By Carolyn Gretton

A Consistent Life-Cycle Management Strategy

* Can Counter Market Threats

TREND: A well-thought out life-cycle management plan — starting in development and extending through patent expiration — can position a brand for optimal market share.


Jason Richardson

Life-sciences companies can strengthen their brands' abilities to preemptively fend off competitive market threats and generic challenges with improved team communications and life-cycle management (LCM) strategies, according to recent analysis from Cutting Edge Information.

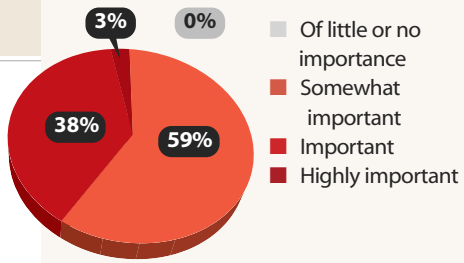
The report, Pharmaceutical Lifecycle Management: Strategy Selection and Execution, observes that even though LCM is a proven strategy for equipping drug brands to face global marketplace challenges, only 21% of surveyed companies have a centralized LCM team to coordinate brands and act as a strategic LCM authority. Executives interviewed for the study recommend a centrally located, midsize team to oversee strategy for all brands.

"Organizational structure plays a big part in how teams can plan and execute strategies successfully," says Jason Richardson, president of Cutting Edge Information.

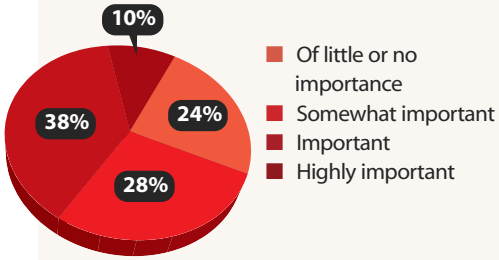
For more information, visit cuttingedgeinfo.com.

LCM STRATEGY

Importance of Execution Timing of LCM Strategy



Importance of Patent Expiration Timing on LCM Strategy



Source: Cutting Edge Information, Pharmaceutical Lifecycle Management: Strategy Selection and Execution.

Innovation Remains Key TO DRUG APPROVAL STRATEGY

Sponsor focus on innovation in the pre-submission period is critical to success in the new drug review process.

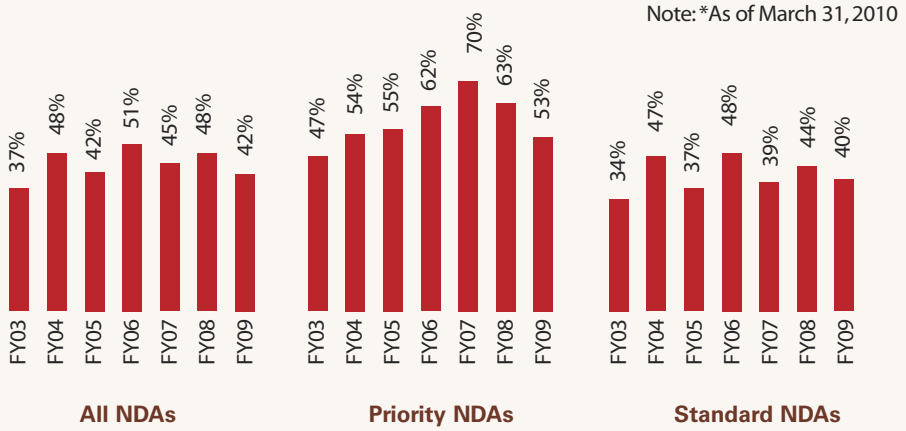
"First-cycle approval rates are a key indicator of the biopharmaceutical industry's success in securing FDA approval for new therapies early in the review process," observes Mark Mathieu, director of strategic research at Parexel Consulting. "While there is often some fluctuation in first-cycle approval rates year-to-year, our analysis of the latest FDA metrics leads us to ask whether there is a 'new normal' emerging, which has significant implications for the drug-review process."

The FDA Amendments Act (FDAAA) continues to put pressure on the agency and sponsors with regard to REMS and other safety measures early on in the development process.

The Parexel Consulting white paper identified a 25% decline in first-cycle approval rates for priority drug applications and a 17% decrease in priority designation rates for new drugs between 2008 and 2009, the time during which the FDA was set-

FIRST-CYCLE APPROVAL RATES FOR ORIGINAL NDAS (FY2003-FY2009)

Note: *As of March 31, 2010



Source: Parexel Consulting, Drug Innovation, Approval, Market Access, and the New Normal: Emerging FDA Review Outcome Trends for New Drugs.

tling into its FDAAA-related responsibilities and the 21st Century Review Process. In addition, the white paper notes that in 2009, the FDA only designated 13% of NDAs for priority approval, mirroring the low rate at which some healthcare plans and other payers are finding value in newly approved drugs.

"This illustrates the need for companies to take into account market-based clinical concerns in the product development process," says Charles Stevens, VP and general manager, reimbursement and market access, Parexel Consulting.

For more information, visit parexel.com.

Targeting Can MINIMIZE PRODUCT CANNIBALIZATION

Pharma companies can reap a number of benefits from introducing a new brand in a category where they already have a legacy product, including expanded market share and improved reputation with physicians. However, according to a Best Practices' study, this practice can create product confusion among internal and external stakeholders if the launch is not carefully managed.

Targeting different patient subtypes and aligning thought leaders are two of the most effective strategies to control or minimize product cannibalization in a category where a company has multiple brands. Almost three-quarters of the participants in the study say they have successfully promoted brands together as a franchise, using attributes such as product efficacy, delivery mechanism, and frequency of use to differentiate the products within the franchise.

MANAGING MULTIPLE BRANDS FOR A SINGLE INDICATION

Source: Best Practices, Expanding a Product Portfolio without Cannibalizing an Established Brand.

For more information, visit best-in-class.com.

Maturing Product Portfolios REQUIRE RETOOLED MARKETING PLANS

In 2011, 40% of the top-selling drugs will be products whose patent protection has either already expired or will do so in the coming two years. According to analysis by Accenture, in 2010, patent protections will expire for medicines with a current sales volume of $25 billion, and that number is projected to balloon to $130 billion by 2015.

"Mature products need to be marketed differently from new drugs," says Andrea Brückner, a senior executive in Accenture's life science practice and author of the study, Managing the Profitability of a Maturing Product Portfolio. "The main goals for new products are growth and market share, but for marketing mature products, it is profitability."

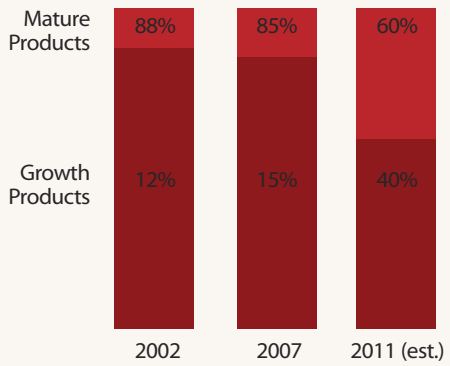
Companies will need to determine whether they will continue to market aging products alongside newer products or transfer them to different or new marketing teams.

Another possible strategy is for companies with a generic product line already in place to integrate their mature-product marketing into their generics efforts. Another strategy is to determine if the drug is suitable for continued sale as an over-the-counter product.

"The important thing is for pharmaceutical companies to mobilize patient loyalty, which can be accomplished by linking products with supplemental services for physicians, pharmacists, and patients, or by updating the brand image," Ms. Brückner says.

For more information, visit accenture.com.

PROPORTION OF MATURE BRANDS AMONG TOP 50 PHARMA PRODUCTS



Source: Accenture, Managing the Profitability of a Maturing Product Portfolio.

Client-Agency Turnover HALLMARK OF MARKETING RELATIONSHIPS

A recent survey fielded by The Core Nation reveals that pharma, biotech, and medical device companies have been with their advertising (55.88%), marketing (74.08%), PR/communications (71.67%), digital/social media agencies (72.55%) for less than three years by a far margin.

When evaluating an ad/marketing firm, respondents ranked creativity as their top criteria, and tied for second were campaign strategy and market expertise.

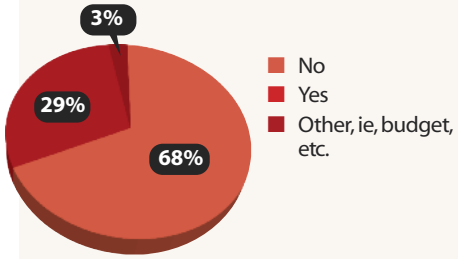
When asked what respondents viewed as their greatest marketing challenge, overwhelming they answered regulatory contraints. The second largest issue was the competitive marketplace, followed by the economic climate and budget contraints.

The Core Nation thanks survey respondents for their time, and offer congratulations to the randomly selected winner of the iPad John Fezzuoglio, senior manager, Centocor Ortho Biotech.

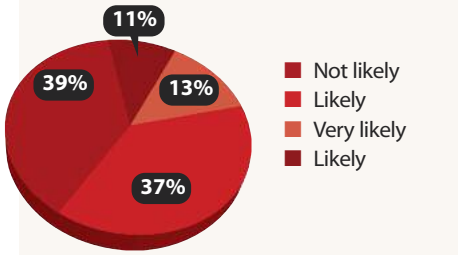
For more information, visit thecorenation.com. PV

AGENCY SELECTION PROCESS

Selection Determined by a Corporate Contract with a Holding Company



Likelihood of Hiring an Ad/Marketing Firm in the Next 12 Months Contract with a Holding Company



Source: The Core Nation

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THERAPEUTIC MARKET FAST TRAX...

BIOMARKERS

The global market for biomarker discovery technologies, such as genomics, molecular imaging, and proteomics, is projected to reach $26.5 billion by 2015, growing at a CAGR of 20.2% during the period from 2007 to 2015.

Source: Industry Experts, Biomarkers: Discovery Techniques and Applications — A Global Market Overview.

For more information, visit marketresearch.com.

CANCER

The combined sales of seven new therapies for the treatment of breast cancer will total almost $5 billion through 2019 in the United States, France, Germany, Italy, Spain, United Kingdom, and Japan. Among the emerging therapies for the indication, surveyed experts are particularly enthusiastic about agents in the Poly ADP-Ribose Polymerase (PARP) inhibitor drug class.

Source: Decision Resources, Pharmacor 2010 findings on Breast Cancer.

For more information, visit decisionresources.com.

Because of generic erosion of key agents, the colorectal cancer drug market is expected to remain relatively flat over the next decade, increasing from $6.4 billion in 2009 to $6.7 billion in 2019 in the United States, France, Germany, Italy, Spain, United Kingdom, and Japan.

Source: Decision Resources, Pharmacor 2010 findings on Colorectal Cancer.

For more information, visit decisionresources.com.

The non-small-cell lung cancer drug market is forecast to increase from about $4 billion in 2009 to more than $6.5 billion in 2019 in the United States, France, Germany, Italy, Spain, United Kingdom, and Japan, mainly as a result of increased uptake of Alimta from Lilly and Tarceva from Genentech/OSI Pharmaceuticals/Roche/Chugai, as well as the launches of premium-priced emerging therapies, such as iniparib from Sanofi-Aventis, BIBW-2992 from Boehringer Ingelheim, and crizotinib from Pfizer.

Source: Decision Resources, Pharmacor 2010 findings on Non-Small-Cell Lung Cancer.

For more information, visit decisionresources.com.

Growth in the leukemia market is likely to be driven mostly by chronic myelogenous leukemia (CML) therapies, such as Novartis's Gleevec and Tasigna and Bristol-Myers Squibb's Sprycel, and chronic lymphocytic leukemia (CLL) therapies, such as Biogen Idec/Roche's Rituxan and Cephalon's Treanda until 2015, when patent and orphan-drug exclusivities of key brands will impact the sustainability of this growth.

Source: Decision Resources, Spectrum report, Strategic Overview of Chronic and Acute Leukemias.

For more information, visit decisionresources.com.

CARDIOVASCULAR

Increasing generic availability of antihypertensive agents is expected to spur a decline in the hypertension drug market, from $26 billion in 2009 to $23 billion in 2019, in the United States, France, Germany, Italy, Spain, United Kingdom, and Japan. By 2019, the drug classes typically used as first-, second-, and third-line therapies — ACE inhibitors, angiotensin II receptor antagonists, calcium channel blockers, and diuretics — will all be subject to generic competition.

Source: Decision Resources, Pharmacor 2010 findings on Hypertension.

For more information, visit decisionresources.com.

Driven primarily by the launch and widespread uptake of novel oral anticoagulants, the combined markets for drugs used in the treatment and prophylaxis of venous thromboembolism are expected to experience robust growth from $2.9 billion in 2009 to more than $5 billion in 2019 in the United States, France, Germany, Italy, Spain, United Kingdom, and Japan.

Source: Decision Resources, Pharmacor 2010 findings on Venous Thromboembolism.

For more information, visit decisionresources.com.

CENTRAL NERVOUS SYSTEM

Over the next decade, the epilepsy drug market is expected to remain relatively flat, increasing from $2.8 billion in 2009 to $2.9 billion in 2019 in the United States, France, Germany, Italy, Spain, United Kingdom, and Japan. The lack of anticipated growth is due to generic erosion, specifically within the second-generation antiepileptic drug (AED) class, which will lose about $400 million by 2014.

Source: Decision Resources, Pharmacor 2010 findings on Epilepsy.

For more information, visit decisionresources.com.

Over the next three years, Bristol Myers-Squibb/Otsuka's Abilify, and AstraZeneca's Seroquel XR are likely to be the fastest-growing drugs in terms of prescriptions for the treatment of major depression. Between 31% and 49% of surveyed psychiatrists, as well as 32% to 52% of surveyed primary-care physicians, anticipate their prescribing of Abilify, Seroquel XR, Lilly's Cymbalta, and Pfizer's Pristiq will increase in the next three years.

Source: Decision Resources, Treatment Algorithms in Major Depressive Disorder.

For more information, visit decisionresources.com.

DEVICES

The infusion pump device market remains more or less flat. The worldwide market for infusion pumps is projected to be valued at almost $6.3 billion in 2010, an increase of just over 3% from last year.

Source: Kalorama Information, Infusion Pump Markets (Large Volume, Ambulatory, Insulin, Enteral and Other Pumps).

For more information, visit kaloramainformation.com.

DIABETES

The market for Type 2 diabetes drugs is expected to almost double in the next decade, propelled by the continued uptake of key agents such as Merck's Januvia, Eli Lilly/Amylin/Alkermes' Bydureon, and Amylin/Eli Lilly's Byetta. The Type 2 diabetes drug market is forecast to grow from $19 billion in 2009 to $36 billion in 2019 in the United States, France, Germany, Italy, Spain, United Kingdom, and Japan.

Source: Decision Resources, Pharmacor 2010 findings on Type 2 Diabetes.

For more information, visit decisionresources.com.

During the period from 2010 to 2015, a number of new diabetes treatments are expected to reach the market, with a steady rate of NDA filings expected between 2010 and 2013. The impact of such developments, along with the steady uptake of recently approved DPP IV inhibitors and GLP-1 agonists, should increase the value of the diabetes market steadily, with a CAGR of 4.7% during the period to 2014.

Source: Insight Pharma Reports, Diabetes Pipeline: Intense Activity to Meet Unmet Need.

For more information, visit insightpharmareports.com.

The total diabetes therapeutic market reached $24.9 billion in 2009, an increase of 16.4% from the previous year. This level of growth is expected to continue for the next two years because of increasing obesity and an aging worldwide population.

Source: Kalorama Information, The World Market for Diabetes Treatments.

THERAPEUTIC MARKET FAST TRAX...

For more information, visit kaloramainformation.com.

DIAGNOSTICS

Molecular diagnostics represent the fastest-growing segment of the in vitro diagnostics industry, with a double-digit growth rate and an estimated market size of $4.8 billion in 2010. Major factors driving growth include increased availability of various tests, increased incidence of chronic diseases due to an aging population, and pharmacogenomics/personalized medicine.

Source: DeciBio, Molecular Diagnostics: Market Segmentation and Opportunities.

For more information, visit marketresearch.com.

GASTROINTESTINAL

The Crohn's disease drug market is forecast to experience moderate growth over the next decade, increasing from $3.2 billion in 2009 to $4.2 billion in 2019 in the United States, France, Germany, Italy, Spain, United Kingdom, and Japan, as growth from newer and emerging biologic agents outpaces the declining sales of older, established agents.

Source: Decision Resources, Pharmacor 2010 findings on Crohn's Disease.

For more information, visit decisionresources.com.

The market for ulcerative colitis drugs is expected to post modest sales of $800 million though 2019 in the United States, France, Germany, Italy, Spain, United Kingdom, and Japan, driven by the uptake of Abbott/Eisai's Humira, Centocor Ortho Biotech/Merck/Mitsubishi Tanabe Pharma/Janssen's Simponi, and Millennium's vedolizumab.

Source: Decision Resources, Pharmacor 2010 findings on Ulcerative Colitis.

For more information, visit decisionresources.com.

HIV/AIDS

The HIV drug market will experience an average annual increase of 3.1% from 2009 to 2014 in the United States, France, Germany, Italy, Spain, United Kingdom, and Japan. Thereafter, market growth will slow to 2.2% annually from 2014 through 2019, owing largely to the generic erosion of several key antiretroviral agents.

Source: Decision Resources, Pharmacor 2010 findings on Human Immunodeficiency Virus.

For more information, visit decisionresources.com.

MEN'S HEALTH

In 2009, the global men's health market was estimated to be worth $4.019 billion, representing a CAGR of 7.9% between 2001 and 2009. However, the patent expiry of blockbuster drug Viagra is expected to slow the category's growth to a CAGR of 4.6% between 2009 and 2016, with the global men's health market projected to reach $5.509 billion by 2016.

Source: GBI Research, Men's Health Therapeutics Market to 2016.

For more information, visit marketresearch.com

NANOTECHNOLOGY

The projected 2010 global market value for nanotechnology — a category encompassing nanomaterials, nanotools, and nanodevices — is an estimated $15.7 billion, and it is expected to increase to almost $27 billion in 2015, for a 5-year CAGR of 11.1%.

Source: BCC Research, Nanotechnology: A Realistic Market Assessment.

For more information, visit bccresearch.com.

NUCLEAR RECEPTORS

Nuclear receptors are a family of intracellular receptors that mediate the transcriptional responses to metabolic ligands. About 13% of drugs approved for sale in the United States are nuclear receptors, with 15 among the top 200 prescribed medicines. These top drugs represented $27.5 billion of sales revenue in 2009, with the top-selling drug in the category, GlaxoSmithKline's asthma drug Advair/Seretide, generating sales of $7.8 billion.

Source: Insight Pharma Reports, Nuclear Receptors: A Pipeline Overview.

For more information, visit insightpharmareports.com.

OPHTHALMOLOGY

The global market for ophthalmology drugs and devices is expected to reach $36 billion by 2014, for a CAGR of 5.4% from 2009 to 2014, due to the increasing incidence and prevalence of eye-related disorders such as presbyopia, macular degeneration, and diabetic retinopathy among the aging population. The ophthalmology drugs segment of the market is expected to post a CAGR of 4% for the period from 2009 to 2014.

Source: MarketsandMarkets, Global Ophthalmology Drugs & Devices Market.

For more information, visit marketsandmarkets.com.

OSTEOPOROSIS

Three-quarters of surveyed endocrinologists and rheumatologists who are aware of Amgen/GlaxoSmithKline's Prolia largely foresee prescribing it as a second- or third-line treatment for osteoporosis, since the drug is approved for treatment of osteoporosis in postmenopausal women at increased risk of fractures or patients who have failed or are intolerant to other osteoporosis treatment. Surveyed endocrinologists anticipate that just 17% of their prescriptions for Prolia will be for first-line therapy by 2012.

Source: Decision Resources, Treatment Algorithms in Osteoporosis.

For more information, visit decisionresources.com.

RESPIRATORY

Because of the rising costs of asthma and chronic obstructive pulmonary disease (COPD) drugs, managed care organization pharmacy directors are expected to tighten their formularies. The majority of surveyed pharmacy directors expect asthma and COPD drug prices to increase over the next five years by an average of 3% annually, and believe they can implement tightened formulary strategies to slow down this trend.

Source: HealthLeaders-InterStudy and Fingertip Formulary, Formulary Advantages in Asthma and COPD.

For more information, visit hl-isy.com or fingertipformulary.com.

STEM CELLS

The worldwide market for human embryonic stem cells is estimated at $3.8 billion in 2010, and is projected to post a CAGR of 24.8% during the period from 2007 to 2015, reaching $10.7 billion by 2015.

Source: Industry Experts, Human Embryonic Stem Cells (hESC) — A Global Market Overview.

For more information, visit marketresearch.com.

URINARY

Although more than 50% of people with overactive bladder (OAB) in the world's major pharmaceutical markets remain undiagnosed, the sizeable prevalent population fuels significant sales for the indication. As a result, the OAB drug market is forecast to increase from about $3 billion in 2009 to almost $4 billion in 2019 in the United States, France, Germany, Italy, Spain, United Kingdom, and Japan.

Source: Decision Resources, Pharmacor 2010 findings on Overactive Bladder.

For more information, visit decisionresources.com.

New Global Supply-Chain MANAGEMENT STRATEGIES COULD REDUCE RISKS

Global pharmaceutical outsourcing has become increasingly prevalent, but is creating a complex and risky supply chain environment that has executives on high alert.

According to a study co-sponsored by Axendia and PricewaterhouseCoopers (PwC), 50% of pharmaceutical and life-sciences executives surveyed said they view raw materials sourced outside of the United States as the greatest vulnerability to the supply chain, and 61% view contaminated or non-conforming raw materials as the top threat in the next five years.


Wynn Bailey

The report — Achieving Global Supply Chain Visibility, Control & Collaboration in Life Sciences: Business Imperative, Regulatory Necessity — found that visibility into the global supply chain is primarily based on snapshots in time, with 77% of respondents saying their primary method of gaining visibility into suppliers' practices is a periodic audit. Only 25% stated that they share common practices and information with suppliers, and only 3% have access to suppliers' data in real time, the study found.

"To meet the demands of globalization, the pharmaceutical supply chain will need to become much more flexible, with different manufacturing routes and distribution channels for different kinds of products," says Wynn Bailey, pharmaceutical and life sciences advisory services partner, PwC. "Companies will need to implement new strategies, processes, and technology to proactively reduce and control risks."

"As the results of our research revealed, the life-sciences industry must gain tighter control over the complete supply chain, from ingredient to the consumer, to succeed in the global economy," adds Daniel Matlis, president of Axendia.

For more information, visit axendia.com.

TOP THREE INFLUENCERS FOR GLOBAL SUPPLY-CHAIN INITIATIVES

Key drivers	% of respondents
Quality improvement	75%
Business profitability	68%
Regulatory requirements	68%

Source: Axendia, Achieving Global Supply Chain Visibility, Control & Collaboration in Life Sciences: Business Imperative, Regulatory Necessity.

Sampling Practices Under GREATER REGULATORY SCRUTINY

Amid uncertainty about the ultimate impact of the healthcare overhaul, one thing is clear: compliance with the Prescription Drug Marketing Act (PDMA), as well as other emerging regulations and guidelines related to the industry practice of distributing free samples, will remain a top priority for pharmaceutical companies.

According to data from the recent TGaS Advisors white paper, Drug Sampling: Key Issues and Best Practices, pharmaceutical companies continue to make good faith efforts to be compliant with PDMA in their sampling efforts, with 91% of respondents indicating their organization is capable of pulling data together from across multiple distribution channels and attributing it to one healthcare provider, as required by PDMA. Most respondents said the process of compiling the data and pulling it together is done internally, with a majority of them doing it manually rather than with automation.

Given the new regulatory initiatives, experts recommend that companies streamline and coordinate their internal procedures so that sampling oversight is efficient and thorough. TGaS also advises companies to dedicate a department to electronically collect and disseminate comprehensive information about all aspects of sampling activity to better facilitate reporting compliance, as well as save time and money.

When asked if they currently track sample disbursements on the practitioner level to determine ROI, 45% of respondents said yes, while 55% said no.

For more information, visit tgas.com.

PROCESSES USED TO TRACK SAMPLE DISBURSEMENT

Key processes	% of respondents
Internal, partially automated/partially manual	36%
Internal, fully manual	27%
External, partially automated/partially manual	18%
Internal, fully automated	9%
External, fully automated	9%

Source: TGaS Advisors, Drug Sampling: Key Issues and Best Practices.

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