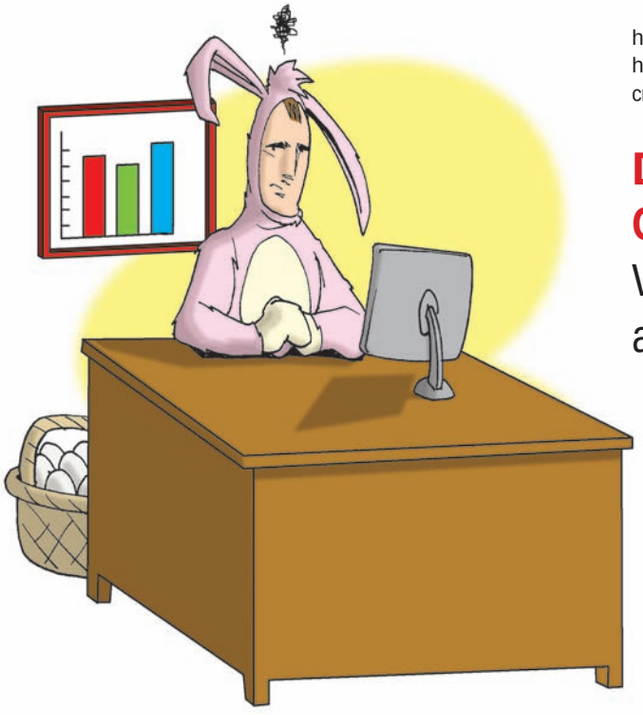

PATIENT EDUCTION PROGRAMS to Grow in Use


Lisa Hunt

These findings demonstrate the importance of patient education in the marketplace, not only for patients, but as a business necessity for the key industry sectors, says Lisa Hunt, Senior VP, Client Services, HealthEd.

Patient education has a strong perceived value across multiple sectors of the healthcare industry. This value is expected to grow in 2007, according to results of a survey on patient education conducted by HealthEd.

Among key findings of the first annual survey, two-thirds of responding professionals from the pharmaceutical, biotechnology, and medical device industries concluded that patient education programs will grow in use in 2007.

The survey, which was based on the input of 87 respondents from the pharmaceutical, biotechnology, and medical-device industries, revealed that the perceived value of patient education is strong in key aspects of patient interactions with the healthcare system, most notably on patient understanding of a product and/or disease state.

Respondents ascribed a high value to patient education programs aimed at patient adherence and building the patient/physician relationship.

The survey shows other key drivers of patient education growth are reduced reliance on traditional industry outreach methods and direct-to-consumer marketing and a more stringent regulatory environment.

"We found that the Internet is driving a need for quality patient education programs online, as well as through conventional means," says Lisa Hunt, senior VP of client services at HealthEd. "This is due to the heightened role individuals now play in their own health advocacy, and the volume and uncertain credibility of information available to the public."

DOCUMENT COLLABORATION Wastes Time and Money

Employees spend up to 25% of their working day on nonproductive, document collaboration-related tasks, according to a report by Butler Group. The report, Document Collaboration, finds that organizations risk a great deal more than poor business performance by not managing the production of their high-value business documents.

"In the ultracompetitive new world of work, document collaboration tools and technologies must support, encourage, and facilitate high-value interactions in a manner that ensures information confidentiality, integrity, and accessibility," says Sue Clarke, one of the report's coauthors and a senior research analyst at Butler Group.

Butler Group estimates that the size of the global document collaboration segment of the enterprise content management (ECM) market is $586 million in 2007 and predicts that the global market for document collaboration solutions will be about $800 million by the end of 2010.

Analysts suggest that this is still an immature sector of the software industry, and that there will be new entrants to the market in the next 12 months.

EUROPEAN UNION Lags Behind United States in NEW DRUG AVAILABILITY

Review times for new drugs in the European Union have met mandated performance goals, but many medicines are available in the United States earlier than in the EU, according to a recent study by the Tufts Center for the Study of Drug Development.

The study found that mean approval times for new products approved in both the EU and the United States during the 2000 to 2005 period were almost identical: 15.8 months for products approved by the European Medicines Agency (EMEA) and 15.7 months for those approved by the Food and Drug Administration (FDA).

Greater collaboration between the EMEA and FDA has the potential to enhance product development in both regions and help avoid duplicative testing, thus providing another way to hold down development costs.

"Looking ahead, we expect that greater collaboration between the EMEA and FDA will further enhance product development in both regions," says Kenneth I. Kaitin, Tufts CSDD director.

The study also found that for 71 products receiving both FDA and EMEA approval, the FDA acted faster than the EMEA in 47 of the cases. Other findings include that the FDA approved a greater number of products faster than the EMEA during the five-year period studied, but there was greater variability in FDA approval review times.

Regulatory designation does not appear to have as much impact in the EMEA as in the United States, as exceptional circumstance approvals are, on average, only 1.5 months faster than nonexceptional approvals, and approval times for orphan products in the EU and the United States were nearly identical for those for nonorphan products in the same region.

Rising Pharmaceutical Expenditures and an Aging Population Propel GROWTH OF THE EUROPEAN GENERICS MARKET

An aging population and rising drug costs are underlining the increasingly critical role of cost-effective generic medicines. Simultaneously, the highly competitive generics industry is putting pressure on the mainstream pharmaceutical sector to develop innovative drugs.

Several countries have resorted to generic substitution and reference pricing to lower pharmaceutical pricing, according to a Frost & Sullivan study, Pricing and Reimbursement Issues for Generics and Biosimilar Markets in Europe. Various studies have indicated the cost savings obtained from generics and several governments are now actively engaged in promoting them.

Faced with the mounting burden of rising pharmaceutical costs , European governments are under immense pressure to implement corrective measures. Some countries are offering incentives to pharmacists and physicians to prescribe generics, a trend that will have a considerable impact on the generics market.

The advent of biosimilars also is projected to be a key factor in pushing down drug prices.

Disparate country-specific policies regarding generics are causing significant variations in market development. Generics manufacturers face further hurdles, such as EU accession and a delay in marketing authorization applications.

"Although accession in the European Union is believed to provide long-term benefits to generic manufacturers, policy harmonization is expected to take a few years," says Sumanth Kambhammettu, a Frost & Sullivan research analyst. "In addition, the lack

Today's pharmaceutical companies deliver so much more than medicine. That's why they partner with HealthEd. Our strategies address the individual needs of patients and the treatment teams who care for them.

Together, our passion is the whole patient.

HEALTHED™
THE PATIENT EDUCATION AGENCY

EDUCATING PATIENTS :: BUILDING BRANDS

PH 908•654•4440 :: WWW.HEALTHED.COM


Sumanth Kambhammettu

Various studies have indicated the cost savings obtained from generics and several governments are now actively engaged in promoting them, says Sumanth Kambhammettu, Frost & Sullivan Research Analyst.

of provisions — such as the Roche/Bolar provision, which allows for research to be carried out before the loss of patent exclusivity — will delay generic approvals in Europe."

To succeed in a highly competitive environment, companies should leverage the potential of low-cost contract manufacturing markets such as India and China. Strategic agreements between companies operating in different countries also will yield synergistic benefits.

Finally, a company's efforts must be directed to optimizing product portfolios and devising long-term research and development strategies.

The Number of PHASE IV TRIALS is Growing

Postmarketing studies, or Phase IV trials, are growing at a 23% annual rate, according to a new report from Cutting Edge Information. Currently, new starts of Phase IV trials exceed newly initiated studies in all other clinical phases combined.

The study found that the number of Phase IV studies conducted for each marketed product depends on the company's relative market size. The report reveals that surveyed companies currently have an average of 1.8 active Phase IV studies running per marketed product. Of these studies, 61% were initiated voluntarily, while 24% were required by FDA as a condition of approval. The remaining 15% were requested, but not required as a condition of approval, by the FDA or another regulatory body. While small and large companies managed an average of 1.2 and 1.4 studies per product respectively, the survey found that midsized companies run twice as many Phase IV trials — an average 2.8 studies per marketed drug.

The Phase IV Clinical Trials: Post-Marketing Study Management Structure, Strategy and Benchmarks report found that company size influences the outsourcing of Phase IV activities; but 42.6% of companies that have the internal infrastructure in place to manage Phase IV studies in-house still choose to outsource much of the work associated with their postmarketing studies. Of the companies surveyed, only 44% of small companies and 40% of midsized companies have the internal infrastructure to support Phase IV management.

This lack of internal infrastructure leads to 68% of small companies' total Phase IV workload being outsourced. Midsize companies outsource an average of 80% of their total Phase IV workload. Even though the majority of large companies (80%) have the means to handle Phase IV activities in-house, 57% still choose to outsource much of their postmarketing operations.

PHASE IV OUTSOURCING TRENDS

- **68%** of small companies outsource Phase IV trials
- **80%** of midsize companies outsource Phase IV studies
- **57%** of large companies outsource Phase IV studies
- On average, Phase IV clinical trials last **27.6%** longer than companies plan; they plan for **400 days**
- Postmarketing studies last **440 days**, on average, at large companies.
- Postmarketing studies last **578 days**, on average, at midsize companies
- Postmarketing studies last **475 days**, on average, at small companies

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

Collaboration is Required for Adoption of TARGETED THERAPIES

Personalized medicine is achievable if industry stakeholders take a fresh look at how the substantial risks associated with discovery are lessened by faster adoption by front-line providers and payers, according to a Deloitte Center for Health Solutions' report, Targeted Therapies: Navigating the Business Challenges of Personalized Medicine.

Advancing targeted therapies that reduce costs from medications and therapies that don't work well requires a change in the way practicing physicians, health plans, academic medicine, and government regulators relate to one another. The potential of targeted therapeutics to deliver personalized medicine is dramatically limited by public policies hindering innovation in discovery and the failure of key stakeholders — providers and payers — to appropriately integrate new ways of treatment in patient-care plans.

Probability of Success in Oncology Increases WITH EARLY-STAGE MARKET RESEARCH

More biopharmaceutical companies are turning to market research earlier in the drug-development phase to ensure that projections and research are on target to produce viable and profitable drugs.

Research by Best Practices indicates that 88% of benchmarked companies commission market research as early as Phase I, while a vast majority, 64% of research participants, invest in market research at the preclinical stage, according to the report, Optimizing Oncology: Market Research and Analytics.

Follow up

BEST PRACTICES LLC, Chapel Hill, N.C., is a research and consulting firm. For more information, visit best-in-class.com.

BUTLER GROUP, New York, a wholly owned subsidiary of Datamonitor Plc., is an independent European IT research and advisory organization. For more information, visit butlergroup.com.

CUTTING EDGE INFORMATION, Durham, N.C., provides research and consulting to the pharmaceutical industry and the financial services industry. For more information, visit cuttingedgeinfo.com.

DELOITTE CENTER FOR HEALTH SOLUTIONS, Washington, D.C., part of Deloitte & Touche USA LLP, researches and develops solutions to pressing healthcare and public-health related challenges. For more information, visit deloitte.com.

FROST & SULLIVAN, San Antonio, integrates growth consulting, growth partnership services, and corporate management training to identify and develop opportunities. For more information, visit frost.com.

HEALTHED, Clark, N.J., develops patient education programs for pharmaceutical and healthcare marketers. For more information, visit healthed.com.

TUFTS CENTER FOR THE STUDY OF DRUG DEVELOPMENT, Tufts University, Boston, provides strategic information to help drug developers, regulators, and policy makers improve the quality and efficiency of pharmaceutical development, review, and use. For more information, visit csdd.tufts.edu.