AdvaMed Code of Ethics on Interactions with Health Care Professionals in China

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13 September 2017
About the Speaker

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Who is AdvaMed?

China Device Industry Environment

AdvaMed China Code

Direct Sponsorships
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Who is AdvaMed?

Advanced Medical Technology Association (AdvaMed)

• World’s largest medical technology association
• Nearly 300 members with a global presence in countries including China, Europe, India, Brazil and Japan
• Advocate on a global basis for the highest ethical standards, timely patient access to safe and effective products and economic policies that reward value recreation
• Act as the common voice for companies producing medical devices, diagnostic products and health information systems
AdvaMed Member Companies in China
Agenda

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Corruption and Bribery: Headline News

**THE ECONOMIC TIMES**
Siemens, Philips, GE medical devices units face bribery probe in China

**COMPLIANCE WEEK**
China Targets Medical Device Companies in Bribery Probe

**THE WALL STREET JOURNAL.**
Medical Device Company Settles Foreign Bribery Charges

**Reuters**
AstraZeneca to pay $5.52 million to resolve SEC foreign bribery case

**sina 新浪财经**
近四百名医生倒在医疗反腐风暴中 医用耗材成腐败新高

**新华网 新闻**
央視曝光醫生回扣占藥價三四成 卫计委连夜回应
China Enforcement Overview

- Enforcement hot spot for U.S. authorities
- Recent settlements show need for adequate internal controls and timely disclosure of misconduct
- China’s domestic anti-corruption campaign continues, including scrutiny of health care industry
  - Major healthcare cases may be jointly handled by several ministries/agencies
  - Local Administration of Industry and Commerce (AIC) continue to target commercial bribery in health care sector
  - Local AIC have broadened scope of misconduct considered commercial bribery
  - New draft amendments to the Anti-Unfair Competition Law (“AUCL”) could reshape the commercial bribery scheme, including more precisely defining commercial bribery, expanding the scope of liability, and heftier fines
2016 Corruption Criminal Investigations in Device Industry

- People’s Procuratorate publicized at least 32 criminal bribery actions against medical device companies
  - Companies and individuals were penalized
  - Largest number of implicated institutions were in Jiangsu and Henan provinces
  - Orthopedics departments and clinical laboratories were most often implicated
- Over 386 HCPs, including well-known director-chiefs of hospitals or hospital departments, were brought down in criminal corruption investigations
Looking Ahead …..

• National Health and Family Planning Commission (NHFPC) announced inspections of 85 third-grade class-A hospitals for potential corruption and compliance problems in 2017

• Trends indicate bribery crackdown in health care sector (including the device industry) will continue, especially with respect to the purchase of consumables
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AdvaMed China Code

• AdvaMed Code of Ethics on Interactions with Health Care Professionals in China (AdvaMed China Code)

• Adopted March 2015; Effective 1 January 2016)

• Jointly signed by China Association for Medical Devices Industry (CAMDI) in October 2016

• Goals & Background:
  – Industry self-regulatory approach designed to proactively address potential anti-bribery/anti-corruption concerns in the Chinese marketplace
  – Derived from best practices and global compliance trends
  – Establishes baseline compliance guidelines for companies to incorporate into their policies on customer and HCP interactions
  – Serves as a foundational document for medical device industry in China
    • Helps ensure collaborative, necessary relationships between device companies and HCPs meet high ethical standards
    • Conducted with transparency and in compliance with laws
AdvaMed China Code (cont’d)

• Addresses critical topics:
  – Company-Conducted Product Training and Education
  – Supporting Third-Party Educational Conferences
  – Sales, Promotional, and Other Business Meetings
  – Consulting Arrangements with HCPs
  – Prohibition on Entertainment & Recreation
  – Modest Meals & Travel Associated with HCP Business Interactions
  – Educational & Branded Promotional Items
  – Research, Academic and Public Education Grants; Charitable Donations
  – Evaluation and Demonstration Products
  – Third Party Sales and Marketing Intermediary (“SMI”) Relationships

• Includes FAQs that provide additional details to assist companies in implementation and decision-making
AdvaMed China Code (cont’d)

Companies may make training and education on products and medical technologies available to HCPs

• Including:
  – Hands-on training sessions
  – Cadaver workshops
  – Lectures and presentations

• Principles for conducting training and education programs:
  – Conducted in settings that are conducive to the effective transmission of information
  – Held in appropriate facilities
  – May provide HCPs with modest meals/refreshments
  – May pay for reasonable travel and modest lodging of the attending HCP
AdvaMed China Code (cont’d)

Companies may conduct **sales, promotional and other business meetings with HCPs:**

**•Purpose:**
  – To discuss medical technology features, sales terms, or contracts

**•Location:**
  – Most commonly occur close to the HCP’s place of business
  – Can occur in other cities within China or overseas

**•Expenses:**
  – May pay for reasonable travel costs of attendees
  – May **not** pay any expenses of guests of HCPs
  – May **not** pay any expenses of any other person who does not have a *bona fide* professional interest in the information at the meeting
Companies may pay HCP consultants for *bona fide* consulting services

- Examples: contracts for research; product development; development and/or transfer of intellectual property; participation on advisory boards; conducting technical training on products
- Must pay fair market value
- Must fulfill a legitimate business need
- Must not constitute an unlawful inducement

**Must:**
- Be in writing, and describe all services to be provided
- Be entered into *only* where a legitimate need for the services is identified in advance and documented
- Be based on the consultant’s qualifications and expertise to meet the desired need
- Include compensation consistent with the fair market value in an arm’s length transaction
- Include a written research protocol where necessary

**Must NOT:**
- Involve HCPs selected, controlled, or influenced by sales personnel
- Be based on the consultant’s value or business volume
- Be paid in cash
Companies may **not** provide or pay for any *entertainment* or *recreational event* or activity for any HCP

- All company interactions with HCPs should facilitate the exchange of medical or scientific information that will benefit patient care

Examples of prohibited activities:
- Theater
- Sporting events
- Lavish meals
- Leisure or vacation trips

Such events and activities should **not** be provided regardless of:
- Value
- Whether HCP is engaged as a speaker or consultant
- Whether the entertainment or recreation value is secondary to an educational purpose
Companies may provide modest meals as an occasional business courtesy

• **Purpose:**
  – Incidental and conducive to a *bona fide* presentation of scientific, educational or business information
  – **Not** part of an entertainment or recreational event

• **Setting & Location:**
  – At HCP’s place of business, unless impractical or inappropriate:
    • Where medical technology cannot easily be transported to HCP’s location
    • When it is necessary to discuss confidential product development or improvement information
    • Where a private space cannot be obtained on-site

• **Guidelines for appropriate participants at meals:**
  – Only those HCPs who actually attend the associated meeting
  – Only when a Company representative is present
  – **Not** provided to an entire office staff (where everyone does not attend meeting)
  – **Not** provided to guests of HCPs
  – **Not** provided to any person who does not have a *bona fide* professional interest in the information shared at the meeting
Companies may provide reasonable travel expenses for individual HCPs

**Purpose:**
- *Bona fide* scientific, educational, or business purpose for HCP travel
- Length of trip commensurate with purpose
- No recreational activities, side trips, city tours, or other activities that do not support *bona fide* professional purpose

**Location:**
- Adopt objective criteria to select locations and venues
- Consider local alternatives before sponsoring travel for HCPs
- Consider China-based alternatives before sponsoring international travel for HCPs

**Reasonable Expenses:**
- Flights
- Hotels
- Meals
- Incidentals

**Reimbursement:**
- Pay airlines and hotels directly if possible / practical
- No cash reimbursement for expenses > RMB 500

**Participants:**
- No reimbursement to guests of HCPs
- Reimbursement only to persons with a *bona fide* professional interest in the activity requiring travel
Companies may occasionally provide HCPs with *items that benefit patients or serve a genuine educational function*

- Should be of modest, fair-market value, with two exceptions:
  - Medical textbooks
  - Anatomical models used for educational purposes
- Branded Promotional Items
  - Should be of minimal value, ≤ RMB 200
  - Ex: stationery items; USB drives; mouse pads; other items bearing the company’s logo

- Prohibited items:
  - Any items banned by local law
  - Items capable of use for non-educational or non-patient-related purposes, such as smartphones, tablet computers, laptops
  - Alcohol
  - Tobacco
  - Cash, gift cards, or other cash equivalents
Companies may provide research & educational grants and charitable donations to HCPs

• Grants/donations may not be provided as an unlawful inducement:
  – Adopt objective criteria, and implement procedures to ensure compliance
    • Criteria should not include sales considerations (e.g., volume of business from the recipient)
  – Fully document all grants and donations
  – Companies should not control or unduly influence who receives grants/donations, or the amount awarded

• Impose requirements on the grant or donation:
  – Must be accepted by the legal institutional entity
    • Not internal departments
    • Not individual HCPs
  – Should be handled by the institution’s financial department
  – Used for bona fide non-profit activities
  – Not conditioned on buying products/services, or other factors affecting fair competition
AdvaMed China Code (cont’d)

Companies may provide reasonable quantities of no-charge products to institutions for evaluation and demonstration purposes

– Allows HCPs to assess appropriate use and functionality of product, to determine future need
– Must **not** be conditioned on buying products or services, or otherwise affect fair competition

**Single Use / Consumables / Disposables:**
- Provide no greater amount than necessary for product evaluation
- Terms of no-charge status and evaluation to be disclosed in writing to the HCP
- Make any additional disclosures required by local law/regulation

**Multiple Use / Capital Equipment:**
- May be provided for a reasonable period of time to allow evaluation
- Terms of evaluation to be disclosed in writing to the institution (not internal departments; not individual HCPs)
- Company retains title to product during eval period
- Promptly remove product at end of eval period, unless institution purchases or leases

**Demonstration Product:**
- Unsterilized single-use products, or mockups
- Used for patient awareness, education, and training
- Must **not** be used in patient care
- Labeled as “Sample,” “Not for Human Use,” or other suitable designation (on product, packaging, and accompanying documentation)
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Addressing Direct Sponsorships in China

• Status of **sponsorships under Chinese law is unclear**
  – Various anti-bribery & competition laws
  – Prohibitions on what health care organizations and professionals can accept
  – Recently issued rules on donations call sponsorships into question

• Recent **enforcement** highlights sponsorships allegedly used as bribes or expenses falsely recorded as “sponsorship fees” to disguise bribes

• Some biotech companies have **voluntarily phased out** direct sponsorships

• **Global Trend** – direct sponsorship not permitted in the U.S. and being phased out by MedTech Europe and APACMed (both effective 1 Jan. 2018); other geographies do not permit direct sponsorship
Phasing Out Direct Sponsorships

**LEGEND**
- Red = Direct Sponsorship Currently Prohibited
- Blue = Committed to Re-evaluate Direct Sponsorship
- Orange = Direct Sponsorship Phase-Out effective 1 Jan. 2018
Addressing Direct Sponsorships in China – Phase Out

Accordingly, **AdvaMed member companies** plan to phase out direct sponsorship of HCPs to attend third-party educational events, **effective 1 Jan. 2018**

- No direct travel, lodging, meals, or registration fees for individual HCPs to attend third-party educational conferences

- Rather, companies can **provide educational grants/donations** to conference organizers (or other legitimate grant/donation recipients) to support third-party educational conferences

- Educational grant/donation recipient and/or conference organizer can use grant funds to defray or underwrite HCP costs

Companies can also provide:

- Company-conducted product training and educational meetings;

- Company-conducted satellite symposia in connection with third-party educational conferences; and

- Direct support for HCPs’ attendance at technical procedure training courses

These changes are intended to help avoid even the appearance of impropriety and ensure transparency of relationships between companies and HCPs in China
THANK YOU!!