



Strategic Planning in the Pharmaceutical Industry: the Pivotal Role of Medical Affairs



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ABSTRACT

The pharmaceutical market is both complex and diverse. It differs from country to country, even region to region and it is constantly evolving. India's pharmaceutical sector ranks among the largest and most advanced science-based industries within developing nations globally. In the rapidly evolving pharmaceutical industry, strategic planning is crucial for maintaining competitive advantage and ensuring sustainable growth. One of the key players in this strategic landscape is the Medical Affairs (MA) department. Strategic planning start from pre-clinical development and continue till the product is in market. A well-developed strategic plan in medico-marketing can significantly impact a company's market presence, brand loyalty, and patient outcomes. Medical Affairs will always remain a cornerstone of strategic planning in the pharmaceutical industry.

Keywords: Medical affairs, Medico-marketing, Pharmaceutical Industry

Introduction

The pharmaceutical market is both complex and diverse. It differs from country to country, even region to region and it is constantly evolving. The pharmaceutical industry is responsible for the research, development, production, and distribution of medications. The market has experienced significant growth during the past two decades, and pharma revenues worldwide totaled 1.48 trillion U.S. dollars in 2022(1)

The Indian pharmaceutical industry is one of the largest and most highly developed science-based industries in the world's developing countries. Fourth largest pharmaceutical producer in the world after the USA, Japan, and Germany, 8% share of global production in terms of volume, ranks 13th in terms of value, Constituting around 1.5% of the world's total value. India's pharmaceutical industry has experienced significant growth in recent years and is projected to account for approximately 13% of the global pharmaceutical market, with continued improvements in quality, affordability, and innovation. There are many

support function, Medical Affairs has now emerged as a strategic pillar, bridging the gap between research and development (R&D) and commercial operations.

The Evolving Role of Medical Affairs

Medical Affairs professionals are uniquely positioned to drive strategic initiatives due to their deep scientific knowledge and strong relationships with healthcare professionals (HCPs). They play a critical role in interpreting and communicating complex scientific data, which is essential for informed decision-making across the organization.(2). The modern pharmaceutical market demands that Medical Affairs act as an "internal consultant," providing insights into therapeutic areas, competitor activity, and healthcare provider needs.

Strategic planning and role of medical affairs

The pharmaceutical industry operates in a highly regulated and competitive environment. To ensure sustained growth, companies must employ strategic planning in medico-marketing—an essential aspect combining medical expertise with marketing strategies.

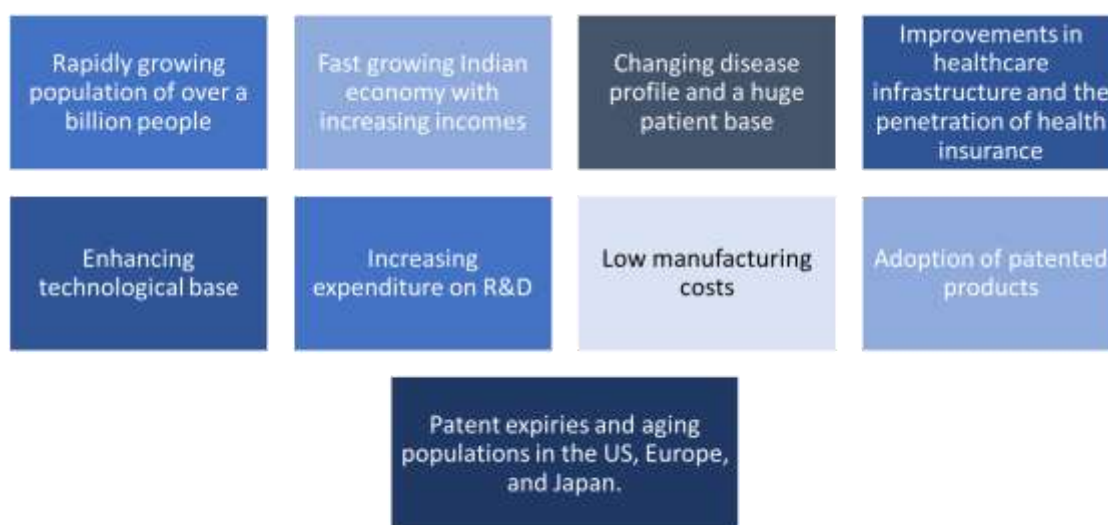


Figure 1. Factors in favor of pharmaceutical market in India

factors which favors pharmaceutical growth in India. (Refer figure 1)

Strategic Planning in the Pharmaceutical Industry. In the rapidly evolving pharmaceutical industry, strategic planning is crucial for maintaining competitive advantage and ensuring sustainable growth. One of the key players in this strategic landscape is the Medical Affairs (MA) department. Traditionally seen as a

Medico-marketing involves promoting pharmaceutical products while adhering to regulatory guidelines, scientific integrity, and ethical principles. Strategic planning start from pre-clinical development and continue till the product is in market. A well-developed strategic plan in medico-marketing can significantly impact a company's market presence, brand loyalty, and patient outcomes. (Refer figure 2)



Figure 2. Key Components of Strategic Planning in Medico-Marketing

Scientific Leadership

Medical Affairs provides scientific leadership by ensuring that the latest research and clinical data are integrated into the strategic planning process. This helps in identifying new therapeutic opportunities and optimizing product development strategies. Medical affairs should explain and discuss the details about the disease, changing landscape of disease, available drugs for treatment with limitations, newer options under development with R &D, marketing, business development time to time and should regularly re-visit the strategy plan. (3)

Market Analysis and Research

Strategic planning begins with a thorough analysis of the market. This includes understanding current market trends, competitive landscape, and unmet medical needs. Market research helps in identifying target demographics, assessing demand, and determining the efficacy of existing products. Quantitative and qualitative market data are utilized to forecast potential opportunities and threats in the industry. By focusing on the needs of healthcare professionals (HCPs) and patients, pharmaceutical companies can develop strategies that align with clinical practices and expectations. Its continuous process should be initiated prior to deciding product pipeline for

pharmaceutical company. Opinion of medical affairs should be taken while analysing market data and before concluding on product pipeline which will increase the probability of right selection of products for launch. (4,5)

Regulatory Compliance and Ethical Marketing

Pharmaceutical marketing is heavily regulated due to the direct impact on patient health. Strategic plans must account for regional and international regulations such as the U.S. Food and Drug Administration (FDA) guidelines, European Medicines Agency (EMA) standards, and those from national drug regulatory authorities. These guidelines ensure that promotional activities are truthful, evidence-based, and non-misleading. Ethical considerations must be factored in, ensuring transparency, particularly in clinical trial data and the portrayal of drug efficacy and safety. (6)

Target Audience Segmentation

A strategic plan should include a clear segmentation of the target audience, such as general practitioners, specialists, pharmacists, and patients. Tailored marketing approaches should be created for each group. For example, for healthcare professionals, providing continuing medical education (CME) programs or hosting scientific symposia are effective ways to promote new drugs. On the other hand, patient education campaigns and patient

assistance programs can increase awareness and facilitate access to treatments. It is always advisable to consult medical affairs while targeting customers for product promotion as well as while defining any promotional activity. (7)

Scientific Engagement and Key Opinion Leaders (KOLs)

Engaging with key opinion leaders (KOLs) and thought leaders in the medical community is crucial. KOLs help build credibility and trust for new products. They can be involved in scientific advisory boards, clinical trials, and peer-to-peer education. Their endorsements are often seen as unbiased and scientifically reliable, providing significant influence over prescribing patterns and drug adoption.

Digital Marketing and Multichannel Engagement

Digital transformation has revolutionized medico-marketing. A strategic plan must incorporate digital platforms such as social media, webinars, mobile applications, and virtual conferences. Pharmaceutical companies can reach a broader audience through online channels, enabling real-time communication, education, and feedback. Digital engagement also allows for more precise tracking of marketing efforts and customer interactions, making the strategy more adaptive to changing needs. (8)

Content Development and Evidence-Based Promotion

Content plays a central role in medico-marketing strategies. Developing educational materials backed by strong clinical evidence is key to earning the trust of HCPs and patients. This includes publishing research papers, clinical study results, and case studies. In addition, companies should ensure that content is tailored to local market conditions, including language, cultural factors, and healthcare policies.

Lifecycle Management and New Product Launches

Strategic planning involves managing a product's lifecycle—from pre-launch, launch, to post-marketing surveillance. Pre-launch activities include market preparation, KOL engagement, and ensuring medical information is disseminated appropriately. During the

launch phase, coordinated marketing campaigns, CME initiatives, and HCP outreach ensure awareness and adoption. Post-launch continued focus on gathering real-world evidence and post-market studies is essential for maintaining product relevance. (9)

Strategic planning while developing marketing plan (10,11)

A marketing plan, always requires considerable thought and clarity of execution and remains under constant revision and updating, depending on changes in marketing needs and targeted patient opportunities. Medical affairs and marketing team should be an integral part of product development from the time of discovery right through the product life cycle from phase I to IV and even after patent expires. Most of the marketing expert still considered first 6 months following the launch are very crucial to decide the success of product. Relaunch of a product in the first year or two following a failed first launch is possible, but very few products are relaunched with any degree of success.

Strategic planning for the medical marketing team determines the balance between the risks of the product getting into the marketplace and how successful it will be commercially once it gets there. The targets need to be clearly defined, and the area in which the product is to be launched needs to be well documented.

Strategy for speciality products will be different from general products, even strategy many are not same for all speciality products, medical affairs should be the part of each and every strategy discussion and decision should not take only on the basis of market survey, looking at market data and KOL (key opinion leaders) advises this will definitely minimize the probability of failure.

Launching first time in world product required different strategy than launching me-too drugs in market. Me-too drugs should have differentiating features like better safety profile, ease of administration (smaller tablet size, better test, accurate dosing, dose calculator, innovative packaging etc.) as compared to drugs which are available in market and marketing should take the help of medical affairs to highlight important benefits of product to consumer scientifically.

In highly competitive pharmaceutical marketplace number of key elements that need to be considered when developing a marketing plan. The strategy and tactics, will vary depending on the stage of the product in its life cycle (i.e. the stage at which it is launched, developed, re-invented and extended as a therapeutic product for the treatment of a particular disease or therapeutic area).

The goal of marketing is to meet the target customers' needs and wants. The understanding customers' behaviour is most challenging. In changing environments of decision making specially in India with wide availability of internet, online pharmacy and affordable generic medicine, patients are also increasingly involved in the choice of medicines specially selection of particular brand.

To conclude on Strategic Planning and Medical Affairs

Incorporating Medical Affairs into strategic planning ensures that scientific insights and patient perspectives are central to decision-making. This holistic approach enhances the

development and commercialization of pharmaceutical products, ultimately leading to better patient outcomes and business success.

Medical Affairs' strategic role is expected to grow as the pharmaceutical industry continues to navigate complex regulatory environments, increasing competition, and the need for innovative therapies. By fostering a culture of scientific excellence and patient-centricity, Medical Affairs will always remain a cornerstone of strategic planning in the pharmaceutical industry.

Strategic planning in medico-marketing is essential for pharmaceutical companies to succeed in an increasingly competitive and regulated environment. By aligning market research, ethical considerations, audience targeting, and digital marketing efforts, companies can optimize their product promotion while upholding scientific integrity. Furthermore, continuous measurement and adaptation ensure that marketing strategies remain effective throughout a product's lifecycle.



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