



# Global Compliance Codes Roundtable: Discussion on the PhRMA Code

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# General Background

- PhRMA Code on Interactions with Healthcare Professionals
  - Voluntary; company signatories
  - Revised Code went into effect in January 2009
  - Reinforces the appropriate nature of the interactions of healthcare professionals
  - Specific to marketed products and related pre-launch activities
  - Focused on fact as well as perception
- It **does not** cover relationships with clinical investigators and others involved in the clinical research process; these relationships are addressed in the PhRMA Principles on Conduct of Clinical Trials and Communication of Clinical Trial Results
- In the U.S., additional focus via Patient Protection Affordable Care Act (PPACA) – effective 2012 – “Sunshine Provision” (Section 6002)
- Ex-US, additional focus by proliferation of country Transparency regulations, Anti-Corruption regulations/guidance, and Global Trade Regulations

# Select Points (numbers below relate to sections in PhRMA Code)

## 1. Basis of Interactions

### Promotional Material

- Should be accurate and not misleading;
- Should only make substantiated claims;
- Should reflect the balance between risks & benefits
- Should be consistent with all FDA requirements

## 2. Informational Presentations by Pharmaceutical Company Representatives and Accompanying Meals

- Occasional meals appropriate as a business courtesy as long as presentations provide scientific or educational value
- Meals must be
  - Modest as judged by local standards
  - Not be part of an entertainment or recreational event
  - Provided in a manner conducive to informational communication
  - Meals offered in connection with informational presentations made by field sales reps must be provided in a hospital or office setting

# Select Points (continued)

## 3. Prohibition on Entertainment and Recreation

- Should not provide any entertainment or recreational benefits **regardless of value**, whether through a healthcare professional as speaker or consultant, or whether the entertainment or recreation is secondary to an educational purpose

## 4. Support for Continuing Medical Education

- New section in the revised code
- Should separate its CME grant-making functions from its sales and marketing departments
- Should establish **objective criteria** for making a CME grant decision
- Financial support should be given to CME provider directly
- Should follow standards for commercial support issued by the Accreditation Council for Continuing Medical Education or other entities that may accredit the CME.
- Should not provide a meal at a CME program nor provide funds to the CME program provider specifically earmarked for meals
- Financial support should not be offered for costs of travel, lodging, or other personal expenses of non-faculty attending CME, either directly or indirectly through event sponsor

# Select Points (continued)

## 6. Consultants

- Selection should be based on **defined criteria** such as expertise and reputation
- Ensure that arrangements are neither inducements nor rewards for prescribing or recommending treatment
- Compensation to be made based on **fair market value**
- Factor to support bona fide arrangement:
  - Written contract
  - Legitimate need established in advance
  - **Criteria for selection directly relates to need**
  - Maintain records regarding use of consultant
  - Venue is conducive to learning; resorts not appropriate

# Select Points (continued)

## 7. Speaker Programs and Training Meetings

- Prohibits speaker-training programs for HCPs to take place at resort venues or to include entertainment
- Permits the company to pay reasonable compensation to HCPs for time, travel, lodging, and meal expenses
- Caps the total amount of annual compensation it will pay to an individual healthcare professional speaker;
- Company to train the speaker on the company's drug products and FDA regulatory requirements;
- Company to develop speaker-hiring policies and address the number of speaking engagements for an individual;
- Company should ensure that speakers disclose that they are presenting on behalf of the company

# Select Points (continued)

## 11. Educational Items

- Can offer items designed **primarily** for education of patients or healthcare professionals
- Items cannot be of substantial value (US\$100 or less)
- Offered **only on an occasional basis**

## 12. Prescriber Data

- A new section of the code provides that companies that use prescriber data that does not identify individual patients must use it responsibly
- Companies should respect the confidentiality of such data, **develop policies** regarding the use of such data, educate employees and agents about such policies, maintain an internal contact person to handle inquiries regarding the use of this data, and **identify appropriate disciplinary actions** for misuse of prescriber data

## 13. Independence and Decision Making

- Nothing should be offered or provided in a manner or on conditions that would **interfere** with the independence of a healthcare professional's prescribing practices

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