Medical Affairs: Compliance Lessons Learned & Best Practices

DMH BioPharm Advisors, LLC

Medical Affairs and Medical Science Liaisons play a critical role in scientific exchange between healthcare companies and the medical community. The OIG and the FDA support scientific exchange and advocate for a clear separation between Medical Affairs and commercial organizations in research, consulting and grant funding. The goal is to ensure that decisions surrounding these areas are independent from product promotion.

Increased Scrutiny of Medical Affairs

Medical Affairs activity has come under increased scrutiny by the Department of Justice and has resulted in enforcement actions and fines due to alleged misconduct by this group. A partial list of these enforcement actions is below.

Year	Company	Criminal Fines	Alleged Misconduct
2004	Pfizer	$430 million	Use of Medical Science Liaisons (MSLs) to promote off-label prescribing
2005	Serono	$704 million	Excessive payments to physicians participating in "observational" studies
2010	Allergan	$600 million	Failure to separate sales and medical affairs activities
2010	Forest	$313 million	Failure to disclose negative results from one study while touting positive results from another study
2011	UCB	$34 million	Use of MSLs to promote unapproved uses
2012	GSK	$3 billion	Improper publication activities in light of negative studies

The 14th Annual Pharmaceutical Compliance Congress, October 2013, KPMG

Lessons Learned from Recent Corporate Integrity Agreements

As a result of these enforcements, there is an increasing trend for Corporate Integrity Agreements (CIAs) to include specific direction for Medical Affairs departments. Recent CIAs have required companies to update their policies and procedures to include the manner under which Medical Affairs colleagues interact with HCPs, guidelines for sponsored and investigator-initiated research, publication guidance, and how to handle and record responses to unsolicited requests for off-label information. Recent CIAs are also requesting increased management accountability through management certifications and financial recoupment and specific training and monitoring requirements.[1]

Compliance professionals are increasingly interested in learning best practices from legal experts and colleagues in their industry. At the 14th Annual Pharmaceutical Compliance Congress last October, it was standing room only during a panel discussion on interactions with Medical Affairs.

Best Practices:

Today's Medical Affairs groups play a critical role in their organizations, and their roles are growing to encompass a list of new tasks, such as health economics and outcomes research (HEOR) and drug safety and pharmacovigilance. Due to the importance of delivering credible medical information and the increased scrutiny on Medical Affairs, it is critical that companies update their policies and procedures and ensure robust cross-training between medical and commercial colleagues.

Below are best practices related to Medical Affairs that organizations should consider:

Commercial and Medical Interactions (Cross-Training)

It has been our experience that many commercial colleagues do not fully understand and/or appreciate the rules and policies governing medical colleagues. As a result, there is a risk that unlawful interactions between commercial and medical colleagues may occur. The best approach to avoid this risk is to cross-train commercial and medical colleagues on their roles and rules of engagement with each other and customers. The training should be real world, with a strong focus on what you can and can't say and do. http://www.dmhbiopharm.com/field-based-medical/

Reprint Dissemination Guidance

The FDA issued guidance in January 2009 for the distribution of medical journal articles and medical or scientific reference publications on unapproved new uses of approved or cleared medical devices. The FDA's guidance documents do not establish legally enforceable rights or responsibilities. Instead, the guidance describes the agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited.[2] Companies should use these guidelines as a starting point to develop their own specific guidance and train their employees to understand this guidance through role-specific learning scenarios. Medical Affairs colleagues need to understand that information in the public domain should not be disseminated without their company's approval.

Unsolicited Medical Inquiries

The FDA has taken the position that firms can respond to unsolicited requests for information about FDA-regulated medical products by providing truthful, balanced, non-misleading and non-promotional scientific or medical information that is responsive to the specific request. The FDA issued draft guidance in December 2011.[3] Medical Affairs colleagues should have specific direction on how to respond to and document off-label questions and inquires from healthcare professionals. Organizations should develop a system to record unsolicited requests received from customers. Many companies use a Professional Inquiry Request (PIR) that should be signed by the physicians to verify that they made the request and to record specifically what the doctors asked.

Separation of Medical Affairs and Commercial Departments

In order to ensure proper separation between medical and commercial colleagues, organizations may want to consider the following suggestions.

- Medical Affairs departments should not report up to a commercial leader. They should report up through medical or research and development. In most organizations, the most senior medical leader reports to the Chief Executive Officer.
- Medical Affairs budgets should appear as separate line items, and funding decisions should not be sales or market-share driven.
- Medical Affairs should not be used as a resource to drive market share and sales growth.

- Companies need to create rules of engagement that outline appropriate communications and interactions between medical and commercial colleagues.
- Commercial colleagues should not participate in the design, content or publication of company-sponsored research.
- Sales and marketing departments should have no involvement in, or influence over, the review and approval of medical grants.

Company-Sponsored Research and Investigator-Initiated Research

- The research conducted should be intended to foster an increased understanding of scientific, clinical or medical issues.
- Assure that all publications are peer-reviewed and that the publication has an editorial board. The reviewer should have expertise in the area.
- Articles should not be ghostwritten or influenced by a pharmaceutical or medical device company.
- Researchers must disclose any financial support and any financial interest the researcher may have in the company.

Evaluation and Compensation

Companies should look at how their Medical Affairs colleagues are evaluated and compensated. The expected activities and performance criteria for Medical Affairs should not look like product sales-related metrics or activities.

Notes:

1) See Corporate Integrity Agreement between the Office of Inspector General of the Department of Health and Human Services and USK, Inc., available at *http://oig.hhs.gov/fraud/cia/agreements/GlaxoSmithKline_LLC_06282012.pdf*

2) Good Reprint Practices for the Distribution of Medical Journal Articles and Medical or Scientific Reference Publications on Unapproved New Uses of Approved Drugs and Approved or Cleared Medical Devices, available at *http://www.fda.gov/regulatoryinformation/guidances/ucm125126.htm*

3) Guidance for Industry: Responding to Unsolicited Requests for Off-Label Information About Prescription Drugs and Medical Devices, available at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM285145.pdf

About DMH BioPharm Advisors, LLC

DMH BioPharm Advisors is a boutique compliance-training firm with a proven proficiency in creating and delivering highly effective compliance training curriculums and learning strategies for commercial and medical employees in the biopharmaceutical and device industries. DMH's effective compliance training not only informs but also demonstrates to learners how the rules and regulations play out in their world—the common situations they might encounter—and how to handle those situations. DMH offers both off-the-shelf and customized compliance-training solutions. http://www.dmhbiopharm.com