

Optimizing the Impact of the Medical Affairs Function

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Introduction

The Medical Affairs function at large and small biotechnology companies alike has undergone a transformation. External changes in the biotech and pharmaceutical industries shifted many functional roles from Marketing to Medical Affairs and thereby heightened the visibility of Medical Affairs groups. This expanded role has also ushered in enhanced pressure to deliver on performance.

To assess the evolving role of Medical Affairs and evaluate current organizational structures, responsibilities, and communication with Marketing, Campbell Alliance conducted primary research to learn how organizations have reacted to their changing environments. Surveys of 13 Medical Affairs directors and vice presidents and 19 Marketing directors across a range of company sizes (Table 1) provided a fascinating look into how the role of Medical Affairs has progressed, and also highlighted the greatest needs for improvement. Our findings and analysis are included in this article.

Regulations Shape the Field

Medical Affairs groups were established to facilitate peer-to-peer interactions between prescribing physicians and company representatives who were doctorate-level scientists, pharmacists, and physicians. Medical Affairs employees were tasked with discussing the science behind the products and were trained to deal with highly technical information; however, these groups typically reported to Marketing functions. As such, there was frequent—real and perceived—influence from Marketing to facilitate sales, and the intended objectivity of the Medical Affairs role was, to a certain degree, compromised.

In 2002, the Pharmaceutical Research and Manufacturers of America (PhRMA), a pharmaceutical industry trade group, published its voluntarily enforced Code on Interactions with Healthcare Professionals that was to be a guideline on ethical practices. Shortly after, the Department of Health and Human Services Office of Inspector General (OIG) issued

Table 1 – Company Representation in Study

Category	Medical Affairs	Marketing
Large Pharma	2	7
Mid-sized Pharma	8	6
Small Pharma	1	3
TOTAL	11	16

its own Compliance Program Guidance for Pharmaceutical Manufacturers that further dictated what constituted compliant behavior from drug companies interacting with prescribing health professionals.

The OIG guidelines and PhRMA codes established regulations for the relationships between pharmaceutical companies and physicians, including the use of informational presentations, educational meetings, employing physicians as consultants, speaker training meetings, and promotional giveaway items. The industry responded dramatically by restructuring organizations, frequently building a wall between Marketing and Medical Affairs functions.

The Evolving Role of Medical Affairs

The separation of Medical Affairs and Marketing assigned many responsibilities—and their correlated budgets—previously in the hands of brand managers to Medical Affairs. For our research, we questioned study respondents about the division of duties and current organizational structures to track the evolution of the Medical Affairs role.

Increased Responsibilities

In response to external industry forces, several programs that Marketing historically relied upon to introduce brands to healthcare professionals, including continuing medical education (CME), publications, and grants, have been shifted to Medical Affairs. For pipeline products approaching launch, respondents indicated that Medical Affairs groups now become involved no later than phase 3 and medical directors frequently become involved by the time a brand manager is assigned to the compound.

Place in the Organization

A majority of respondents within Medical Affairs reported that the increase in external scrutiny on marketing and sales activities elevated the importance of the function. Several noted that Medical Affairs had evolved from a supporting into an equal partner role, and that this change in status had been fueled by the new functions of the Medical Affairs departments. Seven out of 11 Medical Affairs groups we interviewed report to a C-level executive and all Medical Affairs functions were headed by a VP-level executive.

Communication with Marketing

Communication between Medical Affairs and Marketing seems to have generally improved in the last few years, with frequency and format ranging from monthly product planning and update meetings to informal daily contacts. As a result of its elevated role, members of the Medical Affairs staff stated that they are now consulted more frequently by their commercial counterparts. Several respondents mentioned that communications between the two groups is still challenging at times, now that Medical Affairs sometimes performs functions without routine Marketing input.

Role of MSLs

On average, Medical Science Liaisons (MSLs) comprised 50% of the Medical Affairs staff at companies represented. MSLs are distributed across major regions and markets of importance for the company and are involved in a broad range

of scientific exchange activities, KOL interaction, phase 4 planning, product launch support, sales training, and medical information preparation. Most Medical Affairs groups place great emphasis on the development of strong peer associations with KOLs and believe that doctorate-level credentials are key to such relationships.

Greater Accountability

Several Medical Affairs respondents described a heightened pressure for accountability brought about by the growth of staff and budgets. One company recently formed a strategic planning and operations group to provide centralized planning and oversight for its budget and functions. As budgets have grown in size to rival those of the Marketing unit, Medical Affairs respondents now feel increased demands to be better stewards of their budgets and timelines. For the first time in recent history, they are realizing an increased need to justify and perhaps even defend their spending.

Impediments to Organization Effectiveness

During the course of our research, we noted several key areas for potential organizational improvement where conceptual disparities between Medical Affairs and Marketing could hinder effective collaboration between the groups. These included the perceived role of Medical Affairs in the organization, alignment with brand messaging, maximizing MSL utility, and a means to demonstrate value (summarized in Table 2).

Differences in Perceived Role in the Organization

Within the Medical Affairs groups we interviewed, most cited their belief that the primary role of that function was to be the central source of information on company products, both internally to the

Table 2 – Challenges to and Potential Solutions for Optimization of Medical Affairs Functions

Challenge	Description	Potential Solution
Differences in Perceived Role of Medical Affairs	<ul style="list-style-type: none"> Medical Affairs sees its main role as an internal and external information source Marketing believes the primary role of Medical Affairs is to support the brand with scientific information 	<ul style="list-style-type: none"> Clearly define roles of Medical Affairs and communicate to other stakeholders Develop SOP for Medical Affairs activities on brand teams and a means to communicate progress Train Marketing and Medical Affairs to increase understanding of roles and challenges of each
Medical Affairs and Brand Messaging Not Aligned	<ul style="list-style-type: none"> Marketing does not believe that Medical Affairs has a good grasp on brand strategy nor shares its sense of urgency Medical Affairs must maintain its scientific objectivity 	<ul style="list-style-type: none"> Develop brand messaging from science and involve Medical Affairs to obtain buy-in Educate Medical Affairs on brand strategy to inform initiatives for which it is responsible Break down silos and establish regular communication streams between Marketing and Medical Affairs, including with MSL
Sub-optimal MSL Utilization	<ul style="list-style-type: none"> Firewall established to cut off communication between Marketing and MSL Ambiguity of regulatory restrictions leads some to be overly cautious 	<ul style="list-style-type: none"> Obtain a comprehensive understanding of regulatory guidelines Study and apply best practice responses to regulatory environment
Need to Demonstrate Value	<ul style="list-style-type: none"> Medical Affairs under increased pressure to show productivity Activities not linked to P&L Difficult to measure stakeholder influence 	<ul style="list-style-type: none"> Define desired impact of Medical Affairs activities and develop associated metrics Benchmark program metrics against latest techniques to track influence Increase transparency of activities, timelines, and accountability

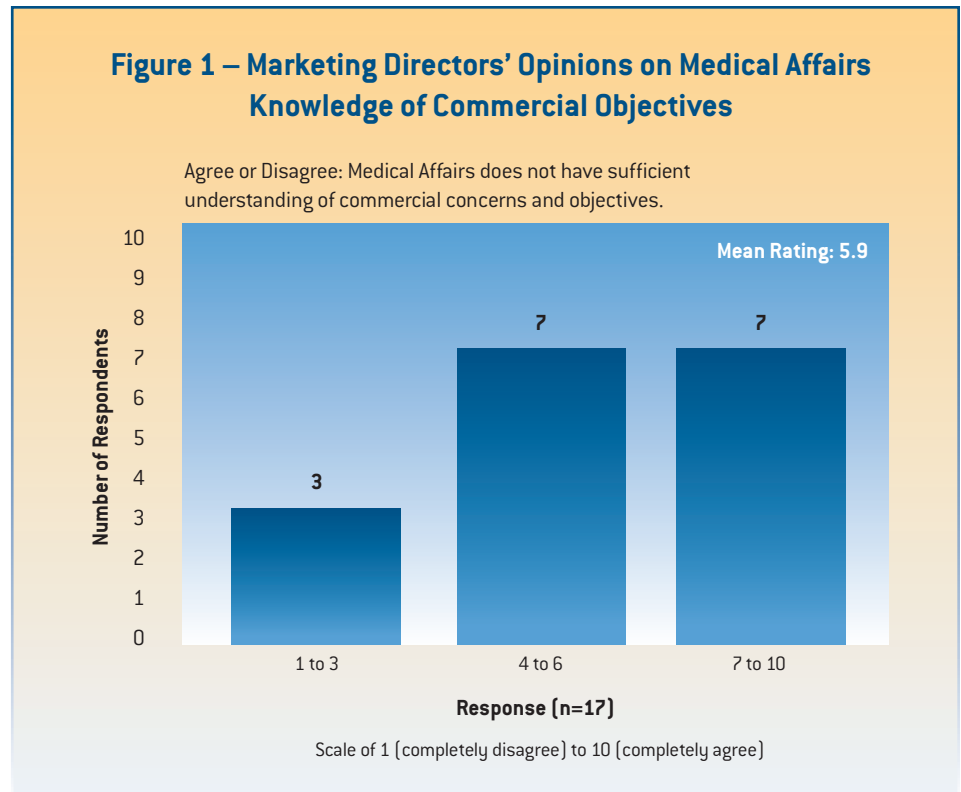
commercial group, and externally to patients and physicians. Some Medical Affairs respondents stated that they had worked arduously to establish the values and processes needed to support scientific credibility to outside stakeholders. One respondent told us that “the biggest challenge for Medical Affairs is to determine how we can position ourselves as honest, credible partners in healthcare rather than as biased commercial people.” As such, they see themselves as responsible for maintaining productive peer-to-peer relationships with KOLs and prescribers around the world.

In response to the same inquiry, Marketing directors opined that the role of Medical Affairs was primarily to assist with commercialization. One respondent directly told us that “the role of Medical Affairs is to support the brand and its goals.” Marketers agreed that Medical Affairs was used to create and disseminate scientific information, but expressed belief that it should be aligned to brand goals and strategies. Clearly, Marketing’s view of the role of Medical Affairs was much more centered on the brand than those expressed by the group itself.

Our research determined that the actual role played by Medical Affairs varies by company and even by product within companies. None of the companies we interviewed have standardized and well-communicated roles and tasks on launch teams. One Marketing director expressed that “Medical Affairs is too ambiguous, not clear on their objectives and what they are getting done.” According to our survey, variable factors affect the extent of involvement of Medical Affairs in new product launch, including resource availability compared with that of the brand group and even the personal relationship between the medical director and brand director. Although some Marketing directors stated that they work effectively with Medical Affairs without the need to get involved in execution, others stated that they routinely took the lead on planning and executing activities that were the responsibility of Medical Affairs. As a caveat to this, nearly two-thirds of Marketing directors also acknowledged that Medical Affairs was understaffed.

Alignment with Brand Messaging

Several Marketing directors highlighted that Medical Affairs groups are now delivering significant value prior to launch through their many undertakings. However, some surveyed expressed concerns that activities transferred to the Medical Affairs group were no longer aligned to brand strategies and objectives. Surprisingly, fewer than 20% of



the Marketing directors surveyed disagreed with the statement that Medical Affairs was lacking in sufficient brand knowledge (Figure 1). One claimed that “Medical Affairs tends to be very good on the science side of issues but not as good on the practical application of the knowledge to the customer.”

Marketing directors from several companies surveyed voiced unease that Medical Affairs and Brand Management were not integrated appropriately, and that Medical Affairs did not have a full appreciation of the commercial needs of the brands. Some claimed they thought Medical Affairs had become too removed from Marketing, and that they would like to see more involvement with the group. Marketing directors also cited belief that Medical Affairs was reluctant, if not averse, to letting commercial needs of the business drive its administration of these programs.

MSL Utilization

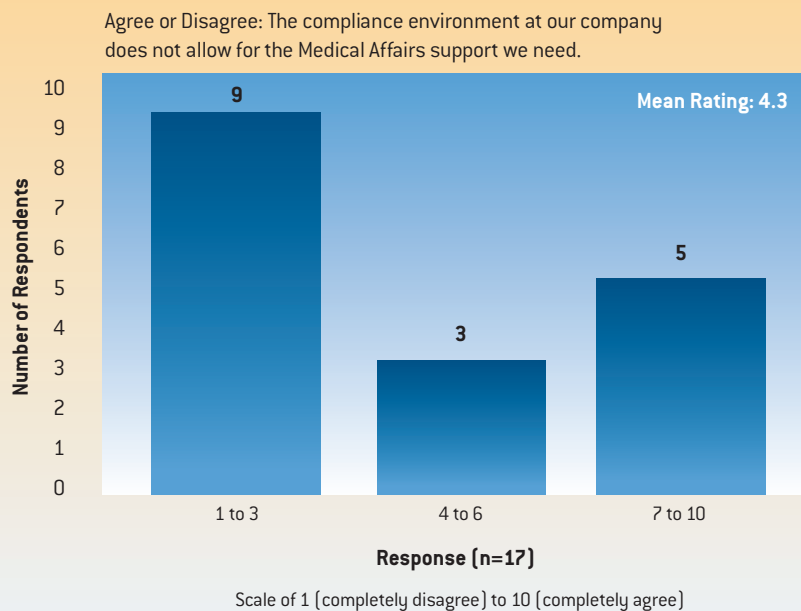
As a consequence of the new regulatory guidelines and limited physician access, the role of the MSL has expanded while that of the field sales representative has contracted. At many companies, field

sales representatives are not permitted to speak directly with the MSL nor can the MSL share certain information with Marketing. Because of this communication firewall, companies often struggle with the best way to align and utilize MSLs despite continually looking for new ways to reach physicians.

Unanimously, Marketing directors expressed belief that their companies have overly restricted the communication between MSLs and sales representatives or brand managers. Some expressed concern that since they are not always permitted to provide input into Medical Affairs communications and presentations, “the information shared with the customer may not be consistent with our brand strategy.”

Although many disagreed, nearly one-third of Marketing directors did state their belief that today’s compliance environment prevented MSLs from fully supporting their brand (Figure 2). According to some, the ambiguity of regulatory guideline interpretations has led their company to be excessively cautious. Many Marketing directors believe that organizations have overly corrected their behaviors

Figure 2 – Marketing Directors’ Opinions on Compliance Environment



in reaction to new guidelines. As one told us, “The pendulum has swung, and there is a wall that is unduly burdensome.”

Demonstrating Value

Medical Affairs managers are looking for better ways to demonstrate the value of their function to senior management. None surveyed were satisfied with the current system of measuring activities and productivity, and they were looking for ways to more effectively measure value and impact. One Medical Affairs respondent stated, “We need to be a lot more proactive and articulate and demonstrate what the company is getting for its money.” Nearly all respondents raised concerns about demonstrating and communicating the value of their headquarters- and field-based activities.

Most Medical Affairs participants in this study mentioned value measurement as an issue before them. Medical Affairs budgets have grown as a result of regulatory guidelines, resulting in greater scrutiny of CME budgets, publications, and salaries for growing MSL groups. Further, a majority of the Medical

Affairs leadership interviewed now report to either the CEO or the CSO, who are looking for quantifiable results. One Medical Affairs respondent explained that “it’s hard to demonstrate what these individuals do so someone doesn’t just view them as a cost center.” With the higher visibility in the organization comes the challenge to demonstrate in a compelling way the value that Medical Affairs brings for the company’s investment.

Potential Solutions

Our study indicates that there are unresolved issues that may be causing sub-optimal performance within the organization, all underscored by a need to find a balance between the role of Medical Affairs as information source and the need to appropriately support commercial interests. The evolution of the Medical Affairs role has created a requirement for clearer process and role definition, increased collaboration with Marketing, better understanding of the regulatory and compliance environment, and a more effective way of demonstrating the value of activities.

Clarified Process and Role Definition

Medical Affairs functions need to further clarify their roles and responsibilities within the organization. Medical Affairs should take ownership of the science behind the brand and proactively recommend ways to leverage the science to support the brand. To maximize influence, Medical Affairs groups should dedicate resources to each brand and seek to support pipeline products earlier in the development process. Other parties, including Development, Marketing, and Sales, should be made aware of and agree to the assignment of duties. Medical Affairs must then be proactive in executing their responsibilities and develop standardized processes to manage the activities. A line of communication must also be established to keep all stakeholders apprised of progress towards completion of activities.

Once clear procedures are established, training of all parties will be critical to deepen the understanding of the roles, responsibilities, and challenges of each function, and to identify ways to integrate planning processes and improve collaboration. Training should also help facilitate the development of shared vision, goals, and objectives towards an effective working relationship, and to gain agreement on processes for the ongoing planning and execution of shared programs.

Increased Collaboration with Marketing

There is a need to find common ground and balance between the role of Medical Affairs as the information source for physicians, patients, and other stakeholders, and the need to support the commercial interests of the organization. As such, Marketing and Medical Affairs should not be segregated. Brand messaging should be driven by scientific data, and the functions should work together to develop messaging strategies. With early involvement in the development of brand messaging, Medical Affairs should have the buy-in needed from staff to help align its activities with the brand strategy.

To become a truly effective partner, Medical Affairs should strike the difficult balance of incorporating an understanding of commercial needs for the brand into its duties while remaining compliant with regulations. Medical Affairs groups should expand their knowledge of brand positioning and how it relates to their plans and activities. Effective communication with Marketing will provide Medical Affairs a clear understanding of the needs of the brands they support in order to deliver value. Increased comprehension of commercial needs should also lead to a

greater focus on priority initiatives that only Medical Affairs can lead.

Medical Affairs should be viewed as a collaborative partner throughout the process of drug development and commercialization. As such, they should be involved in early strategy development, operational planning, and lifecycle management processes and should engage in active dialogue with Development, Marketing, and Sales groups. More frequent communication between Marketing and Medical Affairs, formal and informal, would go a long way towards reducing any disconnect between the groups. Medical Affairs should seek improvement in its cross-functional communication processes that track its activities, and should share its annual plans to reiterate its role and promote transparency.

Improved Comprehension of Regulatory Restrictions

While Medical Affairs leaders recognize the need to integrate planning efforts with Marketing, doing so poses problems for some. These tend to be Medical Affairs groups within organizations that have built compliance firewalls between Marketing and Medical Affairs in reaction to external guidelines. These firewalls hinder useful, open dialogue and collaboration within the organization. Lines of communication need to be re-established and strengthened, as firewalls make it impossible to use MSLs to their capacity and fullest potential. Organization changes need to be administered to allow interchange while maintaining regulatory compliance.

The building of firewalls in some organizations demonstrates a need for knowledge of best practices on the interpretation and application of the regulatory guidelines. A comprehensive, mutual understanding of the regulations would help facilitate an agreement between Medical Affairs and Marketing on how they can collaborate effectively within the letter and the spirit of the OIG and PhRMA guidelines. Best practice knowledge on how other companies have responded to the guidelines, especially as they affect MSLs, will also help determine the optimal balance between regulatory compliance and effective communication and teamwork between Medical Affairs and the commercial organization.

Refined Value Metrics and Accountability Tracking

Along with budget increases that rival those of Marketing comes a new scrutiny for Medical Affairs programs to demonstrate return on investment. Medical Affairs recognizes the value added to the organization, but believes that the value is not always fully understood by the commercial organization and senior management. Defining the desired impact for Medical Affairs, deriving metrics associated with those activities, and developing a format for reporting accomplishments to senior management will be essential to demonstrate value. An updated definition of the role of Medical Affairs should be communicated to the rest of the organization for awareness of how the team can be used as a true partner—both at headquarters and within the field—to help support the common goals.

Many of the challenges in demonstrating the value of Medical Affairs are due to the paucity of useful metrics that can quantify the result of their work. Senior executives are accustomed to seeing value in terms of P&L, but clearly Medical Affairs cannot link revenue to their activities in a traditional manner. The value of key customer relationships in addition to medical, clinical, and scientific expertise are intangible and not easy to measure. Medical Affairs groups need to benchmark their current program metrics against the latest industry techniques developed to monitor and track changes in key subject matter knowledge. An informed determination of what to evaluate and how to measure it is needed to help demonstrate the value of all Medical Affairs activities to senior management.

To further demonstrate value, Medical Affairs groups also need to inform other stakeholders of their ongoing work streams. When appropriate, increased transparency should be established with brand teams to demonstrate activities, deadlines, individuals responsible for the activities, and those who are accountable. Medical Affairs should increase its focus on timeliness in meeting commitments to the Marketing team, and strive to show a greater sense of urgency to achieve execution excellence in all of its activities.

Conclusions

Change in the pharmaceutical industry has clearly impacted the Medical Affairs function, giving them more responsibility than ever. However, responses to the new regulatory and compliance environment can lead to the isolation of Medical Affairs from commercialization activities, and thereby reduce the potential utility of this critically important group. Through pursuit of full comprehension of the regulatory and compliance environment, better clarification of roles, enhanced collaboration with Marketing, creation of cross-functional communication processes, and improved metrics to collect and convey value of activities, Medical Affairs groups will continue to evolve as a true partner and play an increasingly pivotal role in the success of the organization.

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