Life Cycle Management Strategies

Optimizing revenues and defending generic competition
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Executive Summary

- With shrinking R&D pipelines and increasing time and costs involved in drug development, companies need to maximize revenue and the lifespan of their portfolios to compete in the cost-constrained healthcare market by implementing suitable Life Cycle Management (LCM) strategies at the right time.
- There is a strong need to overcome impending challenges such as brand erosion, weak portfolios and the stringent regulatory atmosphere in the pharmaceutical industry.
- Successful LCM planning commences early in the life cycle of a drug, ideally during the R&D phase. Multiple factors such as timing, disease characteristics and market environment should be considered when choosing an LCM strategy.
- This report discusses the key LCM strategies – which can be categorized into developmental, commercial, and regulatory/legal strategies – by providing detailed case studies for each.
  - Developmental strategies are implemented to significantly increase revenue along with the patent duration/market exclusivity period. These strategies include indication expansion, sequencing and drug repositioning, patient subpopulation, personalized medicine, reformulation, new dosage strengths/regimen, Fixed-Dose Combinations (FDC), co-packaging, next-generation products, and modified chemistry.
  - Commercial strategies help in increasing the uptake and commercial value of the product. These strategies include Prescribed (Rx) to Over the Counter (OTC) switch and Behind the Counter (BTC) switch, geographical expansion, pricing strategies, brand loyalty, awareness, and service programs.
  - Regulatory/legal strategies intend to maximize the protected life of the drug, thereby increasing the revenue. These strategies include authorized generics, legal defense, pay for delay, citizen’s petition, patent term extension, and market exclusivity.
Classification and Benefits of Life Cycle Management

**LCM strategies**

**Developmental strategies**
- Indication expansion/sequencing
- Product repositioning
- Patient sub-population
- Reformulation
- New dosage strengths/regimen
- Fixed Dose Combination (FDC)
- Next-generation product

**Commercial strategies**
- Over the Counter (OTC)/Behind the Counter (BTC) switch
- Geographical expansion
- Pricing strategies
- Awareness programs

**Regulatory/legal strategies**
- Authorized generics
- Legal defense and pay for delay
- Citizen’s petition
- Patent/exclusivity extension

**Significant revenue increase for extended time period with developmental strategies**

**Increased commercial value of the product with commercial strategies**

**Extension of patent duration/market exclusivity with regulatory/legal strategies**

**Revenue generated during a typical PLC without LCM strategies**
# FDA Approvals: Pediatric Use 2014–May 2015

<table>
<thead>
<tr>
<th>Drug</th>
<th>Applicant</th>
<th>Indication</th>
<th>Date of approval</th>
</tr>
</thead>
<tbody>
<tr>
<td>Migraine</td>
<td></td>
<td></td>
<td>April 16, 2015</td>
</tr>
<tr>
<td>Perennial and seasonal allergic rhinitis</td>
<td></td>
<td></td>
<td>March 23, 2015</td>
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<tr>
<td>Perennial and seasonal allergic rhinitis</td>
<td></td>
<td></td>
<td>March 23, 2015</td>
</tr>
<tr>
<td>Treatment of cancer (recurrent ependymoma)</td>
<td></td>
<td></td>
<td>March 18, 2015</td>
</tr>
<tr>
<td>Schizophrenia and bipolar disorder</td>
<td></td>
<td></td>
<td>March 3, 2015</td>
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<tr>
<td>Attention deficit hyperactivity disorder</td>
<td></td>
<td></td>
<td>October 17, 2014</td>
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<tr>
<td>Autism and autism spectrum disorder</td>
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<td></td>
<td>June 16, 2014</td>
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<tr>
<td>Allergic conjunctivitis</td>
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<td></td>
<td>December 16, 2014</td>
</tr>
<tr>
<td>Prevention of postoperative nausea and vomiting and chemotherapy-induced nausea and vomiting</td>
<td></td>
<td></td>
<td>April 10, 2014</td>
</tr>
<tr>
<td>Treatment to reduce blood phenylalanine levels in patients with hyperphenylalaninemia due to BH4-responsive phenylketonuria</td>
<td></td>
<td></td>
<td>March 13, 2014</td>
</tr>
</tbody>
</table>

‡ A second period of pediatric exclusivity was granted for this moiety; earlier pediatric use approval was granted for different indications.
Importance of reformulation

- In the past decade, 60% of applications received by the FDA involved molecules that were previously approved.
- Development of a new drug and obtaining a patent require huge investments in capital and time, while with reformulation, a novel product can be launched with less time and money, expanding its PLC.
- A perfect reformulation strategy is one that is advantageous for all stakeholders.
The success of Nexium was based on several key factors:

- It was launched prior to patent expiry of first-generation product – Nexium launched in March 2001, well before generics entered the US market (late 2002) and generic omeprazole didn’t enter the US market until December 2002.

- The key advantages of single enantiomer versions are:
  - Reduced adverse events
  - Increased potency (with lesser dose)
  - Reduced drug-drug interactions

- Moreover, chiral switching can also provide benefits such as more selective pharmacodynamic profile, less complex pharmacokinetic profile, and improved therapeutic index. However, with these advantages, companies are increasingly developing single enantiomer drugs as first-generation products in order to compete effectively.
Multiple Developmental Strategy Approach: Abbott’s Tricor

Revenue of Tricor series

Revenue ($bn)


- **Lowering triglycerides**
- **FDA-approved indications**
- **Lowering low-density lipoprotein**
- **Raising high-lipoprotein**
- **Co-administration with a statin**

Example:

- 1998: XX
- 2000: XX
- 2002: XX
- 2004: XX
- 2006: X
- 2008: XX
- 2010: XX
- 2012: XX
- 2014: XX

TriCor®

FDA-approved indications:

- Co-administration with a statin
- Lowering triglycerides
- Lowering low-density lipoprotein
- Raising high-lipoprotein
Life Cycle Management Strategies of Pipeline Products– GlaxoSmithKline

Note: Pipeline as of April 30, 2015
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