Medical/Commercial Activities and Interactions: Benchmarking and Compliance Insights

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At the October 2025 Pharmaceutical and Medical Device Ethics and Compliance Congress, principals Jennifer A. Romanski and Michelle D. Axelrod participated in a session entitled "Medical/Commercial Interactions: Addressing Patient Needs and Fostering Collaboration While Maintaining Compliance." Attendees answered polling questions during the session, revealing current practices and insights into Medical Affairs and Commercial functions at their organizations. The polling questions related to organizational structure, interactions with payors, disease awareness activities, and communication of off-label information. The polling results underscore the distinct roles of Medical Affairs (focused on informing and educating through communication of scientific information) and Commercial (focused on product promotion, sales, access, and related disease education), highlighting evolving approaches and legal and compliance navigation of potentially challenging situations.

Organizational Structure

The majority of respondents (63%) indicated that their organization maintains a complete separation between Commercial and Medical Affairs functions, with no crossover in responsibilities. According to 37% of respondents, a clear separation between field sales personnel and field medical personnel (Medical Science Liaisons, or MSLs) exists in their organizations, but some overlap exists in more senior roles.

These results align with the best practice of having separation between Medical Affairs and Commercial functions due to their distinct roles. While one function should not control the other, and field sales and field medical personnel have distinct responsibilities to communicate certain information with external parties, complete separation of reporting structures may not always be feasible. This is particularly true in organizations where senior executives may hold overlapping corporate responsibilities for both functions. In such instances, robust training on the distinct roles of Medical and Commercial is crucial. Legal and Compliance teams can also be consulted when navigating relationships and activities of the two functions.

Interactions with Payors

Survey responses revealed a range of practices regarding joint meetings with payors involving Medical Affairs and Commercial/Market Access teams. The majority of respondents (56%) indicated that their organizations permit both teams to attend the entire meeting, subject to certain limitations on Commercial participation during the presentation of Pre-Approval Information Exchange (PIE) data. A total of 20% of respondents indicated both teams are allowed to be present, but require Commercial/Managed Markets personnel to leave when PIE data is presented. According to the respondents, nearly one quarter (24%) of organizations do not permit joint payor meetings at all.

Given the complexity of product access, these results confirm that joint meetings between Medical Affairs and Commercial teams and payors are common. Payors often request a single presentation from manufacturers to cover both scientific and

economic data when evaluating drugs for coverage, reimbursement, and formulary placement. FDA's 2018 guidance, "Drug and Device Manufacturer Communications with Payors, Formulary Committees and Similar Entities: Questions and Answers," codified in part in the Food, Drug, and Cosmetic Act, acknowledges that such communication can occur before product approval to allow payors to plan for potential coverage and reimbursement. However, to mitigate risk associated with communications about unapproved products and uses, companies can implement safeguards, which may include limiting Commercial participation during discussion of investigational product data or requiring Commercial personnel to exit the meeting during such discussions.

For the 24% of respondents who indicated their organizations do not permit joint payor meetings, these results may reflect that, indeed, no meetings with both Medical Affairs and Commercial present are permitted, but it could also reflect differences of opinion on what constitutes a "joint interaction."

Disease Awareness Campaigns Prior to Product Approval

With respect to disease awareness campaigns conducted prior to product approval, 62% of respondents reported that such campaigns are spearheaded by Medical Affairs, while 23% indicated that the Commercial function leads these efforts. A minority (15%) stated that their organizations do not engage in disease awareness campaigns prior to approval.

Physicians have reported that they rely on industry for disease awareness and education, so it is not surprising that 85% of respondents indicated disease awareness activities occur prior to product approval at their organizations. As Medical Affairs personnel are scientific and disease experts, they will typically have a role in the communication of disease awareness information or provide input on disease awareness materials such as disease education websites.

Dissemination of Off-Label Product Information

The polling results showed that practices concerning the proactive dissemination of off-label content vary among organizations, and may depend on their approach in considering FDA's 2025 guidance, "Communications From Firms to Health Care Providers Regarding Scientific Information on Unapproved Uses of Approved/Cleared Medical Products: Questions and Answers. " This guidance describes FDA's enforcement policy for certain firm-initiated communications of scientific information about unapproved uses of approved/cleared medical products (SIUU).

Regarding third-party source documents, 29% of respondents indicated that their organizations permit Commercial to disseminate such off-label information about company products, while 58% of respondents indicated their organizations restrict this activity to Medical Affairs personnel. A total of 13% of respondents indicated that their organizations do not proactively disseminate any information that may contain off-label content about company products.

In a survey question related to the dissemination of company-generated content (in conjunction with source documents) that may contain off-label information about company products, approximately 13% of respondents indicated that their organizations permit Commercial to proactively disseminate such materials, whereas 58% said that their organizations allow only Medical to do so. Nearly a fifth of respondents (17%) indicated their organizations disseminate only information created by third parties that may contain off-label information, and 13% indicated their organizations do not proactively disseminate any information that contains off-label content.

Some of the variability in the answers to these survey questions suggests that evaluating SIUU communications and related activities can be complicated. Additionally, according to the SIUU guidance, SIUU communications should be separate from promotional communications, and there is no stated restriction as to which functions at a company can share SIUU communications. Specifically, in addition to recommending the separation of SIUU communications from promotional communications, FDA recommends that personnel sharing SIUU communications have specialized training in providing truthful, non-misleading scientific information about unapproved uses of the company's approved medical products.

Conclusion

The survey responses, while not scientific, highlight an ongoing approach to maintaining separation between Medical Affairs and Commercial functions, while also recognizing that Medical Affairs and Commercial, although functionally distinct, work for the same organizations and can have evolving roles within companies. These roles can also vary with respect to the type of company, Medical Affairs and Commercial needs, as well as the type of product and disease area, among other considerations. Legal and Compliance professionals can take steps to mitigate potential risks posed by such activities and interactions to facilitate compliance, which can include, for example, reviewing internal business and scientific plans, reviewing external materials and communications, supporting careful consideration and documentation of scientific and business needs, and conducting ongoing training and monitoring.

Porzio's team of Life Sciences attorneys is always available to provide legal and compliance assistance to companies, including assistance related to Medical Affairs and Commercial activities and interactions.