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INSIGHTS

Medical Affairs: Influencers of the Future

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Medical Affairs is in the midst of an exciting metamorphosis. The global shift towards evidence-based care is creating new opportunities for the function to play a more strategic role within pharmaceutical companies, reflecting its growing importance in value generation. As medicines become more targeted and the evidence base more nuanced, Healthcare Professionals (HCPs) are increasingly turning to Medical Science Liaisons (MSLs) to gain a better understanding of complex science. This trusted peer-to-peer dialogue is unlocking real-world insight into the patient experience and putting Medical Affairs in a unique position to amplify the patient voice in pharmaceutical organisations. Leading companies are exploiting this opportunity. They're looking beyond traditional stereotypes of the Medical Affairs function and designing more proactive models which leverage these insights and ensure patient-centric value generation is incorporated into R&D and Commercial decision-making.

This paper examines the drivers for change and describes how Medical Affairs must be re-imagined so that pharma companies and patients derive value from this important function.

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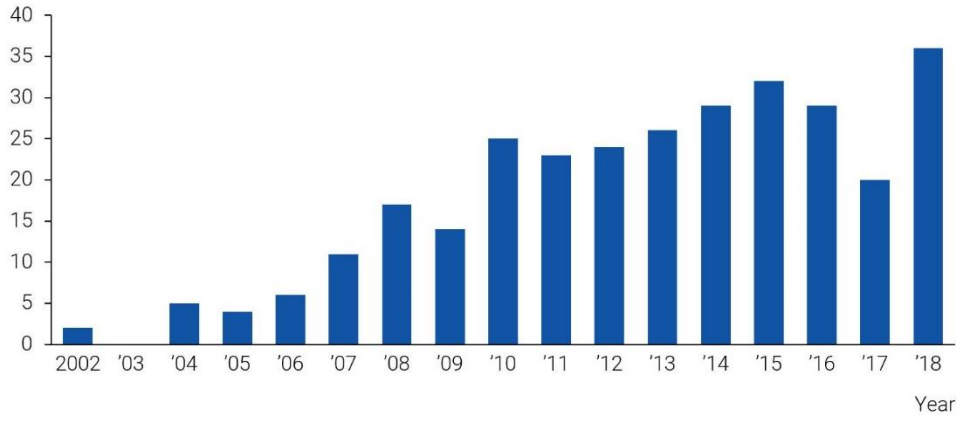
Complexity and globalisation: twin drivers for change

At the macro level, two broad trends are shaping the external environment and extending the remit of Medical Affairs. Primarily, increased complexity across all areas of the healthcare ecosystem is creating novel challenges in the validation and dissemination of medical information. Alongside this, growing demands for transparency and data uniformity, coupled with a universal focus on creating value for both the patient and the healthcare system, are fuelling the need for global consistency in the development and communication of the evidence in support of assets – and encouraging companies to centralise their Medical Affairs functions. Although these trends are testing the traditional capabilities of Medical Affairs teams, they provide a catalyst for progressive Medical Affairs leaders to enhance the value of the function. As more detailed examination of the drivers for change reveals: with every challenge comes opportunity.

Therapeutic complexity

Therapeutic advances, along with the ever-rising number of available treatments, have increased complexity, adding to the already significant burden on doctors. Diagnostic approaches have also increased in complexity; for example, the discovery of genetic biomarkers for cancer has led to the increased use of genetic sequencing to identify mutations in cancer-related genes. Clinical management protocols are also becoming more complex, and the number of guidelines being published has increased substantially in the past couple of decades. For example, the average annual number of guidelines published by the National Institute for Health and Care Excellence (NICE) over the past five years is 29. From 2002 to 2007, the average number was six. The need for greater educational support to help physicians ensure their patients receive appropriate evidence-based care is significant.

One aspect of complexity is the increased number of guidelines published by healthcare bodies



Note

– *Source: www.nice.org.uk Guidance and Advice List*
– *Includes clinical guidelines, as well as guidelines for antimicrobial prescribing, cancer service, medicines practice, public health, safe staffing, and social care*

The trend towards medicines for speciality care is bringing new complexity to clinical decision-making. In the US alone, share of healthcare spending on specialty medicines has increased from 22% to over 40% since 2008 – although the higher prices of specialty therapeutics are naturally a contributing factor. The trend is particularly prevalent in areas such as immunotherapy and rare diseases. For example, there are currently 3,394 immuno-oncology therapies in the global development pipeline – a 67% increase in the past year. Around 1,300 of these therapies are in clinical studies. The number of combination trials with one type of immunotherapy, checkpoint inhibitors, has increased significantly in the past decade, from almost none before 2009 to 469 trials in 2017.

Personalised medicine is also finally becoming more of a reality. Researchers are discovering that many diseases that were once thought of as single diseases can be divided into specific sub-types. Obvious examples include Alzheimer's disease and cancer, with prostate cancer, for instance, now considered as five different diseases. The impact on product pipelines, R&D and healthcare delivery are substantial. More than a third of clinical trials in cancer now use biomarkers to stratify patients. In the UK, the National Health Service (NHS) introduced a Genomic Medicine Service in October 2018 to enable more personalised treatments. Its current focus is on expediting the diagnosis of patients with rare diseases, matching cancer patients with the most effective treatments and reversing adverse drug reactions. In the longer-term it's hoped the service will be able to test for more diseases and identify the risk of early-onset conditions.

These therapeutic trends point to a broader desire to treat smaller groups of patients better, rather than developing one medicine to treat all patients in the same way. For treating physicians, the approach means patients are being segmented into ever smaller groups that might each require a specific, targeted treatment approach; different medications, combinations, doses and cadences. In the process, deciding which specific treatment should be used for a particular patient has become much more nuanced.

With the development of speciality and personalised medicines a clear direction of travel, physicians can benefit from the support of pharma companies – who have intimate knowledge of these drugs – to help determine which therapy is appropriate for a specific patient. Fundamentally, in a complex therapeutic environment, physicians need – and indeed increasingly rely on – insight from Medical Affairs. Medical Affairs functions must therefore ensure that they're well-equipped to deliver that value to doctors.

Stakeholder and data complexity

Pharmaceutical companies now interact with a broader range of stakeholders, including a wider variety of HCPs. This is particularly true for treatments that require teams of specialists, complex diagnostics, or additional service offerings. Decision-making responsibilities are evolving too: patients are becoming more empowered with greater access to

healthcare information; there is a growing culture for shared decision-making; and the influence of formulary committees, payers and pharmacy benefit managers continues to grow globally.

Each of these broad stakeholder groups – and the sub-groups within them – has specific, differentiated information needs that must be satisfied to deliver optimal care. However, the complexity of the therapeutic and stakeholder environments is further enhanced by the growing complexity inherent in the availability, nature and extent of data. Across the industry, we're beginning to see initiatives to address the challenges of big data. For example, Novartis has enhanced its Global Drug Development capability with the introduction of an analytics platform that brings all its clinical trials data together under one roof. Novartis describes the initiative as being driven by a need to 'understand the story our data is telling us'. It's an approach that should inspire every Medical Affairs leader to assess how to do something similar.

If Medical Affairs is to create high-value insights that influence Commercial and R&D decision-making, it must bolster its capability to capture, manage and interpret complex data. These data are wide-ranging, encompassing not just evidence from traditional clinical and scientific studies but also health economic data and real world evidence. These new sources of data will complement opinions on future trends collected from Key Opinion Leaders (KOLs) and advisory boards, which Medical Affairs teams must continue to seek out to stay on top of cutting-edge expert opinion. Multiple pieces of information must come together in a coherent way to paint a picture of the evolving patient journey, and Medical Affairs teams must understand and communicate the data in ways that are meaningful and impactful for individual stakeholder groups – mindful that modern communication channels not only facilitate easy access to information, but also provide a platform to ask questions quickly and proactively. Medical Affairs must be poised to respond.

Forward-thinking Medical Affairs teams have strengthened their infrastructure, enabling them to integrate large, complex data sets to help companies determine the value of their medicines to patients and healthcare systems. They are optimising the value of data – and harnessing the strategic value of Medical Affairs.

Globalisation and value-based healthcare

As the global burden of disease continues to challenge divergent health economies, the regulation and direction of healthcare is converging around common themes. With open access to health information growing day-by-day globally, regulators increasingly seek uniformity in labelling and promotion, which has heightened the need to centralise the Medical Affairs function. More broadly, there is greater pressure on pharma from leaders in the scientific community for more data transparency, with demands for timely open availability of data from all completed studies regardless of publication status. There are widespread examples of progress in this regard and most major pharma companies have developed a global registry that makes a detailed summary of every study available.

The evolution towards value-based healthcare is also dictating the shape and nature of the Medical Affairs role. The increased focus on outcomes and value, to the patient and to the healthcare system, is forcing Medical Affairs to articulate the evidence package differently than before. Demonstrating safety and efficacy is no longer enough; companies need to communicate differentiated patient outcomes and system benefit – clearly – to both payers and patients. However, despite the scale of the challenge, Medical Affairs' window to the patient experience through its trusted interactions with physicians, or possibly directly through patient associations – and its position at the critical intersection between R&D and Commercial – presents a powerful platform from which the function can provide strategic value for the pharmaceutical organisation. The question is: how can companies exploit it?

Build influence and create strategic value

In an ever-complex environment, the Medical Affairs function needs to be much more than local and reactive – it must be agile, proactive, globally consistent and globally connected. With huge demands on its resources from both internal and external stakeholders, Medical Affairs sits at the heart of the new complexity, making it well-placed to inform and influence commercial and pipeline success in healthcare. So how can companies align operations and capabilities to create value? There are two broad but critical steps required to make the most of the opportunity:

1. Align the strategic focus

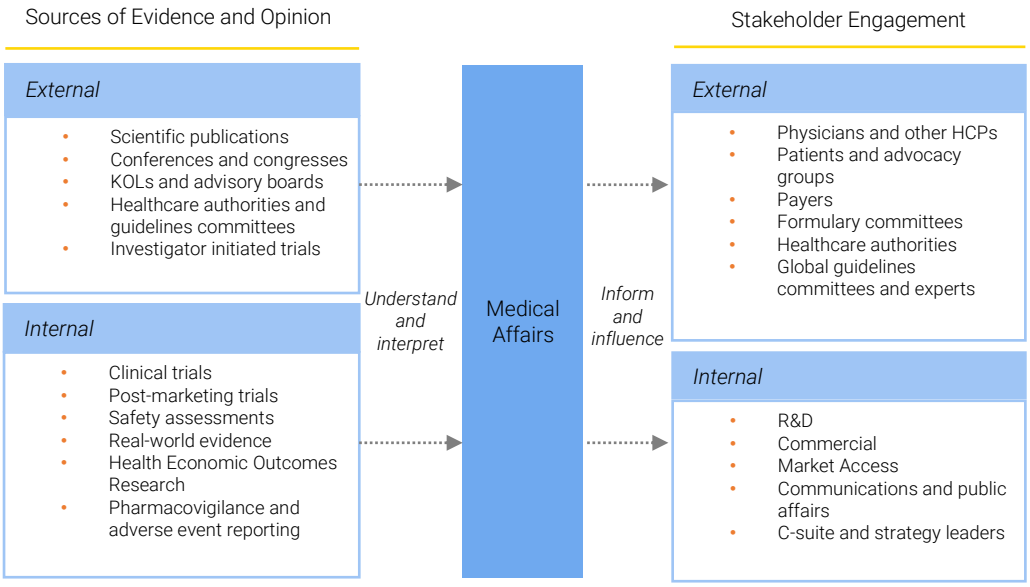
Be considered and 'choiceful' to realise value

It's important for Medical Affairs functions to establish a strategic focus. This must naturally connect with the wider corporate strategy, but agreeing the specifics means being more focused about the investments, capabilities and role of Medical Affairs. There is no out-of-the-box solution. Shaping the right strategy requires a forensic examination of current structures and processes, as well as cross-functional collaboration with internal stakeholders to identify medical affairs outputs that could generate strategic value.

In the emergent era of value-based healthcare, Medical Affairs has two distinct but connected roles:

1. To understand and interpret vast, dynamic and complex information through the lens of patient and healthcare system value
2. To use that understanding to inform and influence external and internal stakeholders

Medical Affairs has a central and influential role to play in pharma companies



In a complex environment, Medical Affairs typically has multiple interfaces with a range of stakeholders. The discipline must not only authorise evidence and opinion for external communications, it also engages directly with HCPs through MSLs. For customers, the value of that interaction is tangible and growing. However, for internal audiences, the value of Medical Affairs is often overlooked. In some companies the function is regarded as, at best, a 'service' and, at worst, a 'barrier' to creative communications. In reality, a wide range of internal disciplines need and rely on insight from Medical Affairs. The most progressive companies have recognised the value of that insight and are leveraging it proactively to influence strategy.

Reframe the vision

Medical Affairs must reframe its role and purpose in the context of a complex and dynamic healthcare environment. Fundamentally, the vision of a modern Medical Affairs function should align with the wider pursuit of value generation. A reframed vision should revolve around the function's three core external stakeholder groups – patients, physicians and payers. For example:

- To pivot to a value-based organisation, where Medical Affairs is the interface between real-world patient value and the products that companies develop and promote to deliver it

To help doctors understand the value of medicines to patients, enabling them to make the best evidence-based decisions
- To ensure a robust, globally consistent and context-sensitive portrayal of the evidence supporting the value to the healthcare system of the company's products

Ask the right questions, early

It's important to ask the right questions to avoid a disconnect between strategy and delivery. Too often, well-conceived strategies fall over because organisations failed to identify capability gaps up front. In the process, opportunities to create value are squandered. To prevent this requires frank questions, thorough evaluation and honest answers. Once again, Medical Affairs leaders must be 'choiceful' in their decision-making. There's much to consider. For example:

- How can you enable better decision-making by doctors? Are there ways in which you can help clarify and distil the available information to ensure customers are making the best decisions for their patients?
- Do you have a strong central governance system for all pre- and post-marketing evidence generation? Do you have a global Medical Affairs strategy with robust feedback and communication with affiliates?
- Is your messaging consistent across all interfaces between the company and external stakeholders? Do you have tailored communications strategies for each group of external stakeholders to ensure information is presented to them in a meaningful, impactful way?
- Do you have the tools and resources required to integrate, analyse and interpret the data? And can you use these data to strengthen your claims or inform future development strategy?
- Does your organisation understand what value means to both patients and to the healthcare system in your specific therapeutic context? Are you having conversations about value early enough in the development process?

2. Enhance capabilities

With much of pharma still relying on traditional, reactive models of Medical Affairs, it's likely that many companies need to enhance their capabilities if they're to transform the function and unlock untapped strategic value. This challenge can typically be broken down into four areas: skills, process, systems and structure. The function's ability to make considered decisions – and take decisive action – in these key areas will determine their success:

Skills	• Invest in the deployment and development of MSLs to maximise doctors' growing preference for peer-to-peer dialogue around the complex therapeutic landscape • Build data science and analytical expertise within Medical Affairs • Dedicate resources to health economics and real-world evidence, to become the 'value experts' that advise multiple functions
Process	• Clarify and strengthen Medical Affairs interfaces with R&D, Commercial and Market Access to fuel collaboration and align on consistent messaging across stakeholder groups • Set up a global decision-making process for new evidence generation • Involve Medical Affairs as early as possible in the R&D process, enabling it to provide design input to clinical development which supports access as well as approval
Systems	• Invest in a centralised evidence management system • Invest in technology to enable big data management and analysis • Develop a range of informational services to help HCPs digest new scientific information and cutting-edge research on new treatments
Structure	• Globalise Medical Affairs and connect more closely to the CEO, Commercial and R&D. With 'Value' and 'patient-centricity' as two of the most dominant issues shaping global healthcare, establishing a Value Evidence and Outcomes organisation or 'Chief Patient Officer' would not be out of step with the market dynamic • Consider introducing specialised roles within Medical Affairs to deal with individual stakeholder groups; for example, Patient Value Leads or Patient Innovation Leads

Seize the moment to create more value from Medical Affairs

Medical Affairs is central to the success of pharmaceutical companies as healthcare becomes more complex, specialised and global. Pharma companies must acknowledge this new reality and reimagine their Medical Affairs capabilities. In turn, Medical Affairs must step up to the challenge of being the integrator of evidence and influencer of external and internal stakeholders. This often requires a fundamental reassessment and change to the skills, processes, systems and structure of the Medical Affairs function. The prize is no less than ensuring patients are both heard and treated with medicines that have value to them, the pharmaceutical companies that develop them, and the healthcare system that funds them.

Novasecta is a specialist strategy consulting firm for pharmaceutical companies.

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