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The Evolving State of Affairs: Medical Marketing Redefined

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Abstract
Rapidly changing global business environment and market conditions compel medical and Pharmaceutical organizations to transform their processes. Organizations adapt in various ways with varying levels of success. Among the many core teams that drive this transformation, medical affairs assumes a crucial role on account of its interoperability with science and marketing. This paper discusses pertinent issues and arising opportunities.

Tenets: Defining Medical Affairs

Medical affairs or Medico marketing is a critical function in pharmaceutical, medical device and diagnostic organizations. It owns and oversees many important responsibilities such as medical communication, scientific liaison with KOLs (Key Opinion Leaders), Healthcare Provider (HCP) engagement compliance. Figure 1 below lists a few tasks for Medical Affairs;

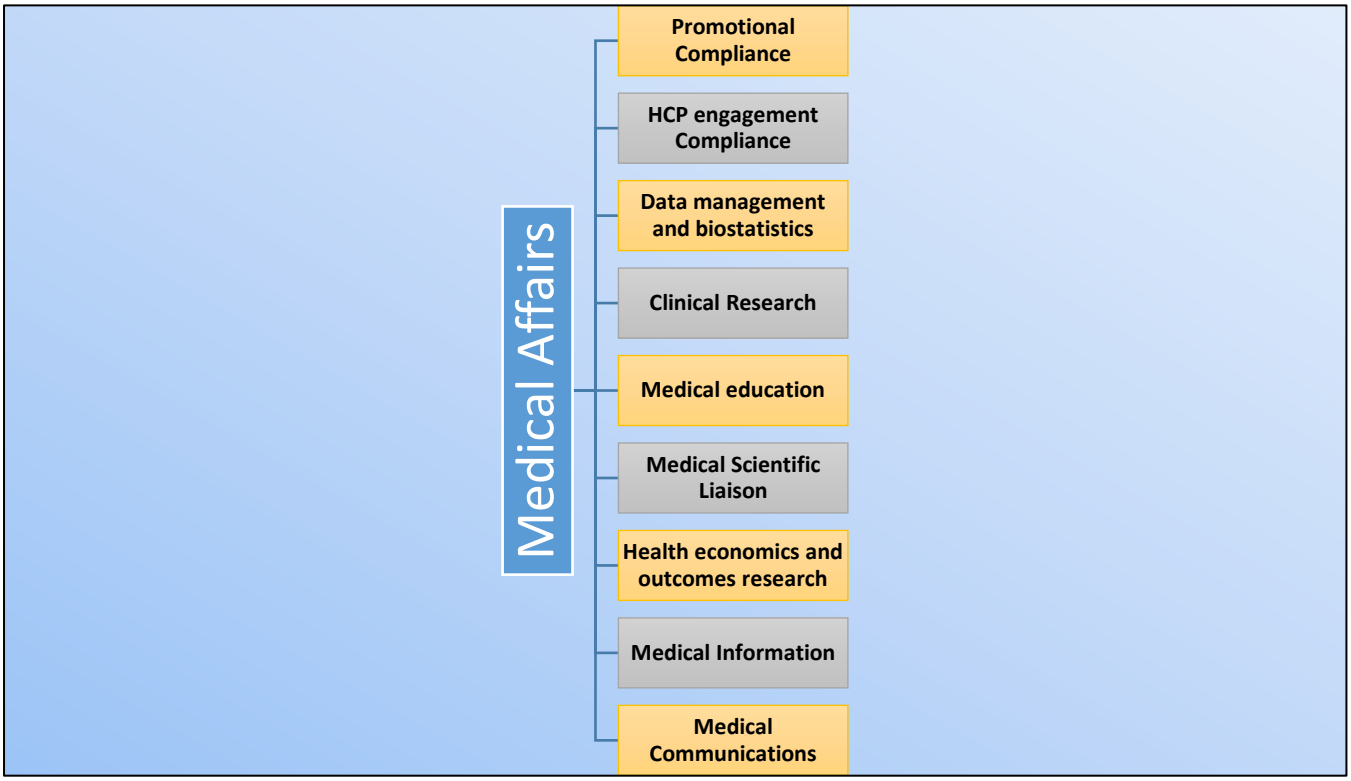

Figure 1: Medical Affairs domain tasks

Medical Affairs support trends in Pharmaceutical and Device Organizations

In the past, the medical affairs function was often narrowly defined and a majority of strategic responsibilities belonged to the commercial teams. But with changes in regulatory guidance, there has been a shift in attitudes and perceptions within the organizations as well.
As medical affairs tasks pertain to increasingly complex sets of clinical data, there is a higher need to manage scientific data compilation and accuracy effectively. With time, there has been an increasing focus on improving patient care quality metrics and enhancing patient experience. There is a trend towards reducing end user costs, whether it be for medication or for accessing drug and disease information, or for collaborative clinical services e.g. physiotherapy, counselling, social worker and nursing personnel.
In Figure 2, since last 10 years, the trend in drug development pipeline is shifting focus increasingly from chronic disease care to orphan diseases.[1]

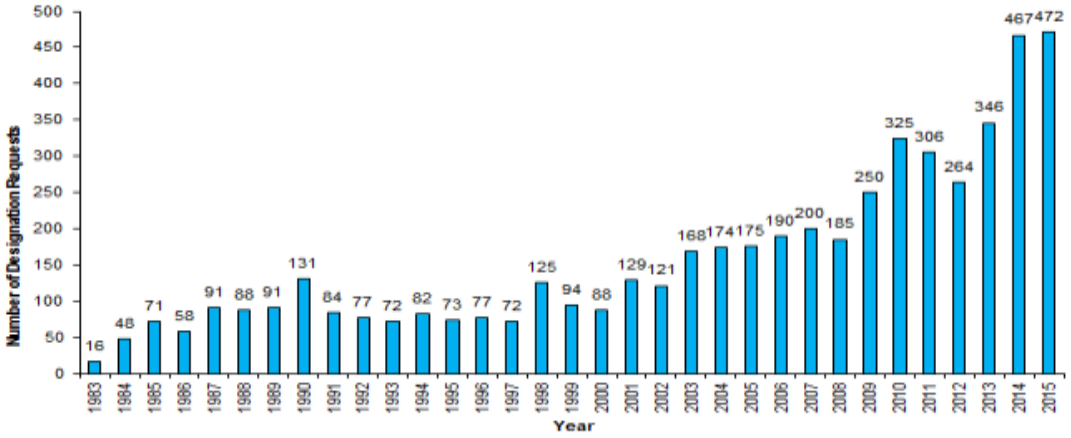

Figure 2: Number of Orphan drug designation requests by year[1]

There is now greater focus on how increasingly complex information is shared through various avenues and advanced communications. Changing regulatory environment in different countries has an impact on strategy, e.g. The Affordable Care Act in United States which is now in a state of transition and Drug Price Control Order in India. Medical Affairs resources are tasked with more specificity and designated medical advisors for therapy areas are increasingly focusing on narrower range of targeted indications. Also in midst of such changes, regulatory guidelines have now defined which type of health/drug information on websites could be accessed by HCPs and consumers separately.

All changes discussed above have broadened the expectations from Medical Affairs.
There is a need to clearly segregate information access differently for HCPs, patients, caregivers, and marketing teams and also information dissemination channels like for electronic mail, telephony, social media or internet websites.
Medical affairs teams are increasingly using quantifiable data sources for insights and to objectify stakeholders. For e.g. measuring and reporting of how many brand strategies are being planned/supported by the medical personnel, number of creative scientific copies are produced per brand or therapy, demand from marketing for insights and support in a specific period.
Taking into account how products are promoted in numerous markets concurrently, keeping a track of product label information and other data is critical. Hence it has also become necessary to create single source of truth to reduce risk of non-compliance and erroneous labelling.
Increased focus is also being given to reporting of medical affairs analytics by using Dashboarding or report generation for a clearer understanding of the work status.

All these added responsibilities have broadened the scope for medical affairs, hence to obtain optimum outcomes, the approach shown in Figure 3 may prove effective:

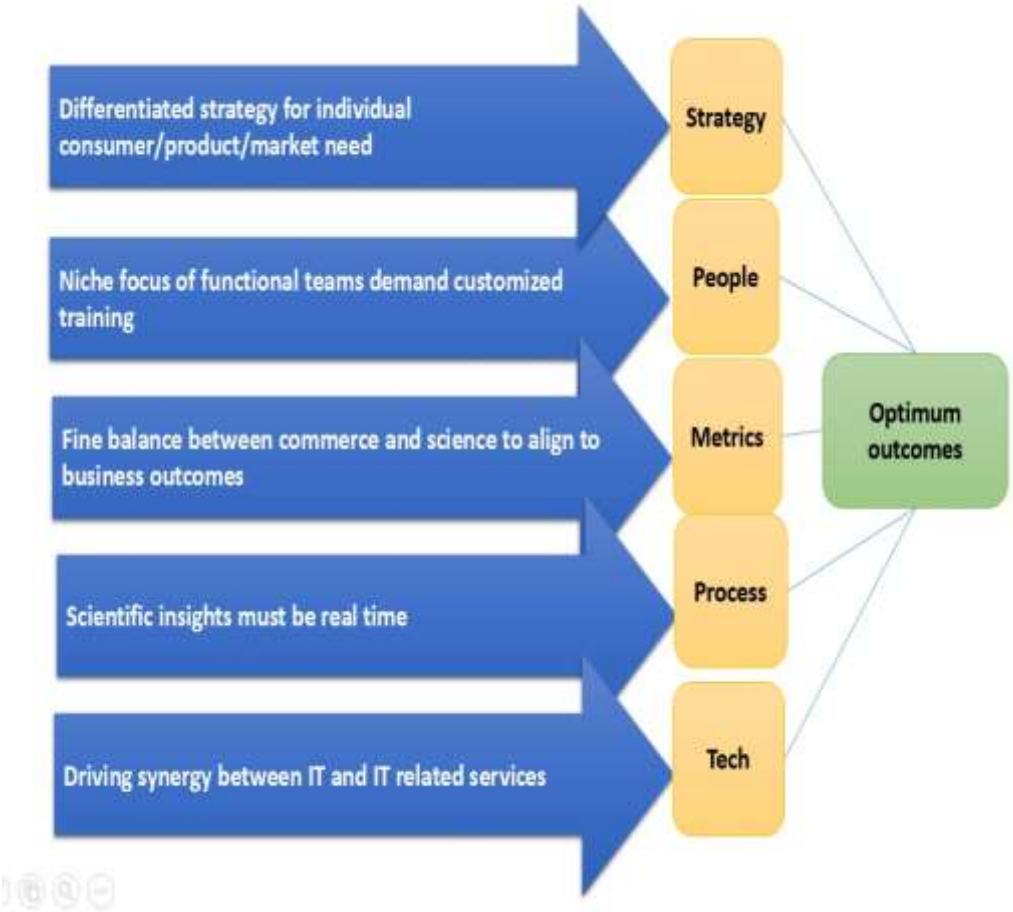

Figure 3: Measures to obtain optimum outcomes in Medical Affairs

Challenges and Concerns in an evolving business environment

Given the industry's Research and Development productivity challenge and a global risk-averse regulatory environment, enhancing medical affairs value is now critical:

Decision-making power is gradually also residing in a new set of stakeholders who are driving cost control, (e.g. Pharmacy and therapeutics committee members at hospitals).

Pharmaceutical organizations' engagement with key opinion leaders (KOLs) and advisory boards has significantly changed under scrutiny and demands for greater transparency through financial disclosures. KOLs are averse to even the misperception of being paid spokespeople for pharmaceutical companies. This exerts additional compliance pressure on Medical Affairs.

Patients are playing a greater role in their healthcare decisions as they actively seek medical information outside their physicians' offices. The use of social media and innovative data collection will continue to expand, to capture the views of patients and physicians (Active Online Listening).

The definition of value continues to evolve across major geographies. E.g. in the United States, rising healthcare costs have obliged employers to rely even more on payers to control costs and influence individual healthcare decisions. Newer healthcare reform will intensify this trend. Europe faces a similar situation with increasingly radical reforms that fundamentally alter the structure and funding of the healthcare system.

A remarkable increase in the generation and usage of real-world data is being witnessed, especially measuring comparative effectiveness. This data is becoming a critical factor in decision making. This real-world evidence and patient-generated data (e.g., genomic information) - which were previously disconnected and discrete data sets –will be considered in the context of broader information sets (e.g., safety data) and will have to be integrated.

Companies are beginning to make detailed patient data, which formed the basis of trials of approved drugs and discontinued investigational ones, more accessible to researchers. New ways of data generation between

life science organizations and other stakeholders (i.e., patient care organizations, integrated-delivery networks, Payers) are being considered (for example, joint clinical trials with leading patient care organizations offering access to their information systems and to real-time data, prospective-outcomes research with Payers in their patient population). However, greater transparency could also lead to potential misuse of the data as pharma may no longer maintain control of the data's interpretations in this new environment.

Supporting Global Market Growth

With time and global business expansion, some challenges arise. Below are a few areas of concern and their possible solutions.

- *Rising Healthcare Cost:* Healthcare as a share of GDP is at 9.3% globally and 17% in the US (Figure 4). These figures have risen 21% and 29%, respectively, over the last 12 years.[2] With such a tremendous portion of global GDP going to healthcare costs, governments and public/private insurers are increasingly more involved in managing the costs. Medical Affairs may help shape how physicians and patients access quality medical information for optimal decision making in this complex legislative and coverage-driven environment.

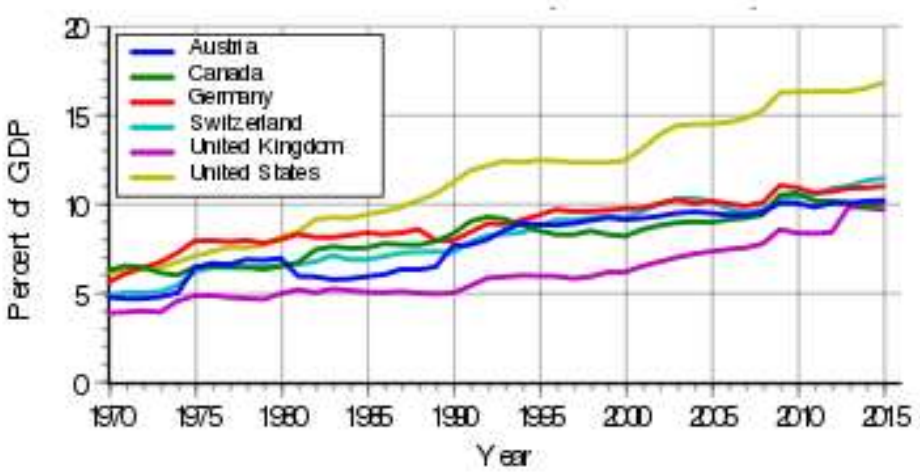

Figure 4: Rising Global Healthcare Cost[3]

- *Population Growth in Emerging Markets*: The global population will grow 10% by 2025 and 25% by 2050 – that is additional 2.4 Billion potential consumers seeking medical information[5]. This growth is overwhelmingly in emerging markets and specific population segments such as the elderly or very young. Medical Affairs may bridge information gap through a mix of educational channels, global/regional/local models for scientific liaisons, and excellence in medical education through scientific content.
- *Advances in Technology:* Statistics show that both consumers and physicians are using technology to find medical information and connect with peers for advice. Coupled with time pressures for the average physician to see more patients per day (due to rising costs and revenue based incentives), Medical Affairs coupled with new technology would be best equipped to self-serve this tech savvy community with compliant medical content on their own terms.
- *Changing Product Landscapes:* Forty five new drugs (37% biologics) were approved in 2014 and a 78% percent increase in spend on specialty care is predicted between 2012 and 2020.[5] There is no doubt that the product landscape is changing and creating new demands for medical information to tackle the

complex science of biologics, specialty drugs, and devices. Medical Affairs, through HCP and patient education, may keep pace with this demand and leverage qualified resources to inform HCPs on new treatment regimens, emerging study data, both on and off label indications, and expected outcomes.

- *Regulatory Pressures Reinforcing the Role of Medical Affairs:* At times inaccurate information, fast track drug and device approvals and regulatory scrutiny result in financial penalties against manufacturers. Medical Affairs may take up a greater role to maintain vigilance and compliance around sharing quality medical communications.

These five trends reflect foreseeable Medical Affairs challenges and their solutions. As the customer (HCP and Patients) demand evolves, Medical Affairs will be the trusted partner to guide healthcare professionals and consumers seeking to make informed *science-based* decisions regarding their health concerns.

Reimagining patient centricity by rethinking medical affairs?

Over past two decades, medical affairs has been transitioning from an offshoot of marketing into an independent function that is bringing definitive value to healthcare stakeholders and the internal organization. One of the most exciting trends is a movement towards patient centricity. A key driver of this shift is due to patients becoming increasingly aware of their disease states and available treatments.
Many teams design physician education materials around how to most clearly discuss a treatment option with patients, or internal organizations may devise methods for bringing back patient insights to drive strategy. Whichever form these patient-centric plans take, patient centricity is an exciting territory for medical affairs teams to continue striving for innovation and proving value.

Avenues for Data Mining and insights
As medical product organizations moves towards 2020, new technologies will allow medical affairs teams to shape their strategies to be increasingly and innovatively patient-centric.

- *Mobile devices and social media*: Patients are interacting with life science organizations like never before. Pharma must continue to carefully navigate this realm of direct patient contact as FDA has issued guidance on responding to public domain queries on social media. However, this Big Data which is collected from mobile and social media sources (Active Online Listening) offers medical affairs teams a window of opportunity to better communicate with and learn from patients.
- *Crowdsourced clinical trial design* – Interacting directly with patients and potential trial participants will accelerate trial timelines and deliver a product more closely aligned with real-life patient need. There are attempts to incorporate crowdsourcing into clinical trial design, encouraging collaboration and input among many stakeholders during protocol development. Transparency in clinical trial data is also at the heart of this approach because it not only drives innovation but also improves pharmaceutical firms' reputation among patients.
- *Ever-growing importance on demonstrating value:* Demonstrating what value the product brings to the patient, is a significant part of the value proposition. Focusing even more on the patient from clinical development through post-launch studies will ensure a strong 'value story'.

Strategic partnering for operational improvement

Stakeholders are constantly searching for better and timelier information. This is especially true when:

- Data is required to determine where and how to deploy R&D capital;
- Physicians demand reliable, impartial data;
- Patients are seeking more information,
- Payers are assessing comparative effectiveness and the economic benefit of new therapies.

The Medical Affairs function is responsible for distilling and disseminating much of these data flows. Historically, this was solely executed by sponsors in-house. But over the past years strategic partnering for some Medical Affairs tasks have increased. We may expect this trend to continue and even grow.

- Core tasks of such strategic medical affairs partners include analyzing clinical trial data and communicating it to providers, patients and payers. Also some groups are responsible for market access assessments and health economics and outcomes research (HEOR) studies. Individuals within such groups include a wide range of professionals. E.g. health economists, market access professionals, medical researchers, medical writers, pharmacists, physicians, regulatory and compliance experts, and scientists.
- The demand for Medical Affairs partner groups is gradually increasing, driven by increased global regulatory and compliance requirements and the sponsors' growing inclination to utilize experts in a shared services model to assist in a variety of Medical Affairs tasks.
- An area of particular interest is global market access assessments of compounds and devices in the drug discovery or development process. Also nowadays, formulary and reimbursement discussions begin much earlier in this process. This market access information and payer feedback is critical and used by sponsors to determine if and to what extent development should continue. As the number of rare-disease and orphan therapies have grown, pharmaceutical firms are seeking assistance to properly position the therapeutic outcomes and economic benefits of these therapies.
- Lastly, strategic partnering allows sponsors to access experienced Medical Affairs expertise and achieve variability with associated costs. This shared services model is growing and includes mostly external providers of one or more point solutions. This has allowed sponsors to add their own resources in Medical Affairs teams and to focus on more crucial strategies and implementation.

Measuring and Managing Medical Affairs Performance

Articulating an effective KPI is not very straightforward for Medical Affairs teams as they are governed by strict regulatory guidelines.

Process based KPIs measure efforts to achieve certain goals. These are created to measure overall value and a company's scientific reputation. These are relatively trouble-free to create and operationalize. Such as:

- Creating strong one-on-one science-based relationships with key opinion leaders (KOLs)
- Providing KOLs with presentation/support materials as needed
- Coordinating educational meetings for KOLs and HCPs
- Providing support for company clinical trials
- Offering KOLs with the opportunity to be part of advisory boards
- Creating speaker programs

Developing an outcome-based KPI to assess the direct or indirect impact that Medical Affairs has on the medical treatment options, is more challenging. Here, there is a need to use more input, especially from compliance teams, to develop such a metric.

Medical Affairs teams have made great strides in gaining recognition within life sciences companies, but proving value to management continues to be a slippery task.

Three broad avenues that can be pursued to demonstrate medical affairs value are:

- **Conventional KPIs:** Traditional MSL key performance indicators (KPIs) include items like the number of KOL relationships per MSL or the number of inquiries medical information call centers receive. These may demonstrate the teams' activity levels, but may not actually show a team's success.

- **KPIs based on outcomes:** These go a step further by tracking the outcome, which is a stronger indicator of medical affairs value. E.g. tracking the number of Investigator Initiated Trial submissions resulting from MSL interactions or the number of HCPs that changed their practices after a medical education event. These present near cause-and-effect relationships, but, once again, these may yet not show the full scope of medical affairs value.
- **Insight based KPIs:** These present a great opportunity to demonstrate capability and play an active role in strategic decision-making. E.g., MSLs may provide physicians' insights to clinical development teams to help design trial protocols, medical information teams can collect frequently asked questions and use these to help train sales reps. While hardest to document, they showcase to management the tremendous impact medical affairs can have on the organization as a whole.

Approaching Medical Affairs Transformation: Key Recommendations

- *Customization*: Many progressive life science organizations offer medicinal products that are better suited to patients as wells as HCPs needs. This comprises of formulation improvements, delivery system changes designed to improve compliance. Similarly in its services towards HCPs, end users and allied health workers with more compliant modes of engagements, Pharma may be better served by 1) improving operational efficiencies, 2) adopting a patient centric approach and 3) using social media as an insight source. Reorienting medical affairs solutions to achieve specificity of outcome is a valuable approach.
- *A closed-loop process*: Medical affairs teams may endeavor evolving from a linear process, i.e. formulate strategy, execute educational initiatives and consolidate scientific dialogue, to a more closed loop approach. Avenues for this approach include ongoing data curation of existing evidence, creating more personalized questionnaires to gauge HCP attitudes and perceptions, analyzing HCPs feedback and using it for adapting or improving an existing communication strategy step by step. In this, the efforts of medical affairs team are periodically validated and continue on a path of self-enhancement.
- *Strategic partnering*: Medical Affairs domain is increasingly becoming innovation driven due to strategic partnering. Using medical affairs partner's expertise in one or more point functions enables a life science organization to augment its own medical affairs strength and to deliver a more strategic role in enhancing business outcomes. Also the services shared through an external partner are usage based, hence cost economy can be optimized.
- *Empowerment through Tech collaboration*: Life science organizations are moving from traditional models of communication and decision making, to methods that better reflect customer needs and allow real-time adaptation to changes in those needs. This is best evidenced nowadays in medical information management through an agile and adaptive ecosystem. Aging legacy software are being withdrawn due to functional lags and poor support to multimedia file formats. In its place, new cloud hosted systems are being customized by organizations for ease of use. As a result, Customer Relationship Management, Call Centers, Self-service portals, product complaint and safety cases intake are more intimately linked. This also provides for true integration benefits like real-time notifications (auto alerts), Dashboarding and reporting, linkages to multimedia library, and better HCP profiling.

Medical affairs shall continue to be a driving force for life science organizations and may be better served in its purpose by integrating its divergent tasks to form unified pathways. With the advent of global business expansion and technological innovation, it may be prudent to partner strategically with niche service providers and achieve functional and business efficiencies.

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