Insights into Pharmaceuticals and Medical Products

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Medical Information (MI) teams are a vital interface between healthcare professionals (HCPs), customers, patients, and the pharmaceutical organization. As such, they are in a uniquely advantageous position to develop a deep understanding of customer needs, and respond to their concerns. Far from being only a research or data-generation function, Medical Information can be a source of differentiation if used strategically, especially if teams are willing to move beyond what has been expected of them in the past. In addition to seizing this opportunity, however, Medical Information teams need to meet the traditional requirements of stakeholders while also contending with various external pressures such as heightened regulatory obligations, increased complexity of medical information, changing communication channel preferences, and intense economic pressure.

In this whitepaper, we propose organizational enhancements for pharmaceutical manufacturers to consider when thinking about enhancing the value of their Medical Information teams, and moving beyond the traditional perceptions of the role while at the same point dealing with the evolving environment.

Medical Information today

To meet regulations from the FDA and other authorities, pharmaceutical manufacturers provide a scientific service that compiles and collates information about their products, whether that information be generated by company representatives or external sources. Manufacturers need to respond to information inquiries about the company's marketed or investigational products from HCPs, customers, patients, and other stakeholders. The objective of the Medical Information function is to satisfy this requirement by having processes and capabilities in place to:

- Document both the inquiring party's contact information and the nature of the information requested
- Respond to inquiries through both verbal and written channels of communication
- Provide standard answers to FAQs in order to accelerate consistent responses to typical inquiries
- Develop non-standard responses to unique inquiries after conducting research of the respective scientific literature and information available
- Keep up to date with the latest publications and literature on the company's drugs

Additionally, Medical Information teams often engage in the following activities:

- Participate in conventions and scientific meetings as a contact for HCPs
- Review promotional material for the accuracy of medical information used
- Provide medical training to Medical Science Liaisons (MSLs) and the sales force

While continuing to fulfill this core objective, Medical Information functions worldwide are also faced with a number of internal and external challenges that require teams to respond and evolve. These challenges include greater compliance risks stemming from heightened regulatory obligations, increased complexity of information, changing communication channel preferences and expectations, and intense economic pressure.

Compliance risk and regulatory requirements

Regulatory authorities across the globe have increased their scrutiny of Medical Information functions while also demanding more effective and speedy sharing of knowledge across geographies to increase overall consistency. For example, manufacturers are required to report adverse events from any part of the world to the European Medicines Agency within 14 days to be compliant. In effect, this necessitates a seamless interface between the Medical Information and Pharmacovigilance departments because many adverse events get reported through the Medical Information teams first. Technological advances such as centralized databases and repositories make this level of transparency easier, and reduce discrepancies or conflicts in Medical Information. Sharing standard letters and FAQs—in addition to adverse event information—across all countries is now more important than ever.

Increased complexity of information content and delivery

The introduction of more complex pharmaceutical products in recent years has resulted in a similar increase in the number and complexity of Medical Information inquiries about them. In a related development, as more products are used for a wider number of indications—both on and off label—responding adequately becomes more complicated, and demands more nuance and insight. The bottom line is that Medical Information teams now need to be able to provide highly specialized answers to a broader set of inquiries more frequently than ever before. In fact, many HCPs expect medical information "on demand." Platforms have sought to respond to the need for on-demand information, but the reliability of the information offered can vary. A recent assessment of online drug information compendia conducted by 11 pharmaceutical companies found that there is a high degree of misinformation through incomplete, inaccurate, and omitted data.¹ Yet, as one path or channel that can link to a company-specific Medical Information website for particular products they are useful.

¹ Randhawa et al, "A Collaborative Assessment Among 11 Pharmaceutical Companies of Misinformation in Commonly Used Online Drug Information Compendia," *Annals of Pharmacotherapy* 1-8, February 2016, available for download: http://aop.sagepub.com/content/early/2016/02/24/1060028016635196.

A shift to digital content and interaction

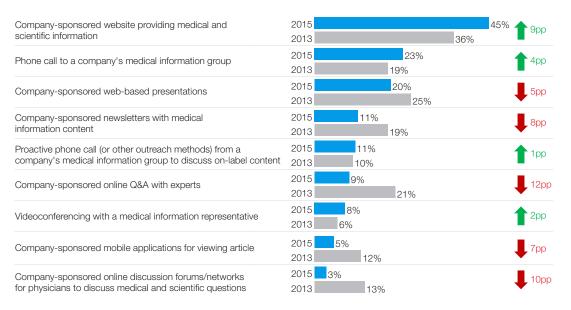
Increased understanding and adoption of digital channels among HCPs, health systems, and patients mean that inquiries come to Medical Information through multiple channels, not just letters or phone calls. While direct telephone calls continue to be of great importance, digital channels such as company-sponsored websites, video conferencing, and online chats are being used more frequently by stakeholders to request information and make specific inquiries about products. McKinsey research shows that, even though personal relationships between HCPs and MSLs continue to be of high importance for general updates and overall information, 23 percent of US HCPs interact with pharmaceutical representatives digitally at least once a month and 33 percent say they would like to.² Findings from our survey of academic and other physicians demonstrate that company-sponsored websites are a preferred source of medical and scientific information from pharmaceutical companies (Exhibit 1). This preference has significantly increased (by nine percentage points) between 2013 and 2015. Equally telling are steep declines in online discussion forums and newsletters as channels to provide medical information.

Exhibit 1

Despite some fluctuations, healthcare providers clearly still want to maintain access to company sponsored research

Preferred Medical Information interactions

% of respondents; multiple selections possible (n = 892)



SOURCE: Medical Affairs Performance Evaluation System (MAPES) 2013, 2015

HCPs are not the only stakeholders who need answers to questions quickly. As more drugs migrate from being prescription based to over-the-counter products, pharmaceutical manufacturers are fielding an increasing number of direct inquiries from patients. Some companies have seen this shift as the invitation it is, and have responded with innovative patient education and engagement strategies. These solutions represent win-win

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approaches, providing patients with the information they need, and allowing pharmaceutical companies to expand the role of Medical Information in supporting therapy compliance and improving the overall brand reputation by being more responsive to patients. However, this development also requires a strategy to manage these unpredictable requests.

Economic pressure

As healthcare spending relative to GDP continues to rise in many countries, pharmaceutical manufacturers are under pressure to find more efficient operating models to reduce operating costs and, in turn, the costs of therapies. One reaction to this pressure is to scale back sales teams—with the consequence that more requests for information are fielded directly by Medical Information teams. For their part, Medical Information teams are also under pressure to operate as efficiently as possible; thus manufacturers need to find the right balance between providing high-quality medical information to stakeholders and generating related insights, while simultaneously decreasing operating costs.

All of these challenges combine to demand new thinking of what Medical Information could be doing and delivering for customers. Neither the traditional role nor the same approaches will suffice in the context of this changing environment. That realization, however, can be tremendously exciting for Medical Information teams, sparking innovation and spurring transformation to better serve internal and external stakeholders.



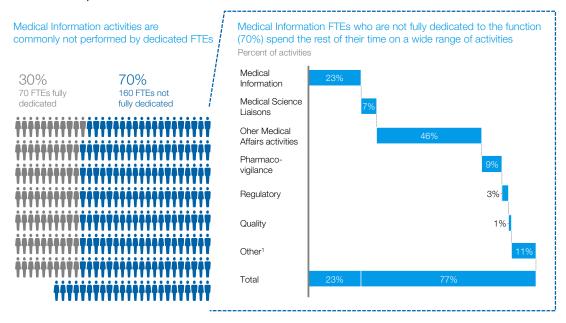
How can Medical Information evolve to meet future challenges?

What's holding Medical Information teams back from moving beyond their traditional remit and taking on a more strategic customer-facing role?

One significant issue is that Medical Information teams are often not cohesive. In fact, Medical Information team members frequently perform multiple activities and roles beyond their Medical Information duties (Exhibit 2). In fact, Medical Information team members frequently perform multiple activities and roles beyond their Medical Information duties, especially in smaller countries.

Exhibit 2

Case example: Global Medical Information resources are highly fragmented across several different functions in a large multi-national company with a diversified portfolio



1 Most common "others" include compliance, medical governance, clinical trial support, and training and development. SOURCE: Disguised client example

We believe that evolution of the Medical Information function is not only possible but imperative if it is to continue to deliver value in future. So, how can companies go about creating the Medical Information function of the future? What elements must be part of that transformation, and how can the historical fragmentation be cured? Using a two-pronged approach to guide improvements firstly uses "no regrets," quick-win investments in the short-term, which focus on implementing efficiency improvements and committing to true customer centricity. Secondly value-enhancing efforts that generate improved or new insights can be the focus over the longer term, with manufacturers making more strategic use of the medical data generated or housed in Medical Information—a

resource that remains largely untapped. In this context, Medical Information teams need to clearly define their mission and role within the organization in order to be seen as a partner to other functions within the organization.

In line with this approach, we propose a strategy focusing on three pillars: identifying and implementing efficiency improvements, committing to true customer centricity, and generating insights from Medical Information data.

Implementing efficiency improvements

In the current economic environment, it is imperative to respond to requests for Medical Information as efficiently as possible. This requires Medical Information to more effectively engage and manage vendors or build clusters of excellence to centralize and align Medical Information operations.

Outsourcing certain Medical Information activities to vendors can help manufacturers increase efficiency and profitability. This is commonly achieved by using third-party technology solutions and skilled human resources that can be deployed when needed. Outside vendors can guarantee 24/7 inquiry

intake, for example, and also minimize process delays at peak times such as around product launch or relabeling. Smaller pharmaceutical companies in particular could benefit from outsourcing, since their Medical Information team members typically wear several hats—a situation that undermines efficiency as employees constantly switch from one activity to another. Utilizing specialized resources that are focused exclusively on

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Medical Information eliminates these efficiency losses. In addition, not having to invest in new or improved technology, training, and infrastructure, but making use of these resources through the vendor, increases the cost effectiveness of Medical Information provision, especially in handling the ever-increasing variety and number of inquiries generated from complex products.

When selecting the most suitable vendor for outsourcing Medical Information activities and then deciding on the exact outsourcing strategy, manufacturers will first of all need to conduct a detailed analysis of the needs and capabilities that exist in-house. Typical criteria to analyze are:

- Cost
- Scalability (temporary versus permanent outsourcing and peaks of inquiries)
- Service hours or coverage needed for support (24/7 or only during typical working hours)
- Technology used and interfaces
- Channels of inquiry intake and response
- Language capabilities
- Scientific background and expertise in the specific therapeutic area required
- Type of inquiries handled (for example, only first-line is usually preferred over second-line)

Every manufacturer will want to add specific criteria and performance metrics relevant to their individual company: for instance, timeliness and customer service. As indicated in Exhibit 3, one common approach is to outsource only first-line response, while retaining the capability to respond to more specialized inquiries in-house.

Outsourcing second-line responses

Exhibit 3

Medical Information groups prefer to retain control over customized responses

% of companies (n = 11)

Outsourcing first-line responses

Internal control retained over both development and Outsourcing first-line responses to decrease customization and leverage efficiencies, eg, delivery of second-line responses due to: Exact response to query approved Compliance concerns Repeat queries entrusted to third party Focus on customer needs (eg, call center) Complexity of science Requires processes in place to ensure quality Degree of customization required "Once the standard response has been "Typically these escalations require higher level approved, there's no need to maintain a lot of of expertise as well as access to the internal internal control. We have enough oversight network to answer, so outsourcing would require a fairly high level of oversight." built in of anyone we outsource to." - Head, Global Medical Information - Head, Global Medical Information 55% 18%

While outsourcing certain activities has its advantages, a manufacturer may decide to build internal clusters of excellence or centralize activities, which are then efficiently handled internally. This is often done in launch or early in the lifecycle so insights can be captured rapidly, but also proves to be a cost-effective alternative when:

- The required expertise is very specialized and can be better built internally.
- There is a need for better integration of the Medical Information team with Medical Affairs, brand teams, and other functions.
- Leadership prefers to keep data within the company.
- Insights from inquiries can be better drawn by internal teams.
- Systems from various departments interface directly, so outsourcing would be disruptive.
- Better control or monitoring of KPIs and customer satisfaction is necessary.
- Quicker handover of cases to the correct department is required given the type of therapy or anticipated inquiries.

Regardless of whether a manufacturer decides to outsource some of its Medical Information activities, every organization needs to define an operating model that allows it to address

the primary Medical Information objectives efficiently and quickly while also being closely aligned with its internal customer needs. Historically, most manufacturers have employed a highly decentralized approach when it comes to creating and sharing Medical Information content as well as responding to inquiries. Given the increased scrutiny from regulatory bodies, this is no longer an option, so there is a strong trend toward more coordinated, if not centralized, structures (Exhibit 4). This allows for sharing of content and responses while still maintaining local

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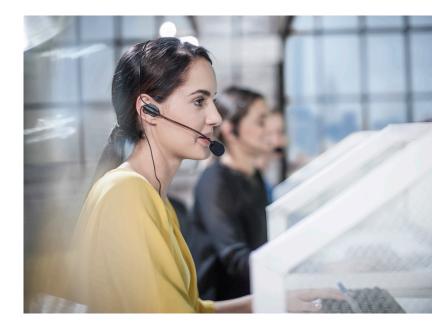
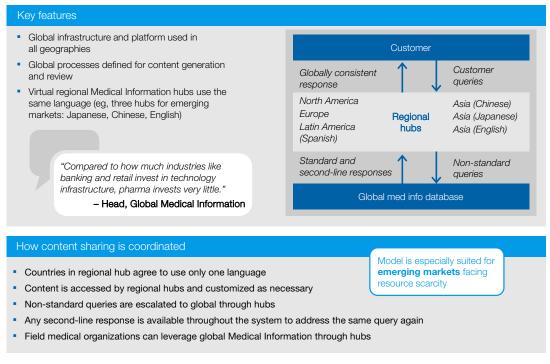


Exhibit 4

Case example: Regional hub enables global consistency in fulfillment



SOURCE: Disguised client example

Committing to true customer centricity

Changing stakeholder demands and expectations make it more important than ever for manufacturers to analyze each stakeholder's needs and adjust their Medical Information services accordingly. Overall we see a change from push to pull information services, as reflected in the decline of print and rise of on-demand information availability online. Some companies have responded by offering more Medical Information resources online or in collaboration with an existing provider. Yet most of these offerings are not global, shared resources but rather targeted toward specific markets. Achieving global alignment, however, is crucial to providing Medical Information in a consistent and compliant manner. Moreover, when done efficiently Medical Information teams can become the "go to" internal reference source for colleagues and provide the relevant materials and information for dissemination across all channels of interaction.

A new US-focused portal, phactMI, has been created by a consortium of pharmaceutical companies that shares and aggregates medical information. This enables companies to improve responses and meet the needs of stakeholders more efficiently (see sidebar).

Medical Information teams also field many HCP requests for treatment regimens. Leading Medical Information functions can respond by developing state-of-the-art patient guides, potentially on interactive digital platforms, or other resources physicians can offer to their patients. It is important that these materials are easy to understand for patients, but at the same time provide accurate and relevant Medical Information on the specific indication and treatment. This level of customercentricity sets the bar higher than it has been previously for most Medical Information teams. Getting there will require testing and refining a portfolio of customer-focused initiatives, scaling promising pilots and then making these part of business as usual.

phactMI aggregates information to speed responses to HCPs

A new not-for-profit 501 c-6 company, phactMI, harnesses the power of



digital platforms to aggregate Medical Information information from leading pharmaceutical companies. phactMI (the name stands for Pharma Collaboration for Transparent Medical Information) was founded by 19 companies with the goals of: improving awareness of the value Medical Information teams deliver; and aggregating and allowing access to Medical Information for many conditions through a single portal (www.phactmi.org). HCPs no longer have to search across each member site individually for product information and can submit queries on specific brands and companies through the website, which are then routed to the appropriate company for response. The member companies (currently 24) are banking on the improved response and increased efficiency of delivering Medical Information to strengthen relationships with HCPs. phactMI is funded by members, and membership is open to most pharmaceutical and biotech companies, which meet the requirements for high-quality provision of Medical Information.

Generating insights from Medical Information data

Since the publication of the Code on Interactions with Healthcare Professionals and the Compliance Program Guidance for Pharmaceutical Manufacturers in 2002, pharmaceutical

manufacturers have clearly separated their marketing and Medical Information functions. Nonetheless, in order to improve patient insights and outcomes, the wealth of interactions and data Medical Information teams collect can and should be used strategically to generate important insights for the Medical Affairs team—as well as the entire organization—including commercial functions.

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Indeed, the Medical Information function should be an important partner in shaping the thinking around patient journeys, potential difficulties with drug application, or detailing additional indications for clinical trials, to name a few potential areas of contribution.

Implementing processes that adequately and accurately capture and share the topics of inquiries fielded by Medical Information is the first step toward providing more valuable insights to other functions. Based upon our experience working with pharmaceutical firms, Medical Information would generate significant value by:

- Acting as an internal medical advisor within the company and proactively offering support
- Offering training to commercial teams on the scientific background of incoming inquiries
- Categorizing and reporting off-label inquiries to R&D teams, so that new indications can be explored
- Using Medical Information inquiries to create a heat map of trending issues with respect to specific products, geographies, or side effects so that they can be resolved
- Analyzing inquiries from HCPs to evaluate whether there are key opinion leaders who can be engaged more broadly

Conclusion

It is both a challenging and exciting time for the Medical Information function within pharmaceutical manufacturers because more is demanded—and expected—from these valuable resources. To better satisfy changing demands and expectations, many companies would benefit from an analysis of their internal and external stakeholders' needs in order to redefine their vision of Medical Information for the future. The optimal solution will most likely require investments in systems, reorganization, and redesign of established processes; if done right, these actions will allow the function to be a true scientific thought partner internally—but even more importantly, externally—to HCPs, health systems, and patients, and also a reliable generator of insights for global and regulatory stakeholders.



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