



AdvaMed China Code

Training Presentation

Roadmap of AdvaMed China Code

- Preamble: Goal and Scope of AdvaMed China Code
- Code of Ethics Compliance
- Company-Conducted Product Training and Education
- Supporting Third-Party Educational Conferences
- Sales, Promotional, and Other Business Meetings
- Consulting Arrangements with Health Care Professionals
- Prohibition on Entertainment and Recreation
- Modest Meals Associated with Health Care Professional Business Interactions
- Travel Associated with Health Care Professional Business Interactions
- Educational Items and Prohibition of Gifts
- Research, Academic, and Public Education Grants; Charitable Donations
- Evaluation and Demonstration Products
- Third Party SMI Relationships
- Company Representatives Providing Technical Support in Clinical Setting

Overview of 2024 Update

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The AdvaMed China Code of Ethics was revised, effective July 1, 2024.

2024 Update relates to:

- Gifts
- Consulting Agreements
- Virtual Meetings
- Company Representatives Providing Technical Support in Clinical Setting
- Interactions with Third Party Sales and Marketing Intermediaries

2024 Update: Gifts

Section X

- As permitted by applicable laws and regulations, a Company occasionally may provide items to Health Care Professionals that benefit patients or serve a genuine educational function for Health Care Professionals. Other than medical textbooks or anatomical models used for educational purposes, any such item should have a modest fair market value. A Company may not provide items that are capable of use for non-educational or non-patient-related purposes, for example, a smartphone, tablet computer, laptop, etc.
- Companies may not provide gifts to Health Care professionals. This prohibition includes: 1) branded items that do not serve a genuine educational function for Health Care Professionals and 2) cultural courtesy gifts. Some examples of cultural courtesy gifts include alcohol, tobacco, flowers, chocolates, gift baskets, cash, gift cards, or other cash equivalents.
- This section is not intended to address the legitimate practice of providing products for evaluation and demonstration purposes, which is addressed in Section XII.

Key Takeaways

- Added language to prohibit Company provisions of gifts to HCPs.
- Gifts to HCPs include (1) branded items that do not serve a genuine educational function for HCPs and (2) cultural courtesy gifts.

2024 Update: Consulting Agreements

Section VI

- Companies should comply with the following standards in connection with consulting arrangements with Health Care Professionals:
 - Consulting agreements should be written and describe all services to be provided. A Company should maintain appropriate documentation which may include documentation regarding the process for determining legitimate need, fair market value compensation, and other relevant factors. When a Company contracts with a consultant to conduct clinical research services, there should also be a written research protocol.

Key Takeaways

- Added language to advise Companies to maintain appropriate documentation for consulting arrangements with HCPs.

2024 Update: Virtual Meetings

Section III, V, and IX

Company-Conducted Product Training and Education

- Programs and events should be conducted in settings that are conducive to the effective transmission of information. These may include clinical, educational, conference, virtual, or other settings, such as hotels or other commercially available meeting facilities.

Sales, Promotional, and Other Business Meetings

- Companies may conduct sales, promotional and other business meetings with Health Care Professionals to discuss, for example, Medical Technology features, sales terms, or contracts. Often, these meetings occur close to the Health Care Professional's place of business but they may occur virtually, in other cities within China, or in overseas locations.

Travel Associated with Health Care Professional Business Interactions

- Purpose. ... Companies may wish to consider whether the bona fide purpose could be met via a virtually-conducted program.

Key Takeaways

- General revisions made throughout the Code to account for/address virtual interactions with HCPs.

2024 Update: Company Representatives Providing Technical Support in Clinical Setting

Section XIV

- Company representatives may play an important role in the clinical setting by providing technical support on the safe and effective use of Medical Technology. Some examples include:
 - Company representatives may need to explain how a Medical Technology's unique settings and technical controls function and may make recommendations.
 - Company representatives may assist the clinical/operating room team to ensure that the appropriate range of necessary devices and accessories are available during a procedure, especially when dealing with Medical Technology that involves multiple devices and/or accessories.

Key Takeaways

- Added new section to the Code to reiterate the important role company representatives play in the clinical setting (i.e., they provide technical support on the safe and effective use of medical technology).

2024 Update: Company Representatives Providing Technical Support in Clinical Setting (cont'd)

Section XIV

- Companies should apply the following principles:
 - Company representatives should enter and be present in the clinical setting only at the request of and under the supervision of a Health Care Professional.
 - Company representatives should be transparent that they are acting on behalf of the Company in a technical support capacity.
 - Company representatives should not interfere with a Health Care Professional's independent clinical decision-making.
 - Company representatives should comply with applicable hospital or facility policies and requirements, including patient privacy and credentialing requirements.
 - A Company's technical support should not eliminate an overhead or other expense that the Health Care Professional should otherwise incur while providing patient care.

Key Takeaways

- Mirrored the principles outlined in the AdvaMed U.S. Code that apply to company representatives in the clinical setting.

2024 Update: Interactions with Third-Party Sales and Marketing Intermediaries

Section I

- To ensure and improve ongoing patient and clinician access to innovative, reliable and effective Medical Technologies, it is often necessary for Companies to engage third party intermediaries to assist in the marketing, sale and/or distribution of the Companies' products or services. The form of, and terminology used by Companies to describe relationships with these third party sales and marketing intermediaries varies, but may include distributors, wholesalers, distribution or sales agents, marketing agents, brokers, missionary commercial agents and independent sales representatives with which the Company has a direct contractual relationship and control over the terms of the contract as well as bona fide sub-distributors and sub-dealers ("Third Party SMIs").
- It is essential that Companies' interactions with Third Party SMIs, as well as Third Party SMIs' behavior on a Company's behalf (including Third Party SMI interactions with Health Care Professionals and governmental officials) are conducted pursuant to all applicable legal and ethical principles.

Key Takeaways

- Added language to expressly include Company interactions with bona fide sub-distributors and sub-dealers within scope of third party intermediaries.

Summary of Current Code

Preamble: Goal and Scope of Code

Section I

- China Board recognizes the obligation to facilitate ethical interactions between Companies and HCPs.
- Outlines benefits of interactions between Companies and HCPs.
- Advises Companies they have an independent obligation to comply with applicable local laws, regulations, and government guidance.
- Advises Companies' interactions with Third Party SMIs should be conducted pursuant to all applicable legal and ethical principles.

Key Concepts

- There is a very broad scope of beneficial interactions between Companies and HCPs.
- Companies' interactions with HCPs and Third Party SMIs should comply with the Code and applicable law.

FAQ: Preamble and General Questions

Section I

- My company's policies and procedures apply standards that are more stringent than those described in the AdvaMed Code of Ethics on Interactions with HCPs in China ("AdvaMed China Code" or "Code"). How does this impact my company's ability to certify as to compliance with the Code?
- Section I of the AdvaMed China Code notes that companies' interactions with Third Party Sales and Marketing Intermediaries ("SMIs") are conducted pursuant to all applicable legal and ethical principles. My Company engages distributors in China. Must my Company's distributors comply with the requirements of the AdvaMed China Code?

Code of Ethics Compliance

Section II

- Encourages Companies to adopt the Code and to implement an effective compliance program.
- Encourages Companies to submit an annual certification of compliance, signed by the most senior executive responsible for the Company's Medical Technology operation in China (CEO, if headquartered in China) and Chief Compliance Officer.
- Acknowledges that AdvaMed has published on its website Companies that submit annual certification and Companies' compliance department contact information.
- Encourages Companies to follow seven elements of an effective compliance program.
- Encourages Companies to appropriately disclose interactions with HCPs.

Key Concepts

- Companies are encouraged to adopt the Code, annually certify to such adoption, and implement an effective compliance program.

FAQ: Code of Ethics Compliance

Section II

- The China Code indicates in several places that Companies must document certain arrangements with HCPs (specifically Section IV (“Supporting Third-Party Educational Conferences”), Section XI (“Research, Academic and Public Education Grants; Charitable Donations”) and Section XII (“Evaluation and Demonstration Products”). What guidelines are recommended for Companies to document such transactions?
- The AdvaMed China Code strongly encourages Companies “to ensure that interactions with individual HCPs (or to individual units within an Institutional HCP) are appropriately disclosed to the institution or employer.” How should a Company handle this requirement in those cases in which disclosure might be impractical?

Company-Conducted Product Training and Education

Section III

- Describes Companies' responsibility to make training and education on their products available to HCPs.
- Identifies principles Companies should adhere to when conducting training and education programs:
 - Programs and events should be conducted in settings that are conducive to the effective transmission of information.
 - Training staff should have the proper qualifications and expertise to conduct such training.
 - Meals and refreshments in connection with program appropriate if modest in value and subordinate in time and focus to the training and/or educational purpose of the meeting.
 - Reasonable travel and modest lodging costs appropriate for HCP attendees, but not guests of HCPs or for any other person who does not have a bona fide professional interest in the information being shared at the meeting.

Key Concepts

- Companies have a responsibility to make training and education on their products available to HCPs.
- Companies should consider whether a virtual setting may be appropriate.

Supporting Third-Party Educational Conferences

Section IV

- Permissible for Companies to support Third-Party Educational Conferences in certain circumstances. Such funding may be used by the organizer to:
 - Defray/reduce costs of conducting the program.
 - Allow HCPs to attend so long as no undue influence in selection process.
 - Provide attendees modest meals and refreshments.
 - Cover reasonable honoraria, travel, lodging, and modest meals for HCPs serving as bona fide conference faculty.
- Permissible for Companies to purchase advertisements and lease booth space for Company displays.
- Prohibits Companies from engaging in Direct Sponsorship of Individual HCPs to attend Third-Party Educational starting January 1, 2018.
 - Permissible if starting before January 1, 2018 under certain circumstances.
- Describes conditions when appropriate for Company to provide Third-Party Organized Procedure Training.

Key Concepts

- Companies may support third-party education, research, and policymaking conferences through the grant or donation of monetary funds.
- All Company support for Third-Party Educational Conferences should be appropriately documented.

FAQ: Supporting Third-Party Educational Conferences

Section IV

- My Company is planning to host a Satellite Symposium one day prior to an upcoming Third-Party Educational Conference of Chinese cardiologists. Can my company compensate a physician who serves as faculty at my company's Satellite Symposium?
- What factors should Companies consider when evaluating whether to support a Third-Party Educational Conference with an Educational Grant/Donation pursuant to Section IV of the AdvaMed China Code?

FAQ (cont'd): Supporting Third-Party Educational Conferences

Section IV

- My company has provided an Educational Grant/Donation to a Third-Party Conference Organizer in support of an upcoming Third-Party Educational Conference. At the event, HCP attendees will be able to participate in a contest. The winner of the contest will have all of his or her registration fees covered to attend a future international Third-Party Educational Conference. Is this a Direct Sponsorship under Section IV of the Code?

FAQ (cont'd): Supporting Third-Party Educational Conferences

Section IV

- My Company has provided an Educational Grant/Donation to a Third-Party Conference Organizer in support of a Third-Party Educational Conference. The Conference Organizer has provided my Company with several free registrations for individuals to attend. Can I provide these free registrations to HCPs?
- In order to facilitate the training of HCPs, my Company would like to engage several HCPs as consultants to attend an upcoming Third-Party Educational Conference (including covering their travel, lodging, meals, and registration fees). These consultants would learn the content presented during the program, collect educational materials from the program, and later train other HCPs on the content on behalf of my Company. Is this permissible under the AdvaMed China Code?

Sales, Promotional, and Other Business Meetings

Section V

- Permissible for Companies to conduct sales, promotional, and other business meetings (including virtually) with HCPs.
- Permissible for Companies to pay for reasonable HCP travel costs when necessary, but not for guests of HCPs, or for any other person who does not have a bona fide professional interest in the information being shared at the meeting.

Key Concepts

- Companies may conduct sales, promotional, and other business meetings with HCPs.
- Companies should consider whether a virtual setting may be appropriate.

Consulting Arrangements with HCPs

Section VI

- Permissible for Companies to pay consultants fair market value compensation for performing bona fide consulting services, provided that they are intended to fulfill a legitimate business need and do not constitute an unlawful inducement.
- Proposes list of standards Companies should comply with:
 - Consulting agreements are written and describe all services, and appropriate document maintained.
 - Legitimate need for consulting services is identified in advance and documented.
 - Selection based on consultant's qualifications and expertise to meet the defined need.
 - Compensation consistent with fair market value in an arm's length transaction for the services provided. Not cash.
 - Reasonable expenses, appropriate venue, modest meals, and no undue influence by Company sales personnel.
- Describes conditions for when appropriate for Companies to enter arrangements involving the payment of royalties to a HCP.

Key Concepts

- Companies should engage HCPs through written contracts that specify fair market value compensation for legitimate needs.
- Companies should maintain appropriate documentation, which may include records regarding legitimate need, fair market value, and other factors.

Prohibition on Entertainment and Recreation

Section VII

- Prohibits Companies from providing or paying for any entertainment or recreational event or activity for any HCP regardless of (1) their value, (2) whether the Company engages the HCP as a speaker or consultant, or (3) whether the entertainment or recreation is secondary to an educational purpose.

Key Concepts

- Companies may not provide entertainment or recreation to HCPs **in any form.**

Modest Meals Associated with HCP Business Interactions

Section VIII

- Permissible for Companies to provide modest meals as an occasional business courtesy to HCPs with certain limitations:
 - Meal should be incidental to the bona fide presentation of scientific, educational, or business information and provided in a manner conducive to the presentation of such information.
 - Meals should be in a setting that is conducive to bona fide scientific, educational, or business discussions. Meals may occur at the HCP's place of business.
 - Meals only for HCPs who actually attend the meeting (i.e., have a bona fide professional interest in the information being shared at the meeting) and when a Company representative is present.

Key Concepts

- Companies may provide modest meals to HCPs if subordinate in time and focus to scientific, educational or business presentation and provided in a manner and setting conducive to the presentation.
- Company may not provide a meal where its representative is not present.

Travel Associated with HCP Business Interactions

Section IX

- Permissible for Companies to provide reasonable travel expenses for Individual HCP travel consistent with certain limitations:
 - 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.
 - Objective criteria to select locations and venues.
 - Reasonable flights, hotels, meal and incidental expenses for Individual HCP travel.
 - Not for guests of Individual HCPs, or for any other person who does not have a bona fide professional interest in the activity requiring travel.
 - 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.
- Prohibits Companies from engaging in Direct Sponsorship of Individual HCPs to attend Third-Party Educational Conferences, including travel-related expenses, starting January 1, 2018.

Key Concepts

- Companies may provide reasonable travel expenses and lodging costs to HCPs if subordinate in time and focus to scientific, educational or business program or meeting.
- In all instances, there must be objective, legitimate reasons that support the need for travel and lodging for HCPs.

FAQ: Travel Associated with HCP Business Interactions

Section IX

- Section IX of the Code indicates that Companies can reimburse HCPs for travel-related expenses of RMB500 and under; however, Section IV of the Code (regarding sponsorship of HCPs to attend third-party educational conferences) indicates that Companies cannot reimburse HCPs' travel expenses directly to the HCP. Are these provisions consistent?

Educational Items and Prohibition on Gifts

Section X

- Permissible for Companies to occasionally provide items to HCPs that benefit patients or serve a genuine educational function for HCPs so long as the items have modest fair market value.
- Prohibits Companies from providing items that are capable of use for non-educational or non-patient-related purposes.
- Prohibits Companies from providing gifts to HCPs. Prohibition includes (1) branded items that do not serve a genuine educational function for HCPs and (2) cultural courtesy gifts.

Key Concepts

- Companies **may not** provide branded items that do not serve a genuine educational function or “gifts” to HCPs.
- Companies **may** provide modest, appropriate educational items or patient benefit items to HCPs.

FAQ: Educational Items and Prohibition on Gifts

Section X

- Would AdvaMed provide a list of educational items or patient benefit items that are permitted under the Code?
- May a Company or its representative provide a gift to recognize a life event for a HCP, such as a wedding, birth, anniversary, or funeral?
- Does the prohibition on gifts apply to a HCP's staff?
- What are examples of non-educational branded items?

Research, Academic and Public Education Grants; Charitable Donations

Section XI

- Advises Companies to adopt objective criteria for the provision of grants and donations to HCPs to not let sales personnel impose undue influence, implement appropriate procedures to ensure such grants and donations are not unlawful inducements, and ensure that all grants and donations are appropriately documented. Also advises Companies to monitor compliance.
- Advises Companies to ensure that any donation or grant is handled by the recipient HCP's financial department and used for bona fide non-profit activities, accepted by the HCP's legal entity, and not tethered to business generation or otherwise linked to unfair competition.
- Identifies circumstances for when it may be appropriate for Company provision of grants and donations. Includes guidance for the provision of research grants, academic and public education grants, and charitable donations.

Key Concepts

- Companies may provide research and educational grants and charitable donations to HCPs.
- Companies should rely on objective criteria for determining recipients of such grants and donations.

Evaluation and Demonstration Products

Section XII

- Acknowledges patient benefits of providing products to HCPs at no charge for evaluation or demonstration purposes. HCPs may assess the appropriate use and functionality of products and determine whether and when to use, order, purchase, or recommend in the future.
- Advises Companies to ensure provision of evaluation and demonstration products cannot be conditioned on buying products or services, nor linked to other conditions that might affect fair competition. Also advised Companies to provide HCPs with documentation and disclosure regarding the no-charge status of evaluation and demonstration products provided.
- Identifies circumstances for when it may be appropriate for Company provision of reasonable quantities of products to Institutional HCPs at no charge for evaluation and demonstration purposes. Includes guidance for the provision of single use products, multiple use products, and demonstration products.

Key Concepts

- Companies can provide reasonable quantities of products to HCPs for evaluation and demonstration purposes at no charge to permit HCPs to evaluate and assess whether to purchase the product.
- Companies may also provide HCPs with unsterilized demonstration products to use in educating patients about the product and its use.

Third-Party SMI Relationships

Section XIII

- Encourages Company adoption of a specific compliance program for Third Party SMI relationships that applies to all relevant personnel, including Company's senior leadership.
- Proposes elements for such programs to include:
 - Written Policy/Procedure.
 - Risk Assessment.
 - Due Diligence Program.
 - Written Contract.
 - Training and Education.
 - Monitor/Audit.
 - Appropriate Corrective Action.

Key Concepts

- Companies are encouraged to adopt a specific compliance program for Third Party SMI relationships that includes the elements outlined in this section.

Company Representatives Providing Technical Support in the Clinical Setting

Section XIV

- Highlights the important role Company representatives may play in the clinical setting by providing technical support on the safe and effective use of Medical Technology.
- Advises Companies to apply five principles:
 - Company representatives should enter and be present in the clinical setting only at the request of and under the supervision of a HCP.
 - Company representatives should be transparent that they are acting on behalf of the Company in a technical support capacity.
 - Company representatives should not interfere with a HCP's independent clinical decision-making.
 - Company representatives should comply with applicable hospital or facility policies and requirements, including patient privacy and credentialing requirements.
 - A Company's technical support should not eliminate an overhead or other expense that the HCP should otherwise incur while providing patient care.

Key Concepts

- Company representatives can play a pivotal role in the clinical setting by providing technical support on the safe and effective use of Medical Technology.
- Companies are encouraged to apply the principles outlined in this section.

“Thank You”



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