



VALUE CREATION AND IMPORTANCE OF MEDICAL AFFAIRS IN A MEDICAL DEVICE ORGANIZATION

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ABSTRACT

At the heart of healthcare industry, the shift is from “price” to “value”. The Medical Affairs’ landscape is also undergoing continuous change. Challenging demands to help balance competitive market dynamics, growing demands from payers and other healthcare stakeholders “on value products” is on rise. Strategic initiatives, consolidated collaboration, uniform and appropriate communication and most important downstream support to R&D innovation can be brought on to table by Medical department. These are brought about by strategic value proposition, Clinical data generation for differentiation and dissemination, product life cycle management, Device Safety initiatives, Medical Information Request and many more. The time is now right to invest in a MA organization that can create a strategic competitive advantage while safeguarding the patient trust.

KEYWORDS: At the heart initiatives, safeguarding the patient trust.

INTRODUCTION

Healthcare Industry today is driven by highly competitive strategies for developing and marketing innovative products. This resonates with the evolving need of healthcare system and value based medicine has never been more important. Along with this changing environment, role of stakeholders and their say in the decision is also evolving. Power Centre for decision making no more lies with physician alone. The traditional sales models are forced to be replaced by increasing access to their physicians and payors. The stakeholders rely more heavily on real world evidence and economic value when making decisions. Healthcare industry is also realizing a critical regulatory change which going forward will dictate stakeholders like physician, payors and others to pursue value based medicine. Culmination of all these landscape changes compels healthcare industry towards more focused initiatives to improve health outcomes, cost-effectiveness and patient impact. To deliver these requirements require deep understanding of research and innovation and related patient outcome behind the development of a product. Ability to communicate this scientific and medical information to the stakeholders to realize the value and make a conscious decision is where major challenge exist. While the regulators like FDA cannot

regulate scientific exchange, it is important for medical device companies to distinguish scientific exchange from marketing activities.

With its unique set of characteristics, Medical Affairs (MA) plays critical role. Therefore, today the role of MA and Health Economic department is very crucial and integrated in the DNA of the healthcare system. The objective of this review is to understand role of MA in device industry and realign with its value. Medical Affairs in Medical device industry plays a key role in disseminating scientific and product related information, differentiate and realize value based market for product and help establish local data generation as long term scientific collaboration with KOL.

Vision for the Medical Affairs Organization

Keeping in mind the current strategies of the organization, the industry requirement and changing regulatory scenario, MA aims to support the commercial organization by providing clinical insights. MA’s strategic vision based upon its value proposition (Figure 1) will help demonstrate value of product innovation through real world evidence of improved outcomes. The Value Proposition of MA provides an organization with a framework to more effectively bridge the gap between

internal R&D and the commercial organization, integrate market input into the science, and communicate medical insights and product knowledge across providers, payers,

patients, physicians and other players who collectively constitute as stakeholders throughout the entire product life cycle.

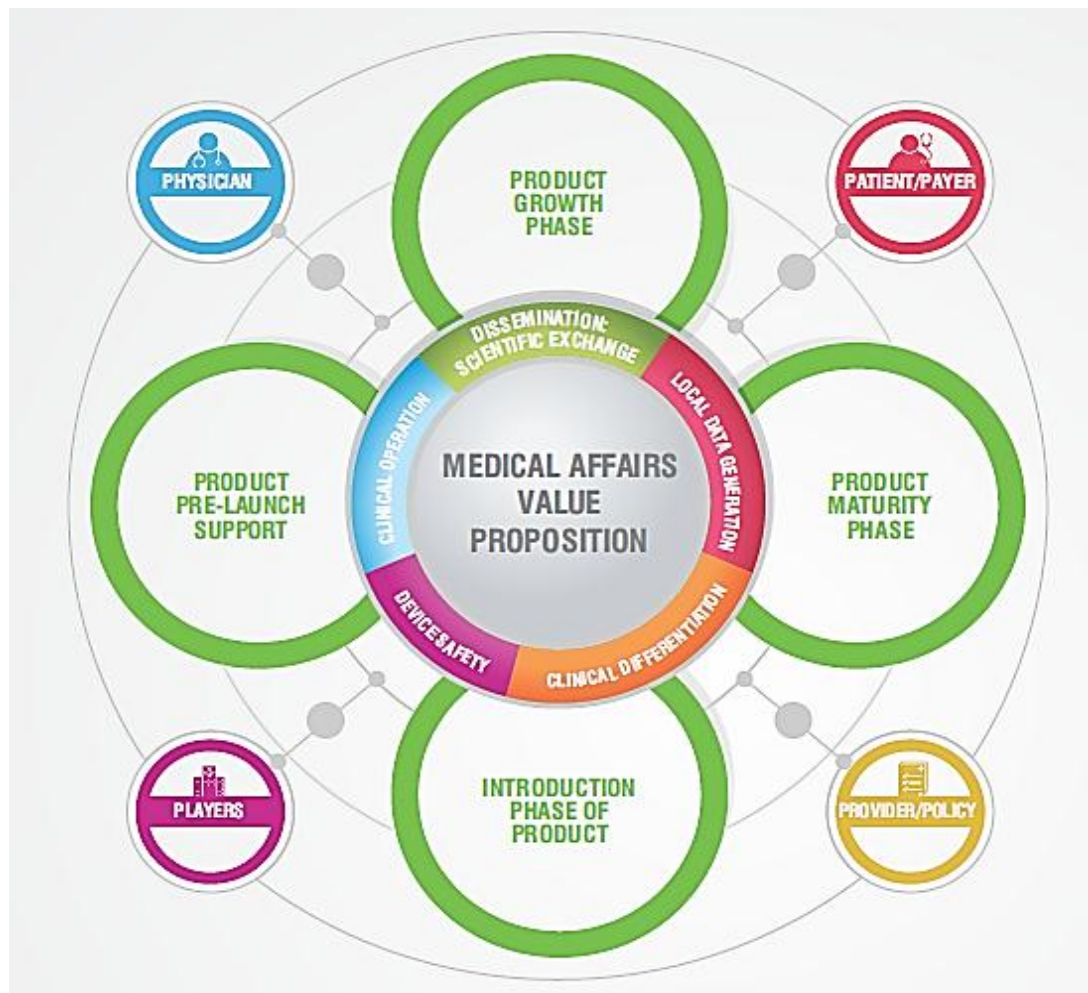


Figure 1: Medical Affairs Value Propositions

Understanding Patient and Developing Patient Centric strategy

Better patient outcome is at the heart of every innovation or research. To make any innovation in product/procedure a success it is essential to understand the research and innovation purpose behind it. It is important that this objective is conveyed to the stakeholders, measured and recorded for improvement from these stakeholders. This is one of the critical objectives for MA. Through a patient-centric development strategy (Figure 2), medical device company can leverage an integrated analysis of all data sources from which these requirements can be derived. Medical Information requests (MIR) or Product related queries from stakeholders provide opportunities to explore customer relationship management, new indications, understanding data sources and its

importance, improving care management services. Thus, MA forms an informative bridge between R&D, Commercial Team and relevant stakeholders.

This role becomes more critical in the medical device industry as the benefits of product engineering needs to be conveyed to the user and help them appreciate technology behind it and realize the value behind each innovation.

MA in device industry helps integrate engineering and other avenues of technology with healthcare and further parameters are set to measure clinical endpoints to improvise on these technical developments usually through Voice of Customers (VOC) or training or by capturing real world evidence. MA thus consciously leads innovation to Patient centricity outcome.



Figure 2: Patient-Centric Development Strategy.

New product Launch and Role in Product Life Cycle

In the value-based care era of population based health metrics, therapeutic value beyond safety and efficacy needs to be demonstrated across the entire device product lifecycle (Figure 3). Leveraging MA to generate evidence-based value indicators or collecting real world evidence or patient related outcome measures including economic parameters help influence the overall treatment of patients. This is very important for new value-based care marketplace. The MA organization can help in effectively shape treatment protocols by focusing on all the phases of a product lifecycle. MA can draw the

importance of product and procedure segmentation across lifecycle with respect to stakeholders. MA in a device company can help adapt to these healthcare landscape changes by coordinating comparative effectiveness research to establish a unique treatment profile that supports current market access and use the available clinical information and KOL engagements to establish diagnostic patterns and treatment paradigms. A new product launch with market driven model along with safety evaluation plan can help fully differentiate product values more clearly and help communicate the same to stakeholders prior to initial marketing.

MA as an integral part of product life cycle - aligning with 4 growth pillars

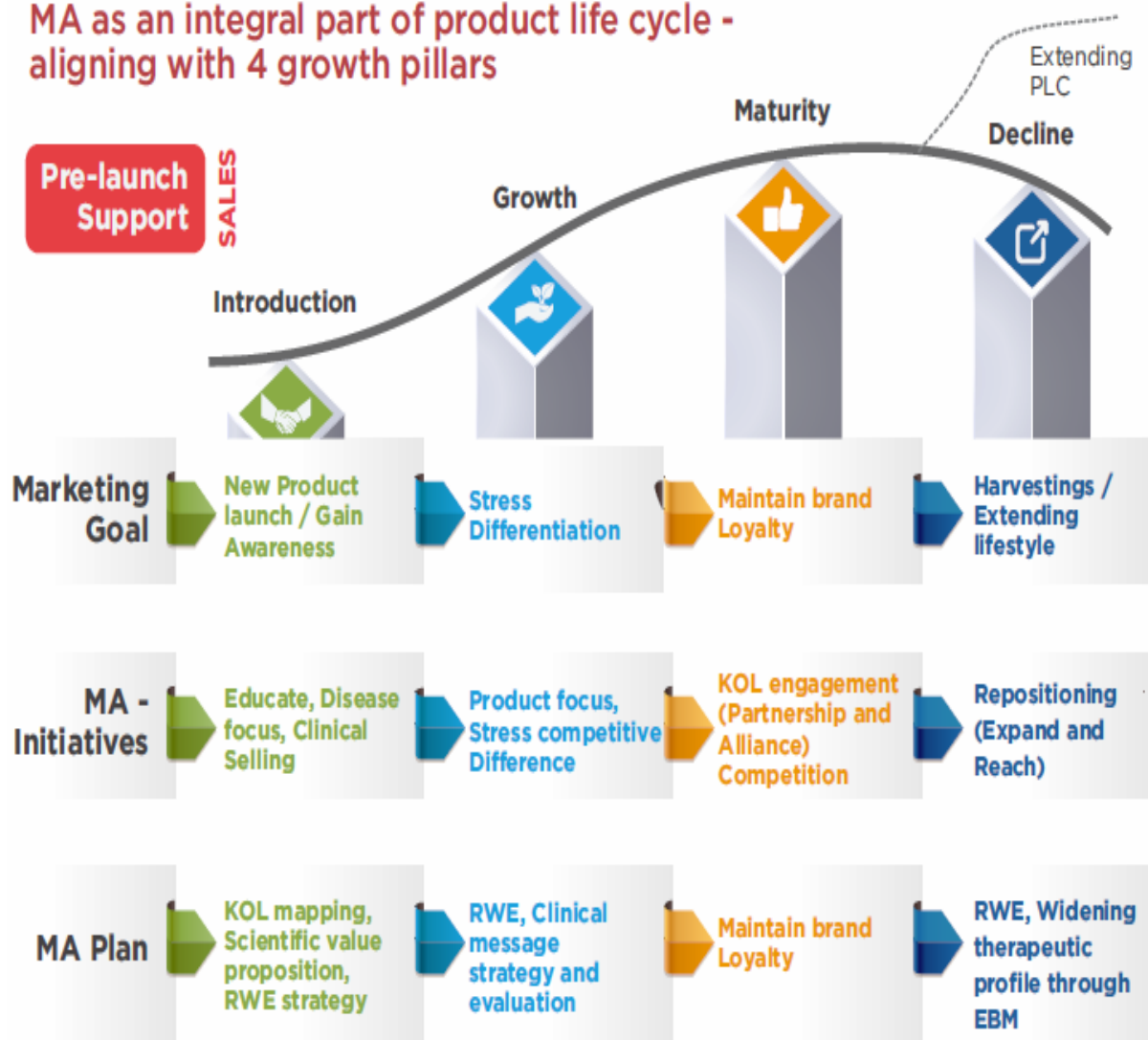


Figure 3: Medical Affairs Role in Product Lifecycle.

Medical led stakeholder engagement in medical device industry facilitates access to disease and treatment information and to promote research initiatives across the various stakeholder groups. With MA engaged to manage the coordination of medical and scientific exchange, helping to determine the most appropriate resources and content for an interaction, medical device industry can share with stakeholder's global strategic objectives. Most MA groups already engage in peer-level conversations with KOL and in collaboration with Professional Education organization disseminate educational information about a treatment or therapeutic

area. These stakeholder engagements lay foundation for many investigator-led research initiatives, real world evidence or product registries. Customer engagements by MA in device organization helps capture the real-time safety value of products and helps to continuously analyses the benefit-risk ratio. The insights captured by MA from these engagements help organization to shape the future commercial strategies.

Medical Affairs: Custodian of 3Ds (Dissemination, Differentiation & Data) for value creation and market access.



Figure 4: 3Ds (Dissemination, Differentiation & Data).

Data: Evidence Generation Evidence generation forms the foundation of a transformative MA organization. today organization should look at data capturing and analysis as an integral part of the organization objective. This information helps the industry/organization to derive insights for better patient or healthcare related outcomes. In today's challenging and changing regulatory environment it will be critical to make available any data that supports the medical and economic impact of a treatment throughout the entire product lifecycle to impact development and commercialization activities as well as to help shape treatment paradigms and reimbursement programs MA plays a critical role in the space of evidence generation and aligns with commercial and R&D strategies of the organization.

Dissemination: Scientific exchange requires a strategic shift in focus from marketing and selling treatments to understanding and solving the 'patient problem.' From an internal perspective, enabling scientific and medical discussions can help incorporate the patient-centric viewpoint into strategic R&D and commercial decisions. When directed externally, the exchange can act as a conduit to help integrate the efforts of industry, academia, and government agencies around meeting patient needs. MA Communicates these scientific results to the healthcare stakeholders to help identify product value especially, when the audience is shifting majorly towards non- clinical stakeholders. MA verifies the appropriateness of these scientific communications and engages with commercial or IT department to devise better and innovative dissemination channels.

Differentiation: Today with the increased focus on evidence and hurdles for proving product value against increasing players, it is the need of the hour to have a

strong differentiation aspect and to address "WHY" the market should pay for your product.

Communicating the Value of Medical Affairs within Medical Device Companies

The Medical Affairs function today with its value proposition is an integral part of the organization's growth. While the importance of the function is recognized, leaders often struggle with communicating the value of the function to key internal stakeholders.

Role of MA in medical device industry

- Regulatory approval for medical devices can be based upon literature or data on similar devices. Technology and science behind medical device innovation evolves and changes over time.
- Real-world evidence is crucial for devices as it may be the only data and generally is prospective.
- MA in medical device comprises of device safety, clinical operations, medical affairs & medico-marketing activities along with health economic responsibilities.
- In some medical device organization MA also included professional education and sales learning and development. Thus, role of MA is widespan but unfortunately usually with limited resources in device industry.
- An increased awareness for "evidence of value" and comparative effectiveness in medical devices is expected. Demand for economic evidence for medical devices is growing. Evidence on time and cost are expected to be determinant in the launch and commercialization of medical devices. Hence role of MA in medical device industry to guide the organization to evidence based marketing is becoming all time imperative.
- MA with its KOL engagements helps stakeholders to publish and represent them in conferences.

- MA in device industry needs to adapt to the ever-changing healthcare landscape and constantly prepares for the changes that will impact the industry in significant ways.

To conclude, Medical Device industry now under extreme pressure to deliver value based superior medical outcomes while simultaneously reigning in costs and reducing excessive spending, the time is right for Medical Affairs organizations in medical device industry to earn their place at the leadership table by creating opportunities to deliver new value for both patients and the health care ecosystem.

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