified in advance and documented; • Selection of a consultant is made on the basis of the consultant’s qualifications and expertise to meet the defined need; • Compensation paid to a consultant: <ul style="list-style-type: none"> ○ Is consistent with fair market value for the services provided and not based on the volume or value of the consultant’s past, present or anticipated business; ○ not paid in cash; and ○ documented and necessary to carry out the consulting agreement; • Venue and circumstances for Company meetings with consultants are appropriate to the subject matter of the consultation; • Company-sponsored meals and refreshments provided in conjunction are modest in value and subordinate in time and focus to the 	<p>Addresses how a Company can establish “fair market value” for goods or services.</p> <p>Addresses arrangements that involve clinical research services by a HCP in return for compensation.</p>			<p>number and amount of speaker fee payments to each HCP per year).</p> <p>Describes practical guidance and points to consider for fee-for-service arrangements with HCPs, including guiding questions.</p> <p>No discussion of HCP arrangements involving payment of royalties.</p>	

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	<p>primary purpose of the meeting; and</p> <ul style="list-style-type: none"> Company’s sales personnel do not control or unduly influence the decision to engage a particular HCP as a consultant. <p>Companies can enter into arrangements involving the payment of royalties to a HCP under certain conditions.</p>					
Prohibition on Entertainment and Recreation	<p>Companies should not provide or pay for any entertainment or recreational event or activity for any HCP (regardless of value, whether the Company engages the HCP as a speaker or consultant, or whether the entertainment or recreation is secondary to an educational purpose) to ensure the appropriate focus on an educational and/or informational exchange and to avoid the appearance of impropriety.</p>	<p>No appreciable differences from AdvaMed China.</p>	<p>No appreciable differences from AdvaMed China.</p>	<p>No appreciable differences from AdvaMed China.</p>	<p>No appreciable differences from AdvaMed China.</p>	<p>Reflects 2017 AdvaMed China Code.</p>
Modest Meals Associated with HCP Business Interactions	<p>Companies that wish to provide modest meals to HCPs as an occasional business courtesy should ensure:</p> <ul style="list-style-type: none"> Meals 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; Setting is conducive to bona fide scientific, educational, or business discussions; and Meals are only provided to HCPs who actually attend the meeting. 	<p>No appreciable differences from AdvaMed China.</p> <p>Encourages Companies to establish meal policies.</p> <p>Addresses per-meal spending limits for meals with HCPs.</p>	<p>No appreciable differences from AdvaMed China.</p>	<p>No mention of this topic.</p>	<p>No appreciable differences from AdvaMed China.</p>	<p>Reflects 2017 AdvaMed China Code.</p>
Travel Associated with HCP Business Interactions	<p>Companies that wish to provide reasonable travel expenses for individual HCP travel consistent should:</p> <ul style="list-style-type: none"> Ensure that there is a bona fide scientific, educational, 	<p>No appreciable differences from AdvaMed China.</p> <p>Addresses what types of controls Companies should consider with respect to limiting HCPs’ travel</p>	<p>No appreciable differences to AdvaMed China.</p>	<p>No mention of this topic.</p>	<p>Similar sentiment to AdvaMed China, although does not expressly refer to any “phase-out of direct sponsorship” rule.</p>	<p>Reflects 2017 AdvaMed China, although does not expressly refer to any “phase-out of direct sponsorship” rule.</p>

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	<p>or business purpose to provide travel to an individual HCP; the length of the trip is commensurate with this purpose; the bona fide purpose cannot be met via a virtually-conducted program.</p> <ul style="list-style-type: none"> • Adopt objective criteria to select locations and venues (e.g., local and China-based alternatives should be considered before sponsoring travel). • Exclude travel or other expenses for guests of individual HCPs, or for any other person who does not have a bona fide professional interest in the activity requiring travel. <p>Notes “phase-out of direct sponsorship” as of January 1, 2018.</p>	<p>and lodging costs associated with Company-conducted meetings.</p>			<p>Companies cannot organize or sponsor a medical interaction program for HCPs that takes place outside of HCPs’ home country or involves foreign travel unless certain IFPMA Code requirements are satisfied.</p> <p>Companies should avoid providing transportation services that “may have public perception of extravagance.”</p>	
<p>Educational Items and Prohibition on Gifts</p>	<p>Companies can occasionally provide items of modest fair market value (exception for medical textbooks or anatomical models) to HCPs that benefit patients or serve a genuine educational function for HCPs, but cannot provide items that are capable of use for non-education or non-patient-related purposes (e.g., laptop).</p> <p>Companies cannot provide gifts to HCPs, including (1) branded items that do not serve a genuine educational function for HCPs and (2) cultural courtesy gifts (e.g., alcohol, tobacco, flowers, chocolates, gift baskets, cash, gift cards, or other cash equivalents).</p>	<p>No appreciable differences from AdvaMed China regarding the standard set for providing educational items.</p> <p>U.S. Code includes specific maximum amount/cap (US \$100) for educational items (exception for medical textbooks or anatomical models).</p> <p>Companies may not provide branded, promotional items or gifts to HCPs, even if item is of minimal value, related to the HCP’s work, or for the benefit of patients.</p>	<p>Companies may not provide gifts to HCPs, including (1) items which are neither educational nor patient related, even if of minimal value, and irrespective of whether such items are branded or not and (2) Cultural courtesies irrespective of the occasion.</p> <p>Includes specific maximum amount/cap (US \$100) for educational items.</p>	<p>Similar sentiment to AdvaMed China.</p>	<p>Companies may not provide promotional aids, including in relation to the promotion of prescription-only medications, except for:</p> <ul style="list-style-type: none"> • Pens and notepads in the context of Company-organized or third-party events as long as they are Company branded only, of minimal value and quantity for the purpose of the event. • The promotion of OTCs if of minimal value (not more than RMB 100 per item) and quantity, and relevant to the practice of HCPs. <p>Companies may provide items of medical utility if:</p> <ul style="list-style-type: none"> • Items are of modest value, do not offset routine business practices, and are beneficial to enhancing 	<p>Reflects 2017 AdvaMed China Code.</p>

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					<p>the provision of medical services and patient care;</p> <ul style="list-style-type: none"> • Not offered on more than an occasional basis; • Not product branded (unless essential for correct use); and • Not valued in excess of RMB 500 per item. <p>Companies may provide informational and educational items if:</p> <ul style="list-style-type: none"> • Primarily for educational purposes and do not have independent value; • Not product branded (unless essential for correct use); and • Not in excess of modest value or, for books and subscriptions, reasonable value. 	
Research, Academic and Public Education Grants; Charitable Donations	<p>Companies that wish to provide research and education grants and charitable donations to HCPs in accordance with applicable laws and regulations, and not as an unlawful inducement, should:</p> <ul style="list-style-type: none"> • 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; • Implement appropriate procedures to ensure that such grants and donations are not used as an unlawful inducement; and • Ensure that all such grants and donations are: <ul style="list-style-type: none"> ○ Documented appropriately; • Handled by financial department of institutional HCP and is used according to the donor/grant agreement 	<p>No appreciable differences from AdvaMed China.</p> <p>Describes ethical guidance for indigent care donations.</p>	<p>No appreciable differences from AdvaMed China.</p>	<p>No discussion about research and education grants.</p>	<p>Companies may give financial support/grant to healthcare organizations to support HCPs under certain circumstances.</p> <p>Mere recognition for support will not be considered as a benefit in return.</p> <p>Acknowledges need for Companies to perform proper due diligence prior to providing any financial support.</p>	<p>Reflects 2017 AdvaMed China Code.</p>

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	<p>for bona fide non-profit activities;</p> <ul style="list-style-type: none"> Accepted by the legal entity of the institutional HCP, not internal departments or individual HCPs; and Not conditioned on buying products or services or otherwise linked to other conditions that might affect fair competition. <p>Company’s sales personnel can provide input about the suitability of a proposed grant or charitable donation recipient or program, but 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.</p> <p>Identifies when support can be provided:</p> <ul style="list-style-type: none"> <u>Research Grants.</u> May be provided to support independent medical research with scientific merit if activities have well-defined objectives and milestones and are not linked directly or indirectly to the purchase of Medical Technologies. <u>Academic and Public Education Grants.</u> May be provided for legitimate purposes (e.g., to support genuine medical education, to support education of patients/public about important health care topics), but not to individual HCPs, or to individual HCPs in training. <u>Charitable Donations.</u> May be provided if motivated by bona fide charitable purposes and only to bona fide charitable organizations 					

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	or other organizations with a bona fide charitable purpose.					
Evaluation and Demonstration Products	<p>Companies seeking to provide products to HCPs at no charge for evaluation or demonstration purposes should:</p> <ul style="list-style-type: none"> • Ensure provision of products is neither conditioned on buying products or services, nor linked to other conditions that might affect fair competition; and • Provide HCPs with documentation and disclosure regarding the no-charge status of products unless applicable law requires disclosure to a different body. <p>Identifies when Companies may provide reasonable quantities of products to institutional HCPs at no charge for evaluation and demonstration purposes:</p> <ul style="list-style-type: none"> • <u>Single Use Products.</u> Number of products provided should not exceed amount reasonably necessary for the adequate evaluation of products. Terms of evaluation should be disclosed in writing to HCP. • <u>Multiple Use Products.</u> Products should be furnished only for period of time that is reasonable to allow adequate evaluation. Terms of evaluation should be set in advance and in writing with HCP. Companies should retain title during evaluation period and have process in place for prompt removal at conclusion of evaluation period unless HCP purchases or leases. • <u>Demonstration.</u> Typically single use products not intended for, and typically identified as not 	<p>No appreciable differences to AdvaMed China.</p> <p>Discusses consigned products.</p>	<p>No appreciable differences to AdvaMed China, although does not expressly encourage providing documentation and disclosure to HCPs.</p>	<p>Similar sentiment to AdvaMed China.</p>	<p>No mention of this topic.</p>	<p>Reflects 2017 AdvaMed China Code.</p>

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	intended for, patient use or patient care.					
Third Party Sales and Marketing Intermediaries (Third Party SMIs)	<p>Companies should adopt a specific compliance program for Third Party SMI relationships that applies to everyone, including Company’s senior leadership.</p> <p>Identifies seven elements to include in a compliance program for Third Party SMI relationships: Includes these elements:</p> <ul style="list-style-type: none"> • Written Policy/Procedure; • Risk Assessment; • Due Diligence Program; • Written Contract; • Training and Education; • Monitor/Audit; and • Appropriate Corrective Action. <p>Companies should require Third Party SMIs with which they have a direct contractual relationship and control over the terms of the contract to comply with Company policies that implement the Code.</p> <p>Companies should communicate Company policies implementing the Code to its Third Party SMIs with the expectation that the Third Party SMIs will take appropriate steps to prevent and detect inappropriate conduct by sub-distributors and sub-dealers.”</p>	<p>Extension of the Code to third parties is discussed in an FAQ although with less detail than AdvaMed China.</p> <p>FAQ provides: “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.”</p>	No appreciable differences from AdvaMed China.	No discussion of this topic, although refers to separate guidance.	No mention of this topic.	Reflects 2017 AdvaMed China Code.
Company Representatives Providing Technical Support in the Clinical Setting	<p>Identifies five principles for Companies providing technical support in the clinical setting:</p> <ul style="list-style-type: none"> • Have representatives enter and be present in the clinical setting only at the request of and under the supervision of a HCP. • Have representatives be transparent that they are acting on behalf of the Company in a technical support capacity. 	No differences from AdvaMed China.	Similar wording to AdvaMed China, although does not include principle about having technical support not eliminate an overhead or other expense that the HCP should otherwise incur while providing patient care.	No mention of this topic.	No mention of this topic.	No mention of this topic.

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	<ul style="list-style-type: none"> • Have representatives not interfere with a HCP's independent clinical decision-making. • Have representatives comply with applicable hospital or facility policies and requirements, including patient privacy and credentialing requirements. • Have technical support not eliminate an overhead or other expense that the HCP should otherwise incur while providing patient care. 					