

# Generic Series: Optimizing Brand Lifecycle Management

## Winning Strategies to Maximize Revenue in the Face of Growing Generic Competition

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### Providing you with:

- **A review** of key reasons why lifecycle management is important now
- **Analysis** of key considerations Pharma need to take care of when devising lifecycle management strategies
- **A discussion** of most commonly used lifecycle management strategies
- **Case** study analysis of successful and unsuccessful lifecycle management strategies employed by Pharma

### *Use this report to...*

*Identify critical considerations for creating the optimal lifecycle management plan*

# Introduction

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As competitive pressures from the entry of generics post-patent expiry and new brands are growing, product lifecycles are evolving for the worst. Effective lifecycle management is becoming a must for Pharma looking to maximize their return on investment, regardless of which stage of the lifecycle a drug is in. However such strategies are becoming most prominent immediately before patent expiry.

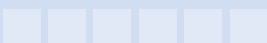
With growing cost-containment pressures and scrutiny of Pharma's actions in reaction to patent expiry, lifecycle management requires early consideration, thorough understanding of each market and strategic planning involving many different functions within a company. Early planning leaves a company with a range of strategies to choose from, however, this is rarely the case in practice.

## Key findings and highlights

- One of the key challenges for Pharma is the loss of corporate memory regarding specific brands as brand managers spend on average only 18 months on one product with mainly short term goals in mind. Pharma need to take a structured approach to lifecycle management with a regular review of their strategies in response to internal and external events.
- Lifecycle management should not be left until only few years are left to patent expiry. Revenues can be maximized during launch and peak phases by employing the right approaches. If a company starts planning its lifecycle management strategy early, it has more strategies available. However, many companies leave planning until late in the lifecycle.
- Payers and physicians are becoming more sceptical of certain steps taken by Pharma as they consider them to be pure lifecycle management. Follow-on products such as reformulations and fixed dose combinations need to ensure they truly satisfy an unmet need in order to achieve even moderate uptake.

## Reasons to buy

- **Identify** critical considerations for creating the optimal lifecycle management plan
- **Understand** when the different lifecycle management strategies are most appropriate
- **Gain** insight into recent successful and unsuccessful lifecycle management strategies



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## EXECUTIVE SUMMARY

- **Scope of the report**
- **Key findings**

## INTRODUCTION TO LIFECYCLE MANAGEMENT

- **What is lifecycle management**
- **Why is lifecycle management so important now**
  - Patent expiries and thinning pipelines are compounded by tougher pricing and reimbursement conditions
  - Payers are stimulating generics use to cut costs
  - Faster brand erosion post generics entry
  - Growing competition and harder molecule differentiation
  - Other stakeholders are increasingly important

## CRITICAL CONSIDERATIONS FOR PRODUCT LIFECYCLE MANAGEMENT

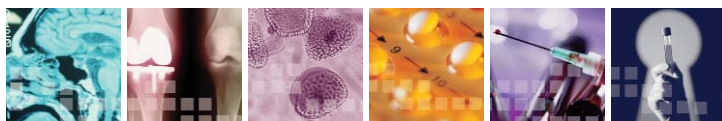
- **What is the purpose?**
  - Be realistic about your expectations
  - Counter-generic strategies are under growing public scrutiny
- **Timing of execution is critical but few companies consider LCM early enough**
  - Think ahead
  - Lifecycle management is a continuous process
  - Capturing internal knowledge
- **What is the best method?**
  - Formal or informal approach to lifecycle management?
  - Marketing- or development-driven LCM?
- **Internal company issues impact the choice of LCM strategy**
  - Portfolio-led lifecycle management
  - What resources are required and what is available?
- **Understanding each market is crucial**
  - Strong market intelligence is important
  - Focus on fulfilling the unmet need
  - Make sure you have a clear message and keep things simple
- **Product characteristics determine the choice of LCM strategy**
- **Local versus global LCM drive and execution**
- **Flexibility and creativity**
- **LCM tactics can act synergistically**

## SELECTING THE RIGHT LIFECYCLE MANAGEMENT STRATEGY

- **Commercial lifecycle management strategies**
  - Authorized/own generics
  - Strategic pricing
  - Brand loyalty programs and increasing share of voice
  - Rx-to-OTC switching
  - Divestiture or market exit
  - Geographical expansion
  - Brand protection in non-exclusive markets
- **Developmental lifecycle management strategies**
  - Reformulations and second generation products
  - Fixed dose combinations
  - New delivery devices
  - Indication expansion
  - Manufacturing process-based LCM
- **Legal and regulatory strategies**
  - Patent litigation
  - Regulatory exclusivity

## CASE STUDIES OF RECENT LIFECYCLE MANAGEMENT STRATEGIES USED BY BIOPHARMA

- **Fosamax Plus D's success was determined by market characteristics and timing of launch**
  - Fosamax Plus D's late launch proved fatal for Merck & Co's alendronate franchise in Germany and the UK...
  - ...while early launch resulted in a more successful brand protection in France and Italy
  - US - launching too early?
  - Will the second strategy to minimize losses work?
- **Novartis's inability to defend its patent for combination drug Lotrel resulted in tremendous loss of sales after Teva's challenge**
- **Biaxin XL - a reformulation offering true benefits**
- **Ambien CR - a moderately successful reformulation strategy**
- **Actiq and Fentora - a mix of strategies gives mixed success to Cephalon**
- **Authorized and own generics**
  - Merck & Co's Zocor - authorized generic launched during 180-days exclusivity
  - Pfizer's Zolofit - own generic launched during 180-day exclusivity
  - Pfizer Zithromax - successful own generic
  - Own generics in Europe



- **Oxycontin legal strategy was a success**
  - The FDA rejected an abuse-proof tablet formulation for Oxycontin
- **Voltaren - success in unprotected markets is driving sales growth even after patent expiry**
- **Strong differentiation of Aclasta from Zometa is the basis for success of this indication expansion strategy**
- **Not only generic defense**
  - Keppra - a case of good or bad lifecycle management?
  - Human growth hormones - a lifetime of lifecycle management?
  - Osteoporosis market - a move to intermittent dosage early in the product lifecycle

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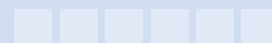
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*“...Both early- and late-stage LCM strategies can reduce the impact of patent expiry, but they cannot erase it completely and it is important to keep this in mind especially when evaluating success levels of particular tactics...”*



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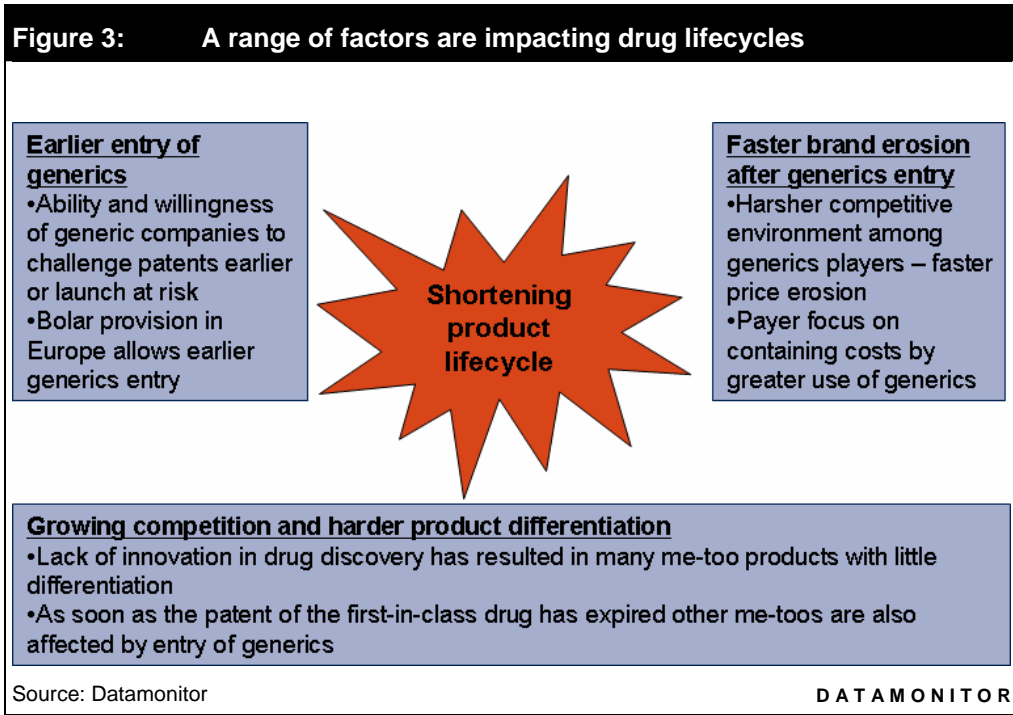
As competitive pressure from the entry of generics post-patent expiry and new brands mounts, product lifecycles are becoming shorter with lower peak sales. Effective lifecycle management is becoming a must for pharma companies looking to maximize their return on investment.

With increasing cost-containment pressures and scrutiny of the pharma industry's response to dealing with patent expiry, lifecycle management requires early consideration, a thorough understanding of each market, and strategic planning involving many different functions within a company.

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However, in some cases, product sales are still growing even as it nears patent expiry—mainly as a result of slow product uptake after launch—and thus every day a brand gains in terms of market protection translates directly into company's profits, making late-stage lifecycle management critical.

The following sections of this chapter discuss factors listed in Figure 3 in more detail and also address other reasons why lifecycle management is so important for most pharma and biotech companies.

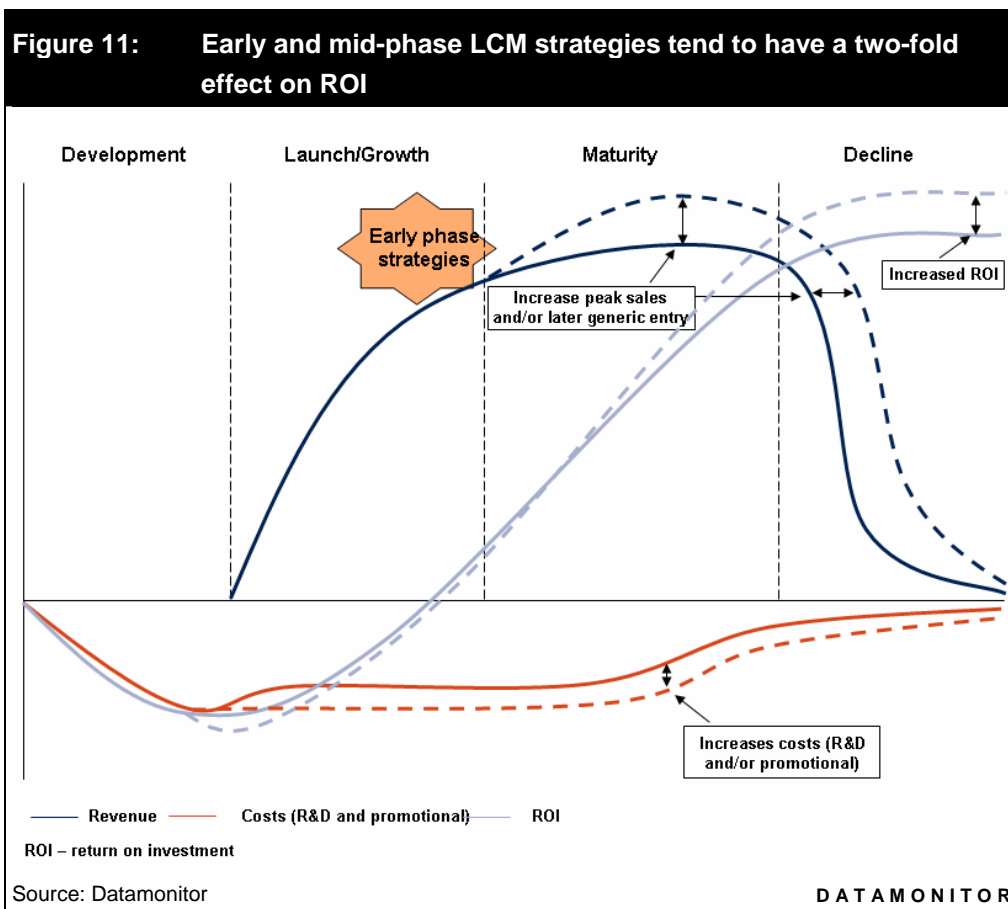
### Patent expiries and thinning pipelines are compounded by tougher pricing and reimbursement conditions

In 2008 alone, \$16.8 billion worth of revenues will be exposed to generic competition, with products going off-patent between 2008 and 2012 responsible for an aggregate of \$102 billion (based on 2007 sales of the 50 top pharma companies in the US).

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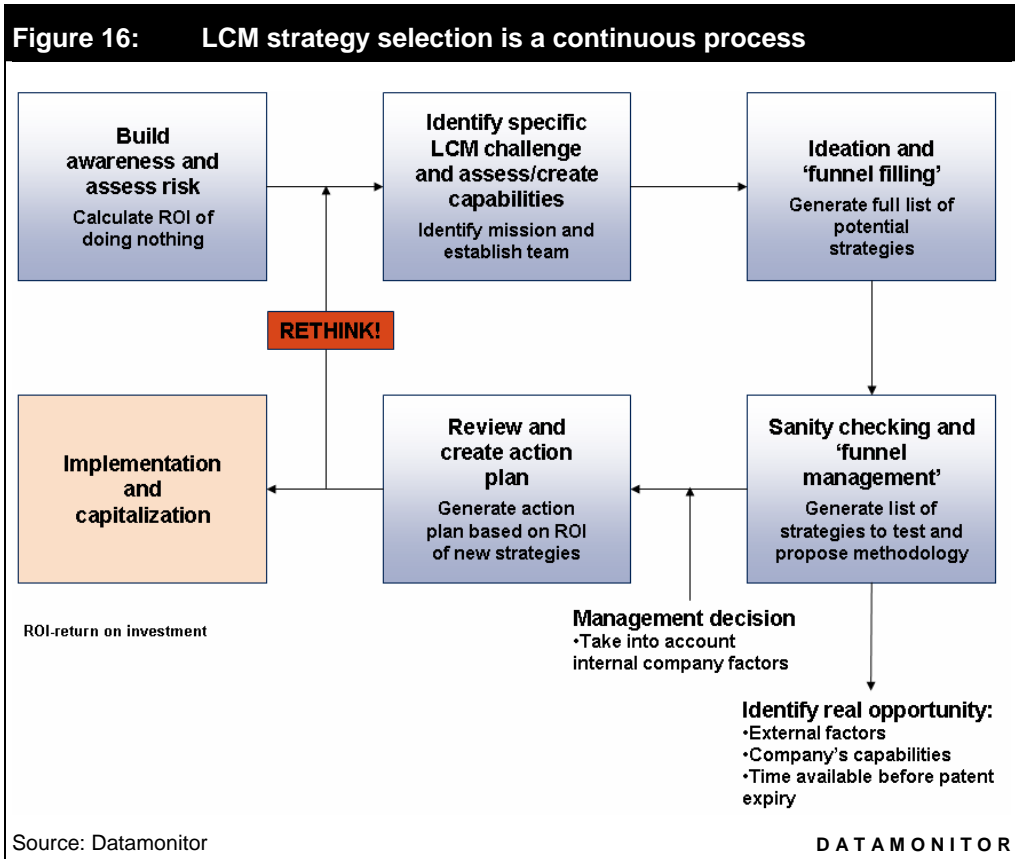
Strategies implemented early or mid-lifecycle can impact sales and return on investment (ROI) in two ways (Figure 11):

- they can maximize sales during the maturity phase (e.g. new indication);
- they can extend the maturity phase by delaying generic entry.



On the other hand, strategies employed in the later phases of the lifecycle tend to focus on reduction of the severity of generic erosion post-patent expiry or delaying patent expiry (Figure 12).

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## Capturing internal knowledge

Capturing internal company and brand team knowledge is critical to optimizing product lifecycle management (LCM) but presents a challenge to most companies, especially those without formalized LCM processes and dedicated LCM teams.

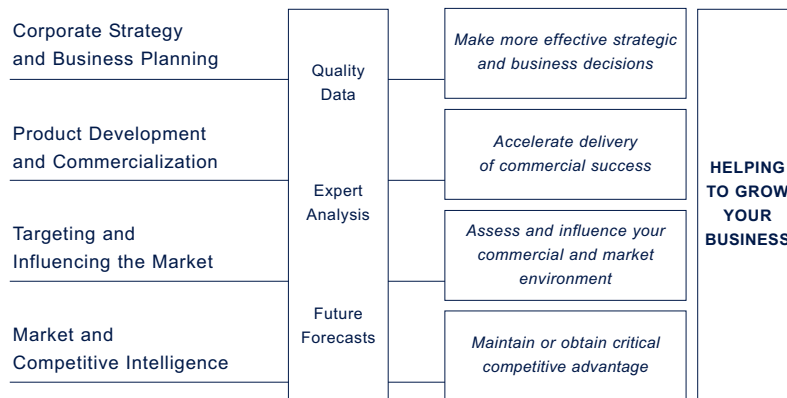
With an average time a brand manager spends working on a particular product only 18 months, it is clear why capturing their brand knowledge is difficult. In order to overcome this difficulty, both brand teams and dedicated LCM teams need to invest effort into recording any ongoing discussions, ideas or thoughts regarding the brand and possible LCM strategies and thus enhance corporate memory. Brand managers' insights into stakeholder opinions and needs, as well as the competition, are invaluable for selection of the optimum LCM plan.

Documenting the LCM process for different brands can also aid best practice sharing across the organization. Typically, one company is very successful in lifecycle

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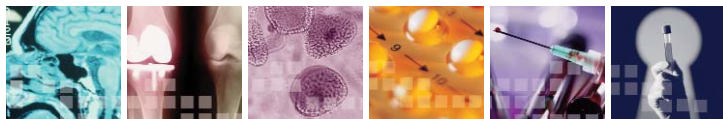


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