Is Pharma Building Firewalls or Silos?

The Medical Affairs/Commercial Conundrum

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It is not the strongest or the most intelligent who will survive but those who can best manage change. ~ **Charles Darwin**

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The successful development of key opinion leaders (KOLs) is one of the most important promotional activities of pharmaceutical branding. Building KOLs pre-NOC clinical experience, sponsoring them to lead CME programs, and having them lend their expertise to regulatory bodies and formularies at national, regional, and community levels is critical to making brands successful right out of the gate. But is the pharmaceutical industry building firewalls or silos in their effort to meet compliance guidelines?

As the ability to gain access to and have an impact on physicians becomes continually more challenging, the industry has combined a double digit decrease in field sales personnel over the past decade with a 48% increase in medical science liaisons (MSLs).[1] With the ever-increasing complexity of therapeutics and devices coupled with an information tsunami of trials, publications, and evidence-based therapeutic guidelines, MSLs have become an indispensable resource for KOLs and industry alike.

While KOL development is ultimately a commercial objective, US, European, and Canadian regulators have driven a major evolution in corporate structure and reporting lines between medical and commercial.

How does industry go about meeting its commercial goals while managing to avoid stepping over the line of scientific exchange into off-label promotion? This is no minor debate, given the $7 billion in fines paid by US pharmaceutical companies as a result of unlawful promotion infractions between November 2010 and July 2012 alone[2], funding that could have been spent on bringing approximately seven new molecules to market.

Firewalls: A Necessary Construct

Historically, scientific exchange was conducted via medical marketing and professional relations functions under the purview of commercial teams with dotted line reporting to Medical Affairs. More recently, the Office of the Inspector General and Food and Drug Administration placed scientific exchange under the direct responsibility of Medical Affairs, with a meaningful separation from commercial departments. This separation includes a distinct reporting structure to the C-suite, compliance officer or research and development versus the commercial department, along with budgets independent of the achievement of commercial targets.

In 2012, Rx&D guidelines supported the utilization of medical personnel for the dissemination of scientific knowledge in response to unsolicited queries delivered by their peers, provided that the distinction between the communication of off label scientific information from promotional activities is clearly made.[3]

Are Corporate Goals Being Achieved?

As the pharmaceutical industry balances its investment in building and maintaining long-term relationships with KOLs under the constraints of ever-tightening compliance regulations, companies face several challenges:

1. **Organizational Design:** As roles and responsibilities have changed and reporting lines have segregated, the potential has arisen for organizational silos. Resistance to change, disconnected reporting lines, and fractured internal communication systems can create rifts between Medical Affairs, CME, and marketing and sales activities, having an impact on cross-functional relationships, and resulting in the delivery of a fragmented strategic plan.
2. **Guidelines:** Strict guidance on reporting structure, budget, and qualifications is available, but there is a lack of clarity on the appropriate nonpromotional activities of Medical Affairs, which leaves companies to create their own guidelines.
3. **KOL Management Skills:** Personnel in MSL roles have transitioned over the past decade from seasoned sales personnel to PhDs, Pharm Ds, and MDs, with accompanying scientific credibility but limited customer management experience. Credibility can be damaged with KOLs who lose confidence in a company due to a lack of organized and/or timely communication.
4. **Metrics:** Unlike sales and marketing, there are often unclear and inconsistent metrics to evaluate and reward Medical Affairs performance. How do organizations appropriately ensure corporate and return on investment goals are met while abiding by regulatory guidance?

With the right organizational design, internal processes, communication guidelines, metrics and training, pharmaceutical companies can ensure their medical plans are aligned with both commercial objectives and regulatory guidelines, while also ensuring they are being executed in the field with excellence. Early adopters will be the ones that gain support internally and externally, and they will stand a much greater chance of achieving both medical and commercial goals.

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