# PHARMA TRAX

SALES, MARKETING, AND R&D TRENDS AFFECTING THE HEALTHCARE INDUSTRY

## Most Doctors Prefer **CME PROMOTION BY E-MAIL**

A vast majority of physicians are interested in receiving information about and invitations to continuing medical education (CME) seminars, and they prefer to receive such information via e-mail.

According to a January 2010 survey conducted by Medical Marketing Service (MMS), 93% of physician respondents are interested in receiving information about and invitations to CME seminars, and 76% prefer to receive such information by e-mail. Physicians are evenly split about whether they prefer to receive e-mail CME promotions at their office or professional address, or at their home e-mail address, and 60% say they prefer to receive HTML e-mails.

Traditional meetings remain the preferred CME format, but online learning is gaining popularity. About 46% of respondents favor the traditional CME format, with lectures and workshops, including specialty society meetings. Online/point-of-care learning is preferred by 22% of respondents, while only 14% favor enduring materials such as journals, CDs/DVDs, and audio/videotapes.

*For more information, visit mmslists.com.*

## Pharma Advised to Focus **SOCIAL MEDIA EFFORTS ON EDUCATION**

The future of the life-sciences industry relies on creating a multichannel marketing strategy, which includes combining traditional practices with new marketing channels, such as the Internet and social media sites. But with a lack of guidance from the U.S. Food and Drug Administration on what type of communication is allowed, executives are cautious about venturing onto the Web.

According to a recent Datamonitor report, Pharma's New Home Lies at the Corner of Facebook and Twitter, the pharma industry will fare better in a social media environment if companies build a trusting relationship with consumers through education, rather than using the Internet solely as a promotional tool.

In order for pharma to truly reap the benefits of the Internet and social media sites, companies must spend some time improving their image and gaining back the trust of the public. Only then will the industry be able to move forward in implementing social media as part of their DTC strategy. According to Datamonitor, regardless of what guidance the FDA puts out, life-sciences companies have a social responsibility to engage and educate consumers about disease and treatment options and to provide information that empowers patients with the right tools to improve physician interactions.

*For more information, visit datamonitor.com.*

## Pharma Ramps Up **REGULATORY AFFAIRS**

***Jason Richardson***

***We're witnessing something of a transformation within regulatory affairs groups, observes Jason Richardson.***

As life-sciences companies' regulatory affairs groups assume larger, more strategic roles throughout clinical and commercial product development, these teams are experiencing budget growth at a time when the industry as a whole is looking to eliminate costs.

According to data from the recent Cutting Edge Information report, Pharmaceutical and Medical Device Regulatory Affairs, 94% of companies' regulatory affairs budgets have stayed the same or risen since 2007; of that percentage, 51% reported a budget increase. Pharmaceutical companies of all sizes, as well as biotech and medical device companies, reported having increased regulatory affairs spending by 18% or more. Midsize pharma firms, often seeking to further expand their presence in new regions, reported the greatest percentage uptick in spending since 2007, at 39%. Large pharmaceutical companies made a significant increase of their own, adding $4.4 million to an average regulatory affairs outlay of $26.8 million.

"Regulatory affairs teams have undergone some sweeping strategic changes, which is appropriate when you consider that the FDA's recent $4 billion budget proposal includes initiatives to reinforce the agency's commitment to promoting regulatory science," says Jason Richardson, president of Cutting Edge Information.

According to the study, it is critical that companies organize regulatory affairs to encourage greater interaction with a number of internal teams, including clinical development, new product planning, and legal to help set a drug's strategy and ensure its successful submission.

*For more information, visit cuttingedgeinfo.com.*

## Delivering Articulate Message Key to **MANAGED MARKETS ACCESS**

To succeed in today's marketplace, biopharma companies must maximize product uptake not only among patients and physicians, but also among government and private payers to win formulary access and improve product placement. Products that earn a favorable formulary tier position with a single large carrier stand to generate hundreds of millions of dollars in potential revenue.

A recent Best Practices benchmarking study, Managed Markets Market Research: Effective Structures & Activities for Gaining Maximum Payer Access & Insight, observes that companies face two main problems in gaining traction with large payers: articulating a clear medical or economic advantage for their products and gaining access to key decision-makers within the managed markets organization.

The study found that ad boards and account manager team meetings were among the most

**Q. WHICH OF THE FOLLOWING GLOBAL ACTIVITIES HAVE THE GREATEST IMPACT ON STRATEGIC CHOICES?**


Source: Best Practices. For more information, visit best-in-class.com.

effective managed markets activities and yielded the best insights.

Ad boards are most effective when innovative approaches are applied to engage diverse payer viewpoints instead of reusing the same small group of traditional payer participants, the report notes.

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

## Pharma Companies See **BRIGHTER FUTURE IN 2010**


***A new normal is emerging as pharma adapts to change and becomes more comfortable with it, says Stephen Gerard.***

The heads of operations at 20 leading large, midtier, and specialty pharmaceutical companies are optimistic about prospects for 2010, both for their companies and the industry as a whole.

The 2010 TGaS Advisors Confidence Index reported an 18.6% rise in respondents' perceptions of the industry's future, rating them at 70 on a scale of 1-to-100, compared with 59 last year. Confidence in their own companies grew 10%, with a rating of 76 this year, compared with 69 in 2009.

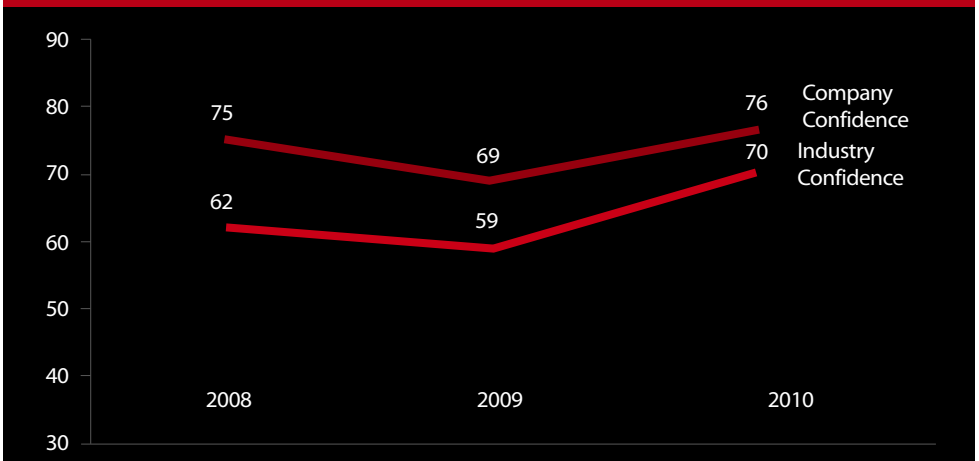
"Some of the fog that engulfed the industry and companies over the last few years has lifted, or at least cleared enough to afford some visibility and ease navigation," says Stephen Gerard, managing partner at TGaS Advisors.

Respondents gave several reasons for their ratings. Primary reasons for optimism included an aging population, the evolution of science, the growth of global markets, new commercial models, the move toward a customer-centric approach, specialty companies' strong pipelines, and midtier companies' agility.

Chief among the worries expressed by the benchmark participants were the uncertainties engendered by healthcare reform; concerns for return on capital; longer approval processes; unknowns in FDA regulations, approvals, and importation; larger products going off-patent; and increasing compliance issues that affect day-to-day operations.

*For more information, visit tgas.com.*

**INDUSTRY CONFIDENCE TREND, INDUSTRY VS. COMPANY**




Source: TGaS Advisors. For more information, visit tgas.com.

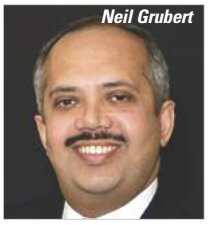
## Pharma Needs to Address **EMERGING MARKET CHALLENGES**

Pharmaceutical companies entering emerging markets must be prepared for market conditions that differ substantially from those of mature markets, including deficient healthcare infrastructures and logistical difficulties in reaching consumers in remote rural markets.

According to a recent Decision Resources Report, Strategic Overview of Pricing and Reimbursement in the BRIC Markets: Brazil, Russia, India and China, pharmaceutical companies entering these markets will also need to address weak intellectual property protection, as well as governments that may not be supportive of large foreign pharmaceutical companies' efforts to establish a strong market presence.

Multinationals also are concerned that governments in emerging markets might increase their use of compulsory licenses to ensure that key medicines are available to their citizens at relatively low prices.

Despite these challenges, Decision Resources says that emerging markets offer significant growth opportunity because of thriving economies, unmet medical needs, increasing healthcare investment, and growing patient populations.



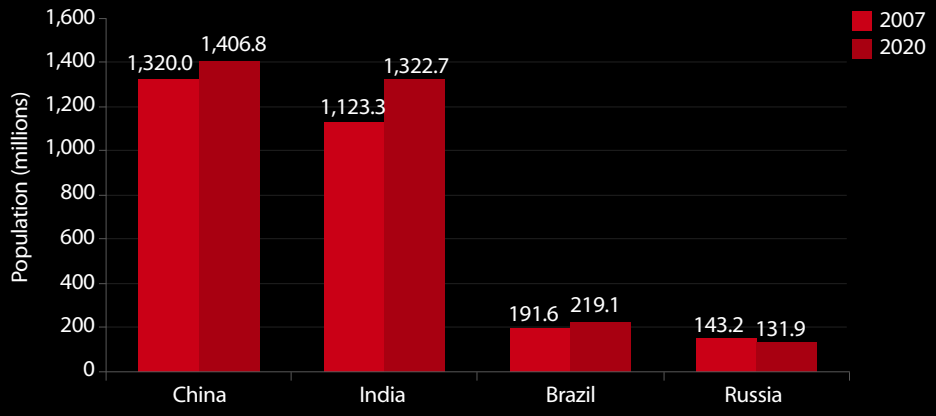

***These markets offer exciting opportunities, but they also present some formidable challenges for multinationals, says Neil Grubert.***

The BRIC markets have been the focus of pharma industry attention for potential growth.

"Faced with declining growth rates in mature markets, pharmaceutical companies are looking to emerging markets, especially the BRIC markets, to boost their sales significantly," says Neil Grubert, director of pricing and reimbursement research at Decision Resources.

*For more information, visit decisionresources.com.*

**PROJECTED POPULATION TRENDS IN BRAZIL, RUSSIA, INDIA, AND CHINA, 2007-2020**




Source: Decision Resources (based on data from the World Bank). For more information, visit decisionresources.com.

# PHARMA trax

## QUICK FACTS

- The global market for drug-device combinations was valued at an estimated $13.7 billion in 2009 and is expected to increase to $27 billion by the end of 2014, for a compound annual growth rate (CAGR) of 14.5%. Coronary stents had the largest share of the market at $4.8 billion in 2009, and the segment is expected to increase to $7.4 billion by 2014, for a CAGR of 9%. The fastest-growing categories in the drug-device sector are projected to be photodynamics therapies, with a CAGR of 11.6% from its value of $1.5 billion in 2009, and antimicrobial catheters, with a CAGR of 11.1% from its 2009 value of $1.3 billion.

Source: BCC Research, Drug-Device Combinations: The Global Market. For more information, visit bccresearch.com.

- Investigator-initiated trials (IITs) provide companies with clinical data to expand scientific understanding of their drugs and reap a number of additional benefits. Data show that 75% of surveyed companies have some form of dedicated IIT management group in place. Such teams accelerate IIT processing and help in long-term trial oversight.

Source: Cutting Edge Information. For more information, visit cuttingedgeinfo.com.

- New research predicts that the cardiovascular disease (CVD) pharma market will grow from $99 billion in 2008 to $107 billion in 2018. Patent expiries and generic competition will have a major impact, and AstraZeneca and Novo Nordisk are expected to emerge as the only major CVD pharma companies to generate positive sales growth over the period.

  In addition, rising obesity levels across the Western world could result in a near doubling of the Type 2 diabetes drug segment by 2018. The antidiabetics market is anticipated to be worth $37 billion by 2018, up from $20 billion in 2008. By contrast, opportunities in the obesity therapeutics sector will likely be extremely limited, reaching an estimated value of $600 million by 2018. The obesity sector continues to be plagued by low efficacy, significant side effect profiles, and lack of reimbursement by healthcare providers.

Source: Datamonitor, Cardiovascular and Metabolic Market Overview. For more information, visit datamonitor.com.

- The oncology supportive care market is forecast to shrink at a compound annual growth rate (CAGR) of -0.6%, with sales dropping from $10.3 billion in 2008 to $9.3 billion in 2018. The decline will be driven by the impact of patent expiration and generic/biosimilar erosion, as well ongoing restrictions on use of erythropoietins. Pipeline launches during this time will be insufficient to offset this sales decline.

Source: Datamonitor, Pipeline/Commercial Insight: Supportive Care in Oncology. For more information, visit datamonitor.com.

- According to surveyed U.S. oncologists, a therapy that improves the median overall survival of unresectable gastric cancer patients compared with capecitabine/cisplatin would earn 58% patient share in the United States. By contrast, in Europe such an agent would earn a lower patient share of 48%, according to surveyed European oncologists. The difference in patient share suggests that in Europe, physician prescribing decisions are strongly influenced by reimbursement policies.

Source: Decision Resources, DecisionBase 2010 report, Gastric Cancer (Unresectable): An Emerging Biological Agent Will Take Over as Market Leader in 2013. For more information, visit decisionresources.com.

- An acute migraine therapy that is not contraindicated in patients with history, symptoms, or signs of vascular disease and also offers improved efficacy and fast-acting oral delivery could earn a 45% patient share in the United States, according to surveyed U.S. neurologists, and a 30% patient share in Europe, according to surveyed European neurologists. While a new acute migraine drug that is free of the triptans' risk of cardiovascular side effects would be valued by clinicians and enjoy a unique competitive advantage, this advantage alone would not be sufficient to fulfill surveyed neurologists' expectations for a new acute treatment.

Source: Decision Resources, DecisionBase 2010 report, Migraine (Acute): Neurologists' Expectations for a New Acute Therapy Extend Beyond Cardiovascular Safety. For more information, visit decisionresources.com.

- A drug approved for secondary progressive multiple sclerosis that reduces long-term disability progression more effectively than Bayer HealthCare's Betaseron could earn 25% to 38% patient share in the United States, reflecting the unmet need for drugs that have the ability to delay disability progression in multiple sclerosis patients over the long term.

Source: Decision Resources, DecisionBase 2010 report, Multiple Sclerosis (Chronic Progressive): Amid Few Approved Therapies and Limited Drug Development, Significant Opportunity Awaits New Therapies for Patients with Progressive Forms of MS. For more information, visit decisionresources.com.

- Sanofi-Aventis's BSI-201 is expected to steal significant market share from Roche/Genentech/Chugai's Avastin, generating projected sales of $1.7 billion in 2018 in the triple negative breast cancer drug market in the United States, France, Germany, Italy, Spain, the United Kingdom, and Japan.

Source: Decision Resources, Pharmacor 2010 findings on Breast Cancer. For more information, visit decisionresources.com.

- Centocor Ortho Biotech/Janssen-Cilag's Stelara will earn sales of nearly $337 million in 2018, following its launch to treat Crohn's disease in 2014 in the U.S. and Europe. Abbott's briakinumab, which is expected to be priced at a significant premium over other marketed biologics for Crohn's disease, is likely to earn just over $130 million in 2018, after launching for the indication in 2015 in the U.S. and in Europe. Although Stelara and briakinumab will achieve robust sales, neither agent is expected to garner substantial patient share.

Source: Decision Resources, Pharmacor 2010 findings on Crohn's Disease. For more information, visit decisionresources.com.

- Emerging oral atypical antipsychotics are expected to gain only limited uptake, because of the increasingly crowded schizophrenia drug market as well as competition from established atypical antipsychotics. Novartis/Vanda Pharmaceuticals' Fanapt is forecast to earn peak-year sales of up to $100 million; Merck's Saphris/Sycrest is expected to earn peak-year sales of up to $250 million; and Dainippon Sumitomo Pharma's lurasidone could garner peak-year sales of as much as $500 million once it is approved in the United States to treat schizophrenia.

Source: Decision Resources, Pharmacor 2010 findings on Schizophrenia. For more information, visit decisionresources.com.

- The targeted cancer drug market is projected to double in value, from $25 billion in 2008 to $51 billion in 2015, driven by increasing sales of existing marketed targeted agents and by sales of new targeted agents introduced to the market before the end of 2015.

Source: Decision Resources, Strategic Overview of the Targeted Cancer Therapies Marketplace. For more information, visit decisionresources.com

- The EMR market is estimated at $13.8 billion in 2009, with at least 70% representing sales to hospitals and health systems. Because of the scale of operation, capital, and support needed to service hospitals, large IT companies such as McKesson, Cerner, Eclypsis, and MediTech have a fairly strong hold on that segment. The remainder of the market, consisting of sales to physician practices and Web sales, is a smaller target, but one with more opportunity.

Source: Kalorarma Information, EMR 2010 (Market Analysis, ARRA Incentives, Key Players, and Important Trends). For more information, visit kaloramainformation.com.

- While clinical laboratories are vital to the diagnostic industry, they are facing multiple challenges that will require increased automation for them to remain competitive. Sales of clinical lab automation hardware and software are expected to reach $5.35 billion in 2010, with growth through 2014 estimated at about 7%.

Source: Kalorarma Information, Lab Automation Markets, 2nd Edition (Systems, Key Companies, Forecasts and Trends). For more information, visit kaloramainformation.com.

- The global market for POC HbA1c tests, used by diabetics to measure glucose attached to the blood protein hemoglobin, was $230 million in 2009 and is expected to rise to $350 million by 2013, a growth rate 50% faster than the average POC testing product. The self-testing portion, performed primarily by mail-in lab services, is only a small percentage of those revenues now, but it is showing faster sales growth than lab-based tests. Mail-in testing is projected to grow at a rate of 25% for the next five years.

Source: Kalorarma Information, Point-of-care Diagnostics 2010 and Beyond: Rapid Testing at a Crossroads. For more information, visit kaloramainformation.com.