

What pharma/med tech firms should know about interacting with healthcare professionals in the US



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Interactions with healthcare professionals have led to the creation of numerous codes of conduct and compliance programs worldwide. Karen Gibbs and Andrew Slade shed light on what every European pharmaceutical and medical device company must know about recent developments in the US.

On 10 July 2008, the Pharmaceutical Research and Manufacturers of America (PhRMA) revised its Code on Interactions with Healthcare Professionals (Code). The revised Code will take effect in January 2009. Compliance with the Code is generally voluntary, however, in a growing trend, two states have incorporated the Code into laws addressing interactions with healthcare professionals. Under California Health & Safety Code § 119402, certain pharmaceutical and medical device companies doing business in California must create comprehensive compliance programs that are consistent with PhRMA's revised Code.

And, under a recently passed and more aggressive law, the commonwealth of Massachusetts has mandated that its Department of Public Health adopt a standard marketing code of conduct for all pharmaceutical and medical device companies and which is no less restrictive than the new PhRMA Code. The new Massachusetts law also sets forth numerous requirements of all covered pharmaceutical and medical device companies. Accordingly, as detailed in this article, European-based pharmaceutical and medical device manufacturers doing business in the United States – and especially in California and Massachusetts – must pay attention to these significant legal developments and associated compliance requirements.

...PhRMA's Code on Interactions with Healthcare Professionals

PhRMA first introduced its Code on Interactions with Healthcare Professionals in 2002. As a representative of America's leading pharmaceutical and biotechnology companies, PhRMA designed the Code to address concerns about relationships between healthcare professionals and industry sales representatives. The Code addressed how pharmaceutical companies could provide educational information to healthcare professionals, while preventing them from utilising sales or marketing practices giving the appearance of undue influence.

In response to the initial Code, certain stakeholders called for federal and state legislative action, and, within the last year, the United States Congress has demonstrated its interest in regulating the marketing and sale of pharmaceutical as well as medical device products more closely. Members of the United States Congress have introduced several bills, including the Physician Payments Sunshine Act, the Transparency in Medical Device Pricing Act and the False Claims Act Correction Act, all of which seek further to deter the improper

influence of healthcare professionals. In response to pending legislation, PhRMA revised its Code on 10 July 2008, with the amended Code coming into effect in January 2009. The revised Code attempts to balance the need of companies to educate healthcare professionals with concerns that certain marketing practices create an appearance of undue influence on healthcare professionals. Accordingly, the new Code contains three significant revisions.

First, the revised Code bans non-educational gifts for healthcare professionals. This ban encompasses items such as mugs, pens and notepads. Previously, pharmaceutical representatives could offer small gifts associated with healthcare professionals' practice. The revised Code's ban on gift giving is supposed to alleviate concerns that pharmaceutical companies' marketing practices inappropriately influence healthcare professionals.

Second, the revised Code restricts companies' provision of restaurant meals to healthcare professionals. Under the original Code, pharmaceutical representatives could provide modest restaurant meals in conjunction with informational presentations to healthcare providers. The revised Code permits meals in conjunction with educational presentations only if they occur in in-office or in-hospital settings.

Third, the revised Code clarifies permissible consultant and speaker arrangements with healthcare professionals. Recreational and entertainment activities in conjunction with consultant engagements and speaker training are expressly prohibited. Consultants and speakers sitting on committees that develop practice guidelines are now advised to disclose the nature and existence of their relationships with pharmaceutical companies to their committees.

Other portions of the revised Code address the following areas: the need for corporate compliance policies and procedures; training of company representatives about the laws, regulations and standards governing interactions with healthcare professionals; certification of the existence of processes for compliance with the Code; and restrictions on pharmaceutical companies' support for continuing medical education events.

...effect on European pharmaceutical and medical device companies

Industry guidelines such as PhRMA's do not normally impose any compliance requirements – compliance is typically voluntary. Accordingly, compliance by European companies with PhRMA's revised Code is largely voluntary.

However, if your company is doing business in the United States, it is recommended that your company consider incorporating PhRMA's Code into a compliance program or code of conduct, or comparable codes developed by medical device trade associations,

including AdvaMed (the Advanced Medical Technology Association) or the MDMA (the Medical Device Manufacturers Association). Indeed, now, both the state of California and the commonwealth of Massachusetts mandate adoption of one or more of these codes by covered pharmaceutical and medical device companies.

...doing business in California

California Health & Safety Code § 119402 requires any “pharmaceutical company” (definition provided below) doing business in California to adopt a Comprehensive Compliance Program (CCP) that is in accordance with the April 2003 publication, Compliance Program Guidance for Pharmaceutical Manufacturers (CPG), developed by the United States Department of Health and Human Services Office of Inspector General. This CCP must incorporate the PhRMA Code dated 1 July 2002, and CCPs must be updated within six months of any revision of the CPG or the PhRMA Code.

California Health & Safety Code § 119400 defines “pharmaceutical company” as “an entity that is engaged in the production, preparation, propagation, compounding, conversion, or processing of dangerous drugs, either directly or indirectly, by extraction from substances of natural origin or independently by means of chemical synthesis or by a combination of extraction and chemical synthesis. . . . [or] an entity engaged in the packaging, repackaging, labeling, relabeling, or distribution of dangerous drugs. . . . [or] a person who engages in pharmaceutical detailing, promotional activities, or other marketing of a dangerous drug in [California] on behalf of a pharmaceutical company”. This definition of “pharmaceutical company” does not include a licensed pharmacist.

The same statute defines “dangerous drugs” as “any drug that is unsafe for self-use and includes either of the following: (1) any drug that bears the legend ‘Caution: federal law prohibits dispensing without prescription’, ‘Rx only’, or words of similar import; (2) any drug or device that, pursuant to federal or state law, may be dispensed only by prescription, or that is furnished pursuant to Section 4006 of the Business and Professions Code.”

European pharmaceutical and medical device companies doing business in California may incur serious obligations under California law. If a European company is a “pharmaceutical company” within the definition provided by California Health & Safety Code § 119400, it will need to update its internal compliance policies to satisfy PhRMA’s revised Code on Interactions with Healthcare Professionals. In addition to the incorporation of PhRMA’s revised Code, concerned pharmaceutical and medical device companies must follow additional guidelines from the United States Department of Health and Human Services Office of Inspector General.

...doing business in Massachusetts

European pharmaceutical and medical device companies also should be aware of recently passed legislation in the commonwealth of Massachusetts, which is even more aggressive than California’s law.

On 10 August 2008, Governor Deval Patrick signed the Act to Promote Cost Containment, Transparency and Efficiency in the Delivery of Quality Health Care into law. Under the new law’s Chapter 111N, entitled: Pharmaceutical and Medical Device Manufacturer Conduct, the Massachusetts Department of Public Health (Department) is required to adopt a standard marketing code of conduct for pharmaceutical and medical device companies. The standard code of conduct is to be no less restrictive than PhRMA’s revised Code and the separate AdvaMed code.

The law sets forth specific requirements for the mandated code of conduct and also sets forth specific requirements of pharmaceutical and medical devices companies. Among other provisions, the

Massachusetts law requires the following of pharmaceutical and medical device manufacturers with agents or employees selling or marketing a drug or medical device in the commonwealth of Massachusetts:

- adopt and comply with the most recent marketing code of conduct as adopted by the Department;
- adopt a training program to provide regular training to appropriate employees including, without limitation, all sales and marketing staff, on the marketing code of conduct;
- conduct annual audits to monitor compliance with the marketing code of conduct;
- adopt policies and procedures for investigating instances of noncompliance with the marketing code of conduct and take corrective action in response to noncompliance and the reporting of instances of noncompliance to the appropriate state authorities;
- identify a compliance officer responsible for operating and monitoring the marketing code of conduct;
- annually submit to the Department (i) a description of its training program; (ii) a description of its investigation policies; (iii) the name, title, address, telephone number and electronic mail address of its compliance officer; and (iv) certification that it has conducted its annual audit and is in compliance with the marketing code of conduct; and
- by July 1 of each year, disclose to the Department the value, nature, purpose and particular recipient of any fee, payment, subsidy or other economic benefit with a value of at least \$50, which the company provides, directly or through its agents, to any physician, hospital, nursing home, pharmacist, health benefit plan administrator, health care practitioner or other person in Massachusetts authorized to prescribe, dispense, or purchase prescription drugs or medical devices in Massachusetts, and such disclosure must be accompanied by the payment of a fee to pay the costs of administration.

The Massachusetts law also requires the Department to make all disclosed data publicly available and easily searchable on its website and to report to the state attorney general any payment, entertainment, meals, travel, honorarium, subscription, advance, services or anything of value provided in violation of the market code of conduct as adopted by the Department.

...conclusion

The trend at both US federal and state level is for the incorporation of the PhRMA Code as well as the AdvaMed code into mandatory codes of conduct and compliance programs of covered pharmaceutical and medical device companies. California and Massachusetts both have referenced the PhRMA Code in their respective laws; Massachusetts also has referenced the AdvaMed code. The District of Columbia and other states, including Maine, Minnesota, Nevada, New Hampshire and Vermont, also have adopted pharmaceutical marketing regulations, and an additional twenty-one states currently are considering pharmaceutical marketing legislation. It is critically important that European-based pharmaceutical and medical device manufacturers pay attention to this trend, the requirements of federal and state laws in the United States, and the consequences of failure to comply. *

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