

MAXIMIZING PHARMACEUTICAL PRODUCT VALUE BEYOND LAUNCH WITH LCM

In the challenging landscape of the pharmaceutical industry, marked by intensifying competition, increasing regulatory standards, and escalating clinical development and launch expenses, it is imperative to adopt a more comprehensive perspective. Astonishingly, the cost to develop a single drug has surged from US\$1.2 billion in 2013 to a staggering US\$2 billion in 2021, all while the average peak sales have mainly remained unchanged.

The traditional fixation on new product launches to generate growth is no longer sufficient. Considering mounting development costs, a more important role should be given to Life Cycle Management (LCM) as a mean to optimize revenue from mature brands in order to fuel continued innovation. Indeed, as a pharmaceutical product's life progresses, amortized investments or process improvements often lead to improved net profit ratios, even as gross sales may decline. Regrettably, many companies tend to overlook these aspects, fixating on the initial development and launch phases, thereby missing out on the opportunity to maximize long-term Return-on-investment (ROI).

LCM is a multifaceted endeavour, necessitating cross-functional expertise that is dedicated to understanding market needs, and answering those needs, yet providing product differentiation and market protection. To embark on this journey successfully, marketers must collaborate closely with other departments to define and evaluate effective LCM options, bringing valuable market knowledge and commercial insights to the table.

These LCM options can be tailored to various stages of a product's lifecycle and cater to diverse stakeholders, ultimately enhancing market retention and share. Although it is not the common practice, initiating the formulation of these strategies during the early clinical development phases is the optimal approach, positioning the product for long-term success.

In light of these considerations, I proposed a comprehensive LCM classification model built upon five key strategies:

- 1 IP Protection:** This strategy encompasses regulatory and patent protection, leveraging advantages such as orphan drug designations and the development of new indications, including pediatric applications.
- 2 Development Enhancements:** Focus on efficacy improvements, safety enhancements, stability optimization, and innovations like new routes of administration and packaging improvements. This may include dosage or formulation adjustments, molecule stabilization, and the use of precursors.
- 3 Commercial Initiatives:** This strategy entails divestiture/rationalization, strategic marketing, efficient commercial operations, and pricing strategies. It can involve expanding into new geographic markets, outsourcing commercial operations, adopting unique pricing models, and incorporating digital tools for enhanced market reach.
- 4 Services:** The services strategy includes comprehensive patient and healthcare provider (HCP) support, such as facilitating early access to treatments, utilizing digital health solutions, and streamlining access to diagnostics.
- 5 Technical Operations Improvements:** Concentrate on enhancing manufacturing and supply chain processes to increase efficiency and reduce costs, ensuring a seamless production and distribution system.

Targeted Stakeholders	LCM strategies				
	IP Protection	Development Enhancements	Commercial	Services	Technical Operations Improvements
Company	Regulatory protection Patent protection		Divestiture / Rationalization		Manufacturing Supply Chain
Patients		Efficacy improvements Safety improvements		Patient support	
HCPs		Stability improvements Administration improvements New route of administration	Marketing Commercial operation	HCP support	
Payers		Packaging improvements	Pricing		

The process of product life cycle definition is a strategic task. It involves a comprehensive analysis of competitive status, strategic insights derived from the evaluation of the patient journey, patient flow, and SWOT analysis, and the identification of leverage and pain points. This multifaceted approach guides decisions on how to capitalize on a medicine and a company's strengths or address weaknesses through LCM strategies.

Through investments in LCM, pharmaceutical companies can attain long-term optimization of the sales of products in which they have invested substantial amounts, frequently totaling hundreds of millions of dollars for development and launch. This optimization results in enhanced profitability, providing them with the means to finance new developments or acquisitions. Essentially, this process revolves around achieving the appropriate equilibrium between early and late-stage investments while attaining independence from the influence of analysts and financial markets. These entities often prioritize speculating about pipeline performance expectations rather than concentrating on more stable, risk-mitigated revenue

streams.

