Medical Information Role in the Pharmaceutical Industry

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What is Medical Information

Overview

Medical information (MI) teams at pharmaceutical and medical device companies primarily respond to inquiries about the company's products. Inquiries can originate from healthcare providers, patients, scientists or anyone interested in information about the company's products. MI teams may also serve as the knowledge hub for company representatives. In addition to responding to inquiries some medical information teams also develop communication tools (such as slide decks) and they review or develop other promotional materials. The medical information team is a customer facing team that helps improve the safe and effective use of a company’s product while gathering real insight from customers.

Medical information teams provide written (email, fax, mail) and verbal responses (by phone) to inquiries. To increase efficiency and ensure that all team members are providing the same response globally they create and use medical information letters (also known as standard response letters or standard letters) and FAQ documents to standardize their response to inquiries. Once FAQ documents and letters are created and approved, team members use them to verbally respond or send them to requesters through email, fax, or mail.

The medical information database or system (e.g., agInquirer) is crucial to the success of MI teams. Imagine that you had to respond to hundreds or even thousands of questions every month using an excel spreadsheet and documents stored in your hard drive. It would be very difficult and time consuming to quickly find answers you provided previously; capture contact details, questions and responses; email requesters and capture a record of the communication; and categorize inquiries and generate reports. Workflow processes and collaboration would be slow and inefficient. Medical information systems help MI teams provide better customer support, increase efficiency, track inquiries and responses, analyze inquiries, and improve collaboration.

MI Team Members and Qualifications

Medical information teams at most companies are staffed by doctors of pharmacy (PharmD), nurses, PhDs, MDs, and other life scientists. Most companies hire PharmDs (pharmacists) for this role since pharmacists have the required scientific and medical training to communicate complex scientific and clinical information and interact with healthcare providers. Moreover, pharmacists are trained to provide drug information, a similar function in hospitals and other practice settings.
How are MI Teams Structured

Medical Information teams in many top pharmaceutical companies are part of the medical affairs department and report to the head of medical affairs or equivalent. In smaller companies the reporting structure may vary, however, MI teams usually do not report to a commercial group (marketing or sales).

Structure of MI Departments

Medical information teams in larger companies may also be divided into local (country, regional) MI teams and global medical information (GMI) teams. In smaller companies one country may be responsible for supporting the whole world with assistance from medical information vendors/outsourced call centers. The hierarchy of MI roles often looks like this:

Local MI team develops content and responds directly to inquiries from that country or region.

Global Medical Information (GMI) teams create global content that local MI teams adapt to meet their local needs by changing the disclaimers and adding specific approved registration (regulatory) information. They may also handle escalated inquiries from the local team. GMI also creates global MI policies. More companies are moving towards developing global MI practices, procedures, policies, and responses. Local MI teams may or may not have a reporting relationship with global medical information. Most often it is an affiliate relationship. GMI usually selects the global MI database in partnership with local affiliates.

In larger companies the medical information role may be divided into call center personnel and content developers (including promotional review). In smaller companies MI personnel answer phones as well as develop content (standard letters) used for answering inquiries.
The medical information function is often mischaracterized as just a call center. Intake of inquiries through a phone channel is only part of the medical information function.

Call Centers respond to phone calls from customers and they use FAQs and standard letters developed by the content team. There is a growing trend to outsource MI call centers.

Content Team: Content teams write FAQs, standard letters, and manage the medical information database. They may also be involved in reviewing marketing materials for scientific accuracy (promotional review).

**Key Activities**

The medical information function is often mischaracterized as just a call center. Intake of inquiries through a phone channel is only part of the medical information function.

<table>
<thead>
<tr>
<th>Intake of Inquiries</th>
<th>Medical information teams use all channels of modern communication to receive and respond to inquiries. The volume and complexity of inquiries determines the workload of MI personnel. MI personnel record information about the contact as well as their medical information request.</th>
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<tbody>
<tr>
<td>Responding to Inquiries</td>
<td>MI teams provide verbal and written responses. Finding, understanding, and using scientific information to respond to customer questions takes time. MI teams use standard responses, FAQs, and customized responses (created from scratch or modification of an existing response) to respond to inquiries.</td>
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<td>Writing Standard Responses (Letter) and FAQs</td>
<td>Developing and managing standard responses (medical information letters) is a very time consuming task. Standard responses are documents written to answer frequent questions so that medical information can easily use them over and over again. Depending on the question and information available they can be several pages long. They contain summaries of published literature, approved product information, and other types of information required to respond to the inquiry. It can take several weeks and input from several individuals to finish creating an approved MI letter.</td>
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<tr>
<td>FAQs</td>
<td>FAQs are usually quick and simple answers to frequent questions.</td>
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<td>Searching for Information</td>
<td>Finding answers to inquiries can be time consuming and frustrating if the information does not reside in the MI database. It may involve searching the literature, using product data, and contacting experts within the company (e.g., research, clinical, publications, and regulatory teams).</td>
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<td>Keeping abreast of literature and training</td>
<td>Medical information personnel need to know the latest publications related to their assigned product(s) since they are a resource for both internal and external customers. They also attend company product training and department training.</td>
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<td>Staff MI booths at scientific meetings</td>
<td>MI personnel staff MI booths at scientific meetings and provide responses to inquiries from healthcare providers at the meeting. For scientific meetings they need full access to the MI database from laptops and mobile devices.</td>
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<td>Review promotional material</td>
<td>The trend is for medical information teams to use their scientific expertise to review the accuracy of promotional materials. This usually occurs outside the MI system. This additional responsibility means that MI teams have to be more efficient in processing inquiries so they can accommodate all their responsibilities. The approved content should be available in the MI database.</td>
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<tr>
<td>Activity</td>
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<td>Develop slide decks</td>
<td>Some MI teams are responsible for developing slides for the organization or customers. These slide decks may be provided to customers and should be available in the MI database.</td>
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<td>Develop AMCP dossiers</td>
<td>The AMCP (Academy of Managed Care Pharmacy) dossier is a comprehensive product document that companies use to present their products to managed care organizations or hospital formularies. It needs to be available in the MI database and provided to customers upon request. MI usually develops the MI dossier.</td>
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<td>Report adverse events (AEs) and product complaints (PCs)</td>
<td>There are specific processes for identifying and reporting adverse events. At some companies the MI department receives all AEs/PCs, evaluates them to confirm if they are in fact inquiries, AEs or PCs and forwards them accordingly to the AE/PC department. They may also meet with the AE/PC department to discuss cases and their disposition. MI team may also send background information about the AE to the requester or answer any related questions.</td>
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<td>Support clinical trials</td>
<td>Some MI teams support clinical trials by providing clinical trial protocol information or explaining how to handle adverse events or dosing challenges associated with the trial.</td>
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<td>Sales training</td>
<td>MI teams may be involved in training the sales team on MI processes, the most frequent inquiries and responses, available FAQs and standard letters, and other resources</td>
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Typical MI Letter Creation Workflow
See Appendix A for a general medical information inquiry process.

The process starts with MI department recognizing that they need a standard response (letter) or FAQ to answer a frequent question from healthcare providers or consumers. These standard responses help MI staff to improve their efficiency and provide consistent responses globally. The entire process of creating and approving a response can take days to weeks depending on the complexity of the question, how much data is available, the audience, and who needs to approve the response.

Who they partner with

MI teams work with all levels of the organization. Their main contact points are:

- Sales
- Medical Science Liaisons (MSLs)
- Pharmacovigilence (Safety)
- Medical Strategy/Communications
- Marketing
- Research
- Publication teams
- Regulatory & Legal

Key customers

Anyone interested in information about a company’s products may contact the medical information team. Most often they are contacted by patients and healthcare providers. Patients only receive on-label basic product information. In contrast healthcare providers receive as much information as needed to answer their question.
Tools they use

- Phone, Fax, Email, Mail
- Websites
- Literature databases
- MI systems
- Desk computing and mobile devices
- Medical Information Standard Letters (Responses)

Regulation

- FDA and EU promotion guidelines and rules
- FDA and EU AE reporting guidelines
- Other regional guidelines
- Pharma Guidelines
- Office of Inspector General (OIG)
- Corporate Integrity Agreements (CIA)

Key Challenges

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<th>Workload</th>
<th>MI teams, especially teams that support blockbuster products used by millions of patients, receive hundreds to thousands of inquiries monthly.</th>
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<td>Diverse customers</td>
<td>MI teams are a resource for internal and external customers. External customers include patients and healthcare professionals. These different groups have different needs.</td>
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<td>Geography and language barriers</td>
<td>Companies have global products and sometimes centralized MI teams. Even companies with global MI teams face the challenge of agreeing on processes of how to best adhere to certain guidelines and regulations.</td>
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<td>Inadequate staffing</td>
<td>MI teams at most companies are understaffed relative to the amount and quality of work they are expected to deliver. Therefore they need to be very efficient.</td>
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<td>Inadequate training programs</td>
<td>Many companies do not have organized product and disease state training processes for MI personnel. They sometimes must learn on their own.</td>
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Finding information

Many companies do not have effective content management and knowledge sharing processes. MI teams spend a lot of time gathering the right information to use to answer questions.

Lack of visibility and appreciation

Until companies started using MI personnel for review of promotional materials the MI function was largely invisible and misunderstood and MI teams did not have a voice. This has changed in some companies (and is changing in others).

Value

Most MI teams do not clearly articulate their value proposition and benefit to the organization. Thus, they are viewed as a unit that is just a cost center that can easily be outsourced (especially when viewed as call centers).

Lack of resources

If MI teams are understaffed then it is also a good bet that their budget for technology and other resources is also very small.

Value of Medical Information

Medical information is a customer, government and practitioner facing function that supports the safe and effective use of a company’s products by providing accurate, fair-balanced, and timely information to healthcare professionals and patients. It is also a strategic role that can unearth deep customer insights that can be incorporated into product life cycle planning and other revenue-driving activities.

Medical Information Systems

Overview

Medical information systems enable MI teams to do their jobs better and improve customer support. MI systems provide MI teams with the following capabilities:

- Increased efficiency
- Standardized content (provide the same response globally)
- A complete record of all interactions
- Manage workflow
- Content management: Create, store, and share content (knowledge)
- Increase collaboration and knowledge sharing within MI and between MI and other groups globally
- Analyze customer insights gained from inquiries
- Regulatory compliance
- Automated audit capabilities

The major gaps and areas of innovation for MI systems to address include enabling collaboration between MI teams and other departments, deep analysis of MI interactions, advanced content management, and complete mobile apps for field staff.
MI systems can be divided into:

1. Complete systems (ArisGlobal agInquirer, IRMS)
2. CRMs or content management platforms adapted for MI (Veeva, Salesforce)
3. Home grown systems using SharePoint, Siebel or similar existing technology

Complete systems provide an end-to-end solution for MI, are rich with features, and usually are cheaper to implement and manage. They include the 5 sections of an MI system which are:

- Contact management
- Inquiry management
- Content management
- Reporting
- Integration

CRMs or content management platforms are not designed for medical information. They only address contact or content management aspects of MI to varying levels. They fall short in inquiry fulfillment, tracking, reporting, and integration with other systems. Departments who opt for this method will have to find a solution for their inquiry fulfillment and tracking, reporting, and integration needs. This is a time consuming and expensive endeavor and typically involves a systems development integration project from a large consulting firm to “augment” Salesforce.com and/or Veeva and periodic additional systems development and integration projects to apply needed periodic updates.

Home grown systems are common in new and smaller companies and are a common first step for a new player. They are deceptively expensive to develop and maintain and usually lack the support and innovation that comes with complete systems. They require a heavy investment of time, creativity, financial resources and typically fall short in functionality and reliability, especially as the company grows.

Why some companies choose to build an MI system

For many years the only viable commercial MI system was IRMS (hence their ~50 legacy clients). Although IRMS has many of the features MI teams need it falls short for many companies in two critical areas:

1. Not web-based, so difficult to deploy globally
2. Does not easily integrate with other company platforms

These challenges reportedly stem from the technology used to build IRMS. The legacy IRMS software is based on Microsoft Access, a client-server application that runs on Citrix and is not an optimal solution for affiliate MI teams across the globe. Realizing this challenge, IRMS launched a lighter web-based version called IRMS-CE in 2012. Companies desire to use platforms that are based on more modern technology, can easily communicate with other systems used in the company (including safety/PV), and are accessible globally without losing performance.

Companies that desire more than the IRMS software could provide sometimes look to develop their own systems (and/or now evaluate the agInquirer solution from ArisGlobal), because the MI-specific functionality is not available there.

Companies that build a system via adapting Veeva or Salesforce.com platforms for MI use reportedly often do so because these platforms are already being used by the sales and marketing teams and they prefer to use the same solution across the organization (despite the custom systems integration project required to develop, implement and update it).
Conclusion

Medical information is an important practitioner and customer-facing department at pharmaceutical, biotech, and medical device companies. Medical information continues to evolve. A variety of complete and systems development-based solutions are now available to empower medical information teams to provide more support to healthcare professionals and patients while reducing risk for the entire organization. Complete MI systems designed for growing organizations (e.g. ArisGlobal agInquirer, IRMS), and Cloud-based solutions (e.g. agInquirer, SalesForce.com, etc.), are on the short list for most growing pharmaceutical companies and those desiring a truly global MI function.

Appendix A
About ArisGlobal

ArisGlobal is the leading provider of integrated solutions for pharmacovigilance and safety, regulatory affairs, clinical research and quality and compliance for medical inquiries. Life science companies using ArisGlobal’s solutions can better build and maintain the trust they need with their customers, medical practitioners and regulatory bodies around the world.

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