

Transforming Medical Affairs in China



“We have seen explosive growth in the number of Medical personnel in most companies in China. Companies are growing staff by at least 20% per year, and in some cases more than 50%.”

— Medical Director, MNC Pharma

Redefining the Role of Medical Affairs in China

Multinational companies have dramatically increased their number of Medical staff, typically moving from a handful to hundreds in the past two years.

Medical staff are being added to help address changing dynamics in the market and a weakening of the core branded generics business. The addition of a highly trained Medical function is a way to provide new value to physicians, payers and patients. However, as the importance of Medical Affairs increases, many executives are left asking: *'how do I best utilize and deploy Medical talent to maximize their value to the business?'*

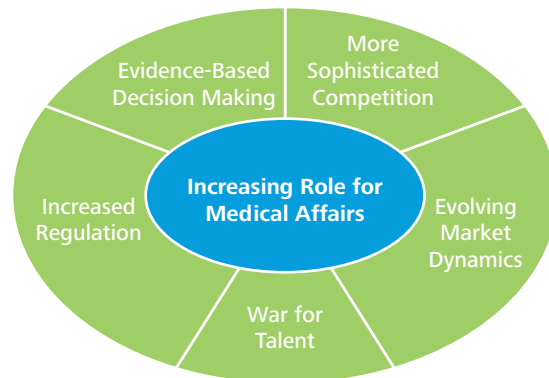
Reshaping Medical Affairs' role into a distinct source of competitive advantage in China will require a deep understanding of the factors driving change and the unique value Medical can create for the business. The purpose of this paper is to provide a perspective on how companies can meet this challenge.

The Traditional Role of Medical Affairs in China

Historically, growth of MNCs (Multi-National Companies) in China has been primarily driven by a rapid expansion of the patient population through increases in government coverage and utilization of established or 'originator' products to serve these patients. These products required support from Sales, and to an extent Marketing but required little support from Medical given long-standing global data generation and publication programs. Standard activities for Medical in this environment included pharmacovigilance, promotional materials review and compliance, trial registration, and Medical Information Services (MIS). It was essential that the Medical function fulfill its role effectively, but its emphasis was mainly on performing its supporting roles adequately over becoming a source of strategic value for the business.

The Current Environment

In recent years the Chinese market has become both increasingly sophisticated and complex as companies, regulations and stakeholders evolve at an accelerated pace. These dynamics have shaped the role that Medical must play in the business. Below is a summary of the change being created by these market forces.



Increased Regulation: The impact of increased regulatory scrutiny, particularly of salesforce-to-physician dialogue has led to a growing customer-facing role for Medical. In contrast, Medical's ability to have a compliant, scientifically driven dialogue with physicians has increased its importance as it fills the void left by an increasingly constrained salesforce.



Evidence-Based Decision Making: Physicians, governments and hospitals within China are increasingly focused on making decisions using the latest scientific evidence. There are an increasing number of experiments with DRGs (Disease Resource Groups), volume capping in large hospitals, and rapid expansion of new programs like the Critical Illness Insurance Program (CIIP) and the Essential Drug List (EDL). Decision makers are increasingly turning to measures of real-life health economics and outcomes value to assess the merits of individual therapies, creating a strong need for Medical to generate and communicate relevant evidence.



Competition: Over the past 2-3 years competition between companies has increased dramatically as new products have been launched across all

therapeutic categories, while overall market growth has slowed. Product strategy, rather than expansion of market coverage is increasingly driving growth. This necessitates new insights and a more sophisticated product strategy development process. Medical can provide key inputs to the strategy development and competitive differentiation process. Examples include providing critical information about physicians, patients and support for Company and Investigator Sponsored Trials.



Evolving Market Dynamics: The pace of change in the Chinese market is accelerating as the government continues implementing healthcare reform.

Increasing focus on new pilots, expanding implementation of changes to reimbursement, changes in hospital governance and changes in the way physicians diagnose and treat patients are just a few of the more prominent trends in the market. The growth in experimentation through pilot projects in the Chinese healthcare system requires an understanding of how to adjust from a market where decisions are made centrally to one where a greater number of smaller projects are being approved.



War for Talent: Shortages of qualified Medical personnel are widely recognized, with higher than average turnover rates in Medical organizations. This

increased competition for talent is forcing companies to offer employees more opportunities for professional development and increased responsibility. At the same time, once personnel are appropriately trained, companies face difficulty in retaining top performers as their skills make them highly valuable to other companies.

The Challenge for Medical

In response to the above trends companies have started making significant changes in the size, responsibilities and structure of Medical. Typically these changes have resulted in the expansion of the Medical management team and addition of Medical field-force personnel. As the size of the Medical organization has expanded, so too have its responsibilities, seeing Medical take more ownership over insight generation, greater emphasis on Medical participation in strategy, KOL (Key Opinion Leader) engagement, and management of advisory boards.



However, as the size and scope of the medical organization has expanded companies have encountered a number of challenges. Typical challenges that have been observed are:



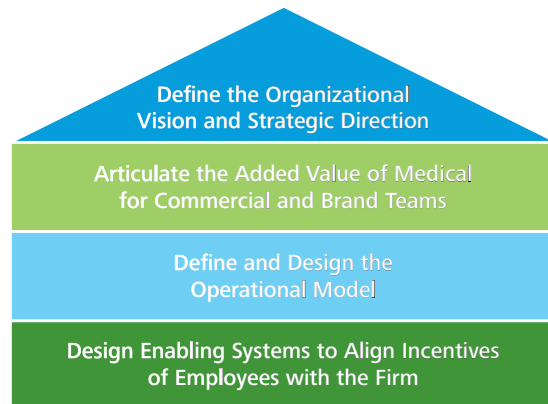
While not exhaustive, these issues present a real challenge to firms that are attempting to develop world-class Medical capabilities. A clearly defined and logically ordered change process can help companies tackle these challenges and create real value during the transformation of Medical.

A New Strategic Vision for Medical Affairs

Medical has a critical role to play in any life sciences company. The importance of deep insight, strong strategy development, and scientific dialogue with doctors, hospital administrators and the government will only increase as the health care system becomes more sophisticated in its approach to diagnosis, treatment and funding.

An excellent Medical Affairs organization that provides real value to the business, both for sales, marketing and product development, will have four key characteristics.

1. A strong mission, vision and strategic mandate for the business
2. Clearly defined activities and areas of responsibility
3. Operating protocols and processes that enable effective collaboration with other business units and external stakeholders
4. Enabling systems and mechanisms that align the interests of individual employees with the firm



1. Medical Mission, Vision and Strategic Mandate



In our work with clients we have seen a range of strategic roles for Medical, but they all have common elements. In most organizations, Medical sits squarely

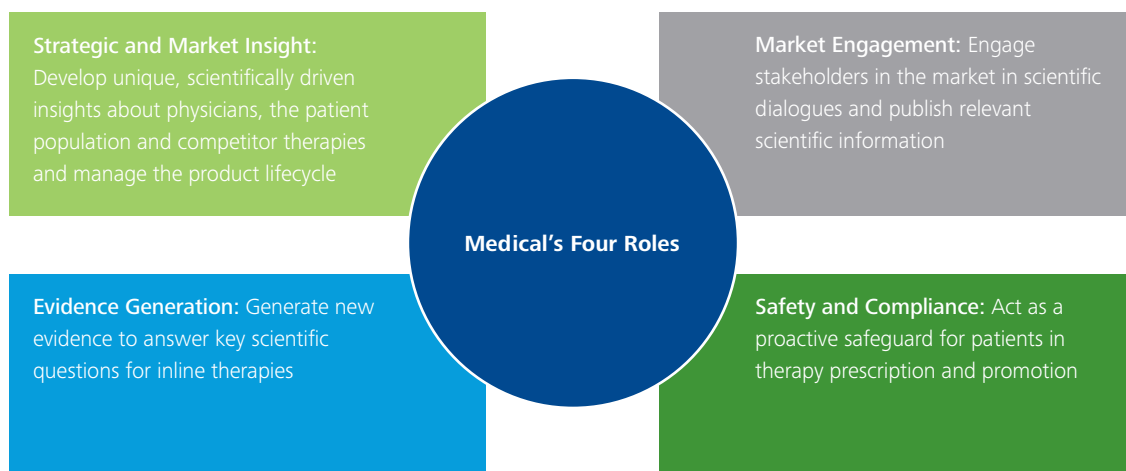
between the R&D and Commercial functions, acting as a conduit between the two. Companies face a choice to orient Medical towards either R&D or Commercial. This decision is primarily driven by a company's portfolio, where companies with a strong pipeline may choose to make Medical more development-focused, acting to shape the market in advance of product launch. Those with strong inline therapies but more limited late stage pipelines may choose a more commercially focused Medical organization, driving market acceptance of current therapies. The choice to focus Medical as a partner to R&D or Commercial is crucially important, as all other aspects of Medical's role in the business depend on this variable.

The following roles are common across organizations, regardless of the strategic orientation of the Medical organization.

Mission: To identify and help address unmet medical needs and maximize the safe and appropriate use of therapies.

Strategic Roles: Medical's ability to interpret and translate scientific information into commercial insights, credibly communicate scientific information to physicians, and publish scientific information in the public sphere provides it with a unique position in the business, and allows Medical to assume a role that cannot be filled by a Commercial function.

Medical will come to fulfill four roles in China in the coming years:



2. Key Activities



Historically, companies have narrowly defined the set of activities for which Medical is responsible, but market leaders in Medical Affairs are rapidly expanding the role of Medical to encompass a number of non-traditional activities.

A new mission and vision for Medical naturally leads to a number of activities that Medical can undertake to create distinct value. These activities tend to be common across organizations, but the precise mix of activities will vary depending on the nature of the firm's portfolio and its business needs.

Strategic and Market Insight

At present, Medical tends to play a limited role in strategy development, often receiving the strategy from the Commercial team after it is completed. As one senior medical executive stated, "We get the strategy from Commercial and are expected to build a tactical plan from it." In most companies Medical attends meetings during the development of the brand strategy, but plays a passive or inactive role.

Moving forward, we believe that Medical will act as a critical source of information and decision support as companies try to differentiate themselves in the highly competitive Chinese market. In order to do so, Medical must become proactive during strategy development, requiring a different set of interactions between Medical and Commercial.

This role is crucial as Medical will have knowledge about physicians, patients, and competitors that will materially impact a given brand's strategy. Medical can contribute to a more robust strategy formulation process by generating information about the following topics:

- Disease epidemiology
- Scientific comparison of available therapies
- Patient and physician behavior patterns and treatment considerations
- Competitive intelligence from KOLs, physicians and other critical stakeholders
- Product lifecycle management

Leading pharmaceutical companies recognize Medical's ability to generate new and relevant information that aids in strategy development, and are already moving towards a more collaborative model of strategy development in China.



Evidence Generation

Generally in China the responsibility over the development of Phase IV or post-marketing trials, either formally or informally, has been the domain of Sales or Marketing. Medical would simply act as an administrator of the evidence generation program once Sales and Marketing had decided what they needed. Medical provided input into the trial design and approval process but acted as an administrator as opposed to an originator of ideas.

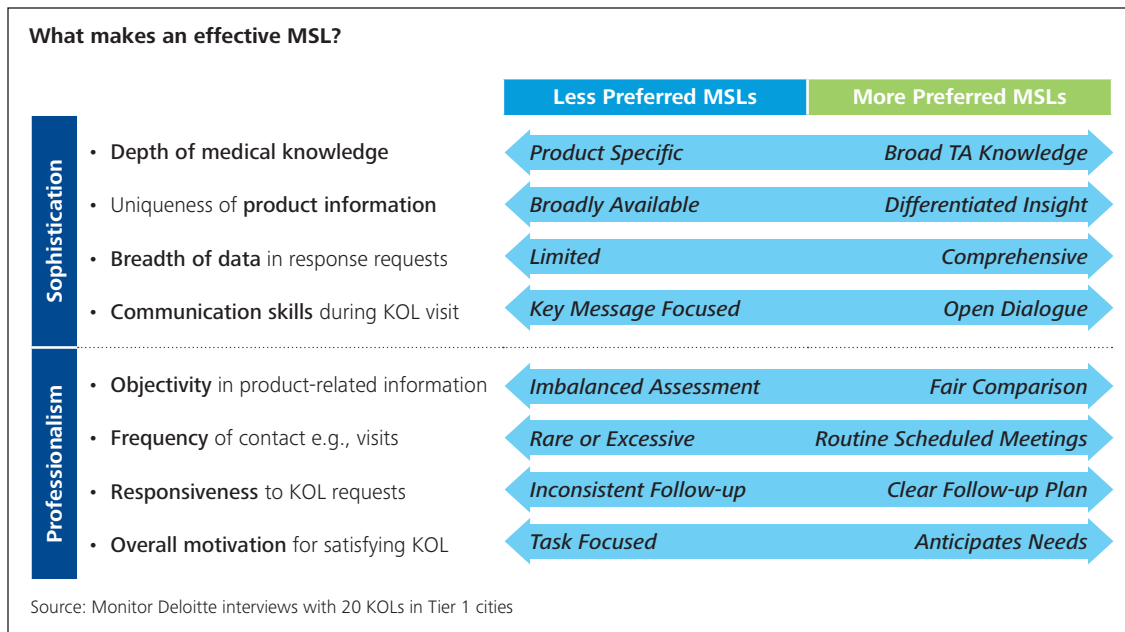
To ensure the most efficient use of available resources this will need to change. Medical's increasingly strong ties to leading physicians (e.g., KOLs) within China make it the best possible source of new trials. Without insight from physicians, trials run the risk of being at best less impactful, and at worst irrelevant.

Leveraging unique insights and a longer-term view of the market, Medical can and should own the development of lifecycle management strategy, including the selection of specific trials to advance the product and answer outstanding scientific questions. This role is particularly important in China where many products are, and will continue to be branded generics that require specific evidence in Chinese patients and continued involvement of local KOLs in trials to gain acceptance in the market.

As a result, Medical should have key decision rights on the Clinical Trial Review Committees (CTRC) for study approval. These rights would include the development of protocols, budgeting and other aspects of Investigator Sponsored Trials support. For Company Sponsored Trials, Medical will remain a key contributor of cross-functional boards that consist of R&D, Commercial and Medical, where the team should collectively select the trials that are best suited to advancing the scientific knowledge and strategy of a given product.

Market Engagement

Traditionally, Medical has a loosely defined responsibility for communication with external stakeholders. In many organizations Medical is a participant but not a leader of advisory boards, symposia and other vehicles for communication with the outside world. Furthermore, Medical tends to play a secondary role in KOL relationship development, relying mostly on Commercial for these activities. The only area where Medical is dominant today is in publishing evidence and papers. However, in most companies these efforts are sorely lacking because of the paucity of data generated in China with Chinese patients. This limits the ability of an organization to build useful insights and to provide physicians with much-needed scientific information about therapies and diseases.



Nonetheless the market is moving from relationships to science, particularly amongst the most respected and influential physicians. Medical will act as a critical mouthpiece for the organization, engaging a wider variety of stakeholders in an increasingly scientific and data driven dialogue. Specifically, we see Medical becoming the primary owner of:

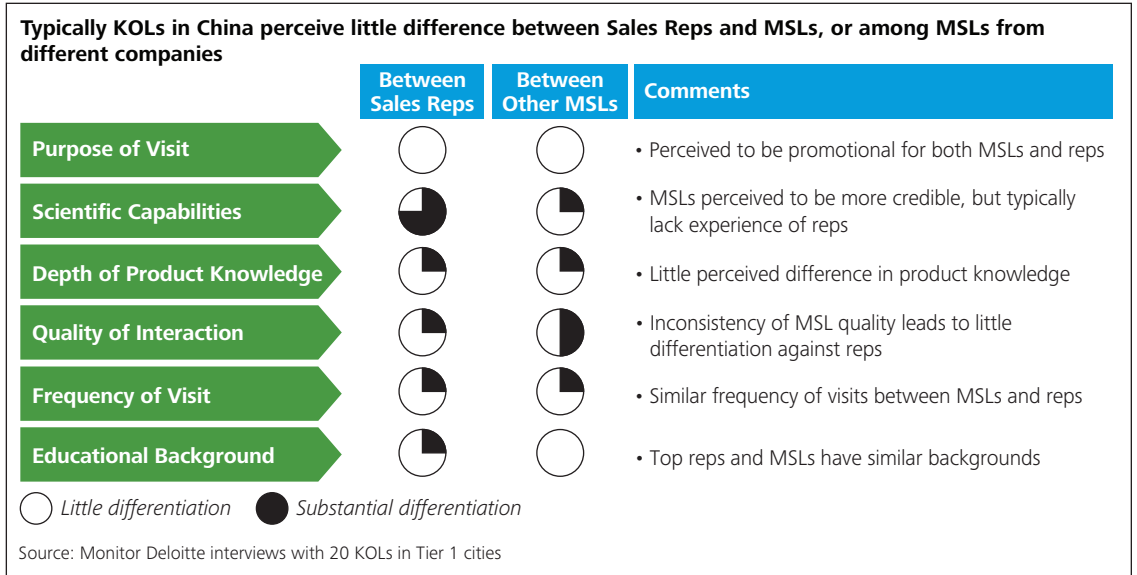
- Scientific publications, abstracts and conference papers
- Symposia, roundtables and other physician forums
- Marketing materials review and approval
- Case studies and real-world information
- Medical information services
- Medical information and physician Q&A
- Patient training and support programs
- Supportive roles in government affairs, market access, health economics
- Physician education and continuing medical education

Allowing Medical to take on these roles provides companies with a clearly distinct set of insights about the market and more channels through which to reach key physicians. This will improve relationships with key stakeholders and enhance decision-making within the organization.

Medical Field Force

To enhance their market engagement efforts many companies have begun to add Medical Field Force personnel. In some cases organizations have added hundreds of field force personnel over the past couple of years. The role of the Medical Science Liaison (MSL) in most organizations is loosely defined, and as a consequence so are reporting lines. We believe that MSLs have a critical role to play both in proactive physician engagement at the local level and as a competitive intelligence arm to inform strategy development.

Companies must decide how to structure their field force (e.g., by therapeutic area, indication, product line, etc.), the role that the field force will play, and how the Medical Field Force will add value in a manner distinct from the sales force. The field force will play a key role in supporting market-shaping efforts in advance of new product launches, supporting scientific consensus with key stakeholders and engaging KOLs in on-going medical dialogue about products and medical concepts.



KOL Relationship Management

Medical is beginning to have a more important role in building and maintaining relationships with KOLs in China. While traditionally one of the roles filled by the Commercial team, as the nature of dialogue with physicians in China has changed, Medical has rapidly come to own some of the top-tier KOL relationships. In addition, Medical is now playing an important role in identifying, mapping and profiling the most important scientific leaders in a given therapeutic field.

As a result the Medical team is being asked to fulfill a new set of activities, roles and responsibilities that relate to identifying and engaging with KOLs.

Safety and Compliance

Finally, Medical should continue to maintain its existing role as the primary owner of safety and compliance information. This role will only increase in importance as the Chinese system evolves towards increasingly tough patient protection. The past 18-24 months have seen a substantial increase in the number of regulations that govern patient safety. Creating and subsequently maintaining clear, digitally enabled compliance systems and processes that enable the organization to efficiently draft and deploy compliant marketing materials and messages will be crucial to success in China's biopharma market moving forward.

3. Operational Model



The current Medical operating model in many companies tends to be insular, both from the outside world and from the Sales and Marketing organization.

Often, only formal communication at pre-defined times occurs. The result is communication that is limited both in frequency and quality. The limited interaction and dialogue between Medical and Commercial leads to organizational inefficiency both in terms of duplicated effort and lack of knowledge transfer. This is in part due to necessary limitations to ensure Medical remains compliant with all regulations. However, companies can avoid a pitfall that was seen in the West during the late 1990's and early 2000's. Companies rapidly isolated Medical from other functions in response to tightening regulation, leaving Medical with little interaction with other functions. This forced containment of Medical limited its impact on the business for many years and in some cases it remains below its potential to this day. Creating an operational model that allows Medical to be appropriately and compliantly integrated with the Sales, Marketing and other functions will ensure companies can maximize the value they receive from their Medical team.

To achieve this, a new operational model that emphasizes communication and coordination with Commercial and R&D will be required to improve organizational efficiency and effectiveness.

The following are important components of the system that will enable Medical to build truly emphatic value for companies in China:

- Structure and reporting lines for Medical
- Key interfaces with Commercial and R&D
- Individual decision rights and decision processes
- Critical processes including strategy development and Medical tactical plans
- Supporting tools, templates and standard operating manuals for Medical personnel

To build an effective operational model companies will need to ensure that the model facilitates the creation of alignment between Medical, Sales and Marketing in two critical areas. First, the operating model must ensure each function is aligned to the product strategy and its individual role in developing the strategy. Second, the model must help companies manage operational complexity to ensure functions remain aligned as they execute a given strategy.

4. Enabling Systems



One critical observation we have had during our interaction with Medical Affairs organizations both in China and abroad is the discrepancy between

the growing expectations of Medical and the inadequate enabling systems that support it. Currently, most organizations use systems that are either ported from Sales or Marketing, or informal systems that are developed on an as-needed basis.

In order to realize the mission, vision and objectives of the Medical organization, fit-for-purpose enabling systems are needed to promote desired behaviors in staff. These systems help enable organizations to attract and retain top-tier talent within China.

Four types of enabling systems must be designed to support the transformation towards a more effective Medical function in China, including

- Performance Metrics and KPI's
- Culture and leadership
- Rewards and recognition
- Talent management and capability building
- CRM systems

Leading Medical organizations are able to integrate their key enabling systems to support the team in optimally carrying out their responsibilities and strategic mission.

How do we approach this problem?

The transformation of Medical should be logical and ordered with a very specific activity sequence. Where an organization begins to implement this transformation will depend on how far along in their evolution of Medical they are. Organizations should proceed from the highest order decisions to those that are dependent on other choices. Failure to proceed in the proper order will result in organizations that are misaligned and therefore at a competitive disadvantage.



Organizations must first clearly define the mission and vision for Medical, and generate alignment to this between the Medical and Commercial teams. Then, the activity set and operating procedures must be clearly defined for the team. Finally, the enabling systems should be designed to support the other aspects of Medical.

What are the benefits of this approach?

Organizations will realize several benefits from improving their Medical function. Simply put, Medical touches all aspects of the business, including development, sales, marketing, and government affairs. For clients who have successfully implemented a change program and dramatically upgraded the capabilities and business acumen of their Medical team, we have seen several benefits consistently emerge, including:

- Stronger and more robust product strategies that result in a greater proportion of patients receiving an appropriate therapy for their condition
- Accelerated time to market and more efficient spending of development funds through greater insight about unmet needs and physician expectations for supporting data
- Greater Commercial effectiveness through increased physician understanding, evidence-based support and Medical alignment to Commercial objectives
- Reduced cost and greater efficiency through a reduction in duplicated or wasted effort between Medical and Commercial
- Stronger relationships with key opinion leaders, physicians, and the government through enhanced medical insight and value-based medical discussions

While not exhaustive, these tangible benefits accrue quickly from a targeted, well-designed campaign to upgrade the capabilities and effectiveness of the Medical team. In our experience, the returns of this program become evident immediately.

Now is the Time for Change

We see five factors that make a strong case for beginning to build a more prominent Medical organization now.

1. Tightening Regulation and Compliance

China's regulatory framework is becoming increasingly complex and burdensome, while also becoming increasingly patient centric. Increased regulatory scrutiny on what can be communicated by sales people has placed greater monitoring and accountability burdens on pharmaceutical companies.

Implication: For most companies this means that Medical will play a greater role in communicating with physicians, answering questions and engaging in dialogues that the salesforce is no longer allowed to. There will also be greater need for Medical to play an active role in ensuring patient safety both in the field and at company headquarters.

2. From Origination to Innovation

Branded Generic drugs, which by some estimates represent 80% of total MNC sales, are expected to gradually give way to innovative products in MNC portfolios as price cuts and increasing generic competition erode the profitability of these products. In response, MNCs are increasingly focused on bringing innovative pharmaceutical products to China as early as possible.

Implication: As new products launch, Sales and Marketing support will not be enough to ensure their success. Medical will play a critical role in developing the market and communicating the on-going value of new products to a wide variety of stakeholders (e.g., physicians, payers, hospital administrators, government officials) and supporting sales reps, as they learn new ways of communicating value to physicians. There is substantial evidence (see exhibit) to show that companies with market-leading Medical evidence programs have stronger sales trajectories than those with limited Medical evidence programs. Medical can also provide a unique perspective on new products as companies diversify and embrace higher growth areas.

Exhibit: Pre-launch value data generation for Chinese patients can lead to significant post-market success

Demonstrating the economic impact early...

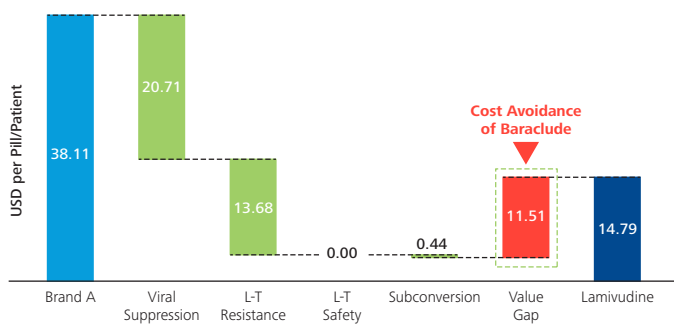
- Identified key clinical differences between therapies
- Validated clinical value drivers with KOLs
- Created links between clinical events and treatment economics to leverage real-world data
- Calculated total economic value of those drivers

... to help secure KOL endorsements...

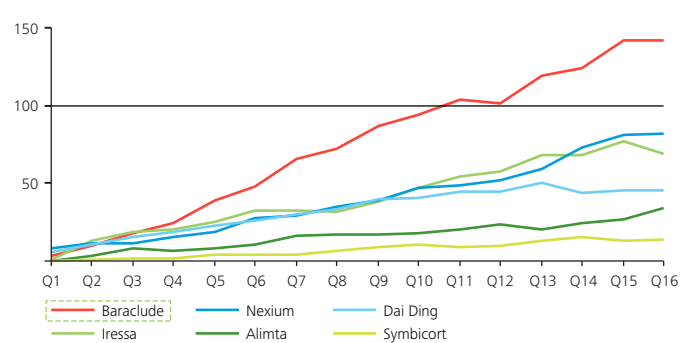
- Engaged KOLs in a cost-effective manner
- Gained KOL support by articulating clinical value and total economic value
- Collaborated with KOL to define treatment guidelines

... resulted in a successful launch

Comparative Economic Value of Baraclude vs. Lamivudine



Selected New Drug Launches (Quarterly Sales)



Note: All data used in this case study is publicly available: <http://dx.doi.org/10.1016/j.vhri.2013.02.002>
 Source: Journal of China Medical Insurance, Expert interviews, Monitor Deloitte analysis

3. Science Driven Relationships

Previously, the sales model was primarily rooted in relationship-based selling to a number of key physicians and stakeholders. However, over the past five years, physicians have become increasingly disengaged from sales reps and have begun to adopt an increasingly evidence-based approach to medical decision-making. A recent Monitor Deloitte and HaoYiSheng survey of more than 1,000 physicians in China revealed more than two-thirds rank sales reps as their least preferred source of information about therapies.

Implication: Medical will play a crucial role in engaging physicians in dialogue, both communicating evidence to the market and gathering intelligence from physicians about patients, therapy effectiveness and unmet market needs.

4. Shifting Decision Power

Patients have an increasingly important role in the decision-making process, and are more educated about their therapeutic options. For example, more than three-quarters of the patients we surveyed sought information about their condition online and had a strong opinion about which treatment they felt was best.

At the same time, clinical decisions are also becoming more institutionalized. Government-sponsored (or supported) clinical pathways and guidelines are making an impact on decision making for physicians, as seen in recent measures to control the use of antibiotics.

Implication: Led by Medical, companies must effectively interact with KOLs, Medical Societies and other key stakeholders to communicate the clinical and economic value of their products as standardized treatment guidelines are established. Medical will also play a crucial role in developing easy to understand information for patients that answers their questions about new therapies relating to their condition.

5. Demand for value

Over 95% of the population in China now receives some form of reimbursement, even if only at the minimal levels afforded under the Rural Cooperative Medical Scheme. While this represents a tremendous achievement for the government and Chinese patients, it has placed a significant and growing burden on government finances.

Implication: The value of a given therapy will increasingly be measured on the basis of its contribution to patient welfare relative to its cost to the healthcare system. Companies will need Medical to step up and engage a wide variety of stakeholders, using strong evidence from real-life studies to support therapeutic value across all lifecycle stages. Without strong evidence of therapeutic value to patients on a cost efficient basis, companies and the new therapies that they launch cannot hope to be successful in China moving forward.

Where to begin?

Companies looking to improve the Medical function should:

1

Consider the unique value Medical can bring to your specific portfolio of products and current base of business and identify areas where the Commercial and Sales teams need additional support from a science-based perspective

2

Work with senior Medical and Commercial leaders to generate alignment to the value Medical can add to the business, including the vision and mission for the Medical organization moving forward

3

Conduct an internal evaluation to develop an understanding of gaps between Medical's expected performance and actual performance

4

Identify 2-3 strong leaders within the Medical organization who can act as champions for the change and lead by example

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