Research Synopsis

Title: Lifecycle Management Strategies for Off-Patent Brands: Enhancing Brand Sustainability and Market Share Post Loss of Exclusivity

Researcher: Abhishek Tyagi
Affiliation: IIHMR University
Submission Date: Monday, 18 May 2025

Abstract

The expiration of drug patents signifies a critical juncture in a pharmaceutical product's lifecycle, marking the onset of competition from generic entrants and posing significant risks to revenue and market position. This study aims to examine strategic lifecycle management (LCM) approaches that pharmaceutical firms implement to sustain brand equity and market share after the loss of exclusivity (LOE). Through a mixed-methods design incorporating both quantitative market performance indicators and qualitative insights from industry experts, the research will investigate tools such as brand repositioning, line extensions, authorized generics, strategic pricing, and regulatory extensions. The ultimate objective is to propose a robust, evidence-based framework that pharmaceutical companies can adopt to mitigate post-LOE decline and achieve sustained competitiveness in dynamic markets.

Introduction

Loss of exclusivity (LOE) represents a pivotal shift in a pharmaceutical brand's lifecycle, typically leading to rapid erosion in market share due to the influx of generic competition. For innovator companies, strategic lifecycle management becomes essential to protect brand value and profitability. This study explores the array of tactical and strategic measures that pharmaceutical companies deploy in response to LOE. It examines how brand-centric initiatives, such as differentiation, pricing optimization, line extensions, and regulatory opportunities, can help extend the commercial life of a product. The study will also assess the interplay of these strategies in real-world scenarios and explore how companies can align such efforts with broader corporate objectives to maintain a competitive edge.

Literature Review

Extensive research indicates that pharmaceutical brands can lose up to 80% of their market share in the first year following patent expiry without proactive interventions. Key LCM strategies highlighted in the literature include:

- **Brand Differentiation**: Physician outreach, direct-to-consumer communication, and outcome-based pricing are cited as effective tools for retaining prescriber loyalty and patient preference.
- **Line Extensions**: Reformulations—such as extended-release versions or novel delivery mechanisms—are shown to delay generic substitution and address niche patient needs.

- **Authorized Generics**: The launch of company-controlled generics under a separate label can enable market retention while appealing to cost-conscious segments.
- **Strategic Pricing**: Competitive pricing of the originator brand can blunt the initial impact of generic entries, especially in branded generic-dominant markets.
- **Regulatory Extensions**: Exploiting provisions like pediatric exclusivity, new indications, or orphan drug status can yield additional exclusivity windows.

Despite the existing body of research, limited studies holistically evaluate the synergy among multiple LCM strategies. This study aims to bridge that gap through an integrated evaluation of both successful and underperforming post-LOE cases.

Objectives

1. To evaluate the effectiveness of lifecycle management strategies for off-patent pharmaceutical brands.
2. To analyze the impact of individual and combined strategic approaches on long-term brand sustainability post-LOE.
3. To identify key drivers and barriers influencing market performance after the expiry of exclusivity.
4. To offer strategic recommendations for maximizing brand performance and mitigating market erosion post-LOE.

Methodology

- **Approach**: Mixed-method research using both qualitative and quantitative techniques.
- **Data Collection**:
    - Secondary data from sales reports, market performance analytics, and industry publications.
    - Primary data via in-depth interviews with industry professionals including brand managers, regulatory experts, and healthcare providers.
- **Sampling**: Selection of branded pharmaceuticals that experienced LOE in the past 5–10 years, across diverse therapeutic categories.
- **Analysis**:
    - Quantitative: Statistical analysis of pre- and post-LOE sales trends.
    - Qualitative: Thematic coding of expert interviews to extract strategic patterns and insights.
- **Ethical Considerations**: Adherence to confidentiality, informed consent, and voluntary participation for all interviewees.

Expected Outcomes

- A detailed mapping of lifecycle strategies employed by pharmaceutical companies post-LOE.
- Evaluation of the impact of individual strategies on brand retention and financial outcomes.
- A proposed model for best practices in lifecycle management for use by pharmaceutical companies and policymakers.
- Academic contributions to the field of pharmaceutical strategy and marketing.

Tentative Timeline

Phase	Task
1–2 Weeks	Literature review, formulation of objectives
3–4 Weeks	Identification of key theoretical frameworks and industry cases
5–6 Weeks	Data collection (quantitative and qualitative)
7–8 Weeks	Analysis of findings and synthesis
9–10 Weeks	Drafting of core chapters
11th Week	Peer review, revision, and structuring
12th Week	Final submission

Budget

This research will not incur any significant costs and does not require external funding.

References

1. EY. (2020). *Navigating Pharma Loss of Exclusivity*. https://www.ey.com/en_us/insights/life-sciences/navigating-pharma-loss-of-exclusivity

2. Pharmaceutical Executive. (2023). *Loss of Exclusivity: Strategies to Maximize Product Value*. https://www.pharmexec.com/view/loss-exclusivity-strategies-maximize-product-value

3. American Journal of Managed Care. (2017). *How Drug Life-Cycle Management Patent Strategies May Impact Formulary Management*. https://www.ajmc.com/view/a636-article

4. DrugPatentWatch. (2021). *Strategies to Maximize Product Value Amid Loss of Exclusivity in the Pharmaceutical Industry*. https://www.drugpatentwatch.com/blog/strategies-to-maximize-product-value-amid-loss-of-exclusivity-in-the-pharmaceutical-industry