By Carolyn Gretton

EMR Market
Shows Robust Growth

TREND: The fastest sales growth and heaviest competition is being seen in EMR-related products sold to physicians, particularly solutions sold over the Internet.


Bruce Carlson

Propelled by government incentives, a desire to improve patient outcomes, and the bottom line, sales of electronic medical records grew 14.2% to $17.9 billion in 2011, according to Kalorama Information.

The Kalorama report, EMR 2012: the Market for Electronic Medical Records, found increasing physician and hospital acceptance, robust competition, and growth in EMR budgets.

"Paperless medicine is no longer a concept in a few model hospitals," says Bruce Carlson, publisher of Kalorama Information. "It's something that hospitals and physicians are incorporating into their workflows, and that is showing up in budgets and increased vendor sales."

The revenue growth mirrors increased physician and institutional usage. Statistics from the National Ambulatory Medical Care Survey (NAMCS) indicate that 56.9% of office-based physicians used partial or full EMR systems in 2011, an increase from 2010.

The fastest sales growth and heaviest competition in the EMR market is in products sold to physicians, particularly solutions sold over the Internet. Sales of EMR systems to physicians grew at an estimated 22% in 2011 vs. 2010, higher than the growth of EMR sales to hospital systems, according to the report.

"The physician segment will likely drive growth and it's the part of the market where new entrants can realistically stake a claim," Mr. Carlson predicts. "It takes infrastructure and legacy relationships to support hospital conversion."

Incentives have been a factor in the increased usage and growth of EMR systems. As part of the ARRA legislation passed in February 2009, the federal government set aside almost $20 billion in incentives for hospitals and physician practices to adopt electronic medical records. The first incentives were paid in 2011 based on 2010 performance. More than $1.3 billion in Medicare EHR Incentive Program payments have been made between May 2011 and the end of December 2011, and more than $1.1 billion in Medicaid EHR Incentive Program payments have been made between January 2011 and the end of December 2011.

For more information, visit kaloramainformation.com.

U.S. Contract Manufacturing Outsourcing
MARKET EXPERIENCES REVIVAL

The upturn in the fortunes of pharmaceutical companies after the recession is mirrored by the U.S. contract manufacturing outsourcing (CMO) market, which is expected to grow at a compound annual growth rate (CAGR) of 8.3% from 2011 to 2016.

Research from Frost & Sullivan's Analysis of the United States Contract Manufacturing Outsourcing Market finds that the market earned revenue of $10.73 billion in 2011, and projects this to reach $15.97 billion in 2016. The sterile segment accounts for the highest share of revenue, with 38.7% in 2011, and is expected to rise to 47.5% by 2016.

"The continued expansion of the U.S. pharmaceuticals industry and big pharma's increased outsourcing to improve cost structure and focus on core competencies will significantly augment the market's revenue growth," predicts Frost & Sullivan Consultant Jesse Sullivan. "The pharmaceutical companies that had used their excess capacity during the downturn to retain in-house manufacturing are expected to gradually outsource as the economy improves."

Despite the inclination for pharmaceutical companies to outsource, R&D spending dipped from 2010 to 2011, resulting in fewer drugs being developed and marketed. As the CMO market's revenue inflow is contingent on drug development, the torpid R&D activity has slowed the pace of market development.

"To demonstrate value to clients, CMO providers are likely to continue focusing on strategic relationships and promoting more services such as formulation improvements, alternate dose forms, real-time order tracking, and logistics support," Mr. Sullivan says. He observes that numerous CMO providers now offer preclinical development services, which creates long-term relationships with manufacturers and helps them win projects early in a drug's development cycle.

For more information, visit frost.com.

Pediatric Study Requirements
REMAIN CHALLENGING, CONFUSING

Premier Research's recent survey of 55 biotech and pharmaceutical firms in both the North America and European markets reveals confusion with pediatric clinical trial rules as well as a lack of awareness and understanding by biotech and pharma companies about the extent to which regulatory agencies in the United States and Europe are willing to amend or revise obligations on compliance issues and timing.

According to the study, one of the biggest problems cited by biotech and pharma companies in complying with pediatric regulations is the difficulty in finding children who are both accessible and can meet the often-stringent study criteria to participate in required clinical trials.

Almost three-quarters of U.S.-based survey respondents feel that identifying a sufficient number of pediatric patients for PREA (Pediatric Research Equity Act of 2003) studies is a major challenge, and more than half say pediatric patient recruitment is the No. 1 area where they need help from a CRO in satisfying PREA requirements.

THERAPEUTIC FAST TRAX...

AUTOIMMUNE

The market for biological drugs that treat autoimmune and inflammatory diseases is lucrative and expected to grow from more than $24 billion in 2010 to more than $42 billion in 2017. Although current biological therapies for immune and inflammatory diseases have been successful and the market for diseases such as rheumatoid arthritis is crowded, opportunities for new drugs exist through patients who are refractory to these therapies and unmet needs not addressed by current drugs.

Source: Decision Resources, Innovative R&D and Dealmaking Opportunities: Immune and Inflammatory Disease Biologics.

For more information, visit decisionresources.com.

The systemic lupus erythematosus (SLE) market is projected to experience dramatic growth, increasing from about $300 million in 2010 to $2.8 billion in 2020 in the United States, France, Germany, Italy, Spain, United Kingdom, and Japan. Growth will be driven in part by the launch and uptake of Lilly's tabalumab and ImmuPharma/SymBio Pharmaceuticals' forigerimod.

Source: Decision Resources SLE drug market analysis.

For more information, visit decisionresources.com.

The autoimmune disorders therapeutics market — comprising rheumatoid arthritis (RA), multiple sclerosis (MS), psoriasis, inflammatory bowel diseases such as Crohn's disease and ulcerative colitis, and systemic lupus erythematosus (SLE) — which was valued at an estimated $16.9 billion in 2002, recorded a compound annual growth rate (CAGR) of 7.5% reaching $30.2 billion in 2010. The autoimmune disorders market is forecast to reach $61.4 billion in 2017, indicating a CAGR of 10.7% during the forecast period.

Source: GBI Research, Autoimmune Disorders Therapeutics Market to 2017 — Launch of Gilenya and Benlysta to Drive the Growth of Multiple Sclerosis and Systemic Lupus Erythematosus Therapeutic Segments.

For more information, visit gbiresearch.com.

The global hereditary angioedema (HAE) therapeutics market had an estimated value of $338.5 million in 2011 and is forecast to reach almost $1.19 billion in 2019, for a CAGR of 17%. Despite the high cost of newer HAE therapies, physicians have not been deterred from prescribing these treatment options given their superior efficacy in relation to control of symptoms such as subcutaneous and abdominal swelling.

Source: GlobalData, Hereditary Angioedema Therapeutics - Pipeline Assessment and Market Forecasts to 2019.

For more information, visit globaldata.com.

CANCER

In the treatment of advanced non-small-cell lung cancer (NSCLC), two-thirds of surveyed U.S.-based medical oncologists agree there is a higher unmet need in squamous-cell patients compared with non-squamous patients because of a reliance on chemotherapy in the squamous-cell setting.

Source: BioTrends Research Group, Treatment Trends Non-Small-Cell Lung Cancer.

For more information, visit bio-trends.com.

The overall global oncology orphan disease market is expected to grow at a CAGR of 3.3% from $4.9 billion 2010 to $6.4 billion in 2018 in the United States, the top five European countries, and Japan. This growth follows a higher CAGR of 7.4% between 2004 and 2010.

Source: GBI Research, Orphan Diseases Therapeutics in Oncology to 2018 - Strongly Diversified Developmental Pipelines Indicate Long-Term Growth Potential despite Moderate Scope of Current Late Stage Molecules.

For more information, visit gbiresearch.com.

CARDIOVASCULAR

The global pulmonary arterial hypertension (PAH) therapeutics market was worth an estimated $3.3 billion in 2011, having posted robust CAGR of 38.6% for the period between 2002 and 2011 amid increased patient volume and the launch of eight premium-priced drugs. But a significant number of upcoming patent and exclusivity expiries are expected to shrink the PAH market to a value of $3.1 billion in 2020, for a negative CAGR of 0.6% from 2011 to 2020.

Source: GlobalData, Pulmonary Arterial Hypertension Therapeutics - Global Drug Forecasts and Treatment Analysis to 2020.

For more information, visit globaldata.com.

Demographics, the aging of the population, and accompanying rates of heart failure are the main drivers of the U.S. market for heart failure-specific diagnostic and therapeutic technologies. In 2010, U.S. sales of heart failure-specific diagnostic and therapeutic technologies totaled about $3.19 billion. This market is expected to increase in value at a compound annual rate of 2.8%, with sales reaching an estimated $3.68 billion in 2016.

Source: Medtech Insight, U.S. Markets for Current and Emerging Technologies for the Treatment of Heart Failure.

For more information, visit lifescienceintelligence.com.

CENTRAL NERVOUS SYSTEM

Although surveyed neurologists do not anticipate a significant change overall in their prescribing of first- or second-generation antiepileptic drugs (AEDs) over the next six months, prescribing of third-generation AEDs is expected to increase from 16% to 19% of AED patient share, driven predominantly by an anticipated increase for Vimpat. The uptake of Vimpat over the next six months will be driven by UCB's strong company support of AEDs and strong performance of efficacy-related attributes.

Source: Bio-Trends Research Group, Treatment Trends: Epilepsy.

For more information, visit bio-trends.com.

The global antipsychotics market has shown a rising trend, recording a CAGR of 4.8% from 2002 to reach $14 billion in 2010, driven by newer agents with better efficacy. But the impending patent expiries of blockbuster antipsychotics such as AstraZeneca's Seroquel, Lilly's Zyprexa, Bristol-Myers Squibb's Abilify, and Pfizer's Geodon are expected to increase price competition, resulting in a projected decline to $13.8 billion in 2017.

Source: GBI Research, Antipsychotics Market to 2017.

For more information, visit gbiresearch.com.

In 2011, the global Parkinson's disease (PD) therapeutics market was estimated at $2.99 billion, having grown at a CAGR of 5.8% during the 2002-2011 period. The market is projected to record a more modest CAGR of 2.2% and reach $3.65 billion by 2020.

Source: GlobalData, Parkinson's Disease Therapeutics to 2020 - Global Drug Forecasts and Treatment Analysis.

For more information, visit globaldata.com.

DIABETES

The unique feature of weight reduction associated with the use of glucagon-like peptide-1 receptor (GLP-1R) agonists clearly differentiates this antidiabetic drug class from other established antidiabetics. The profound blood glucose lowering effect without significant hypoglycemia also has made GLP-1R agonists a strongly emerging antidiabetic drug class. Although the first GLP-1R agonist was approved in 2005, it was the 2010 launch of the blockbuster once-daily GLP-1R agonist Victoza from Novo Nordisk that boosted the market to $1.7 billion in 2011.

Source: La Merie Business Intelligence, Glucagon-Like Peptide-1
(GLP-1) Receptor Agonists - A Target Pipeline and Stakeholder
Analysis 2012.

For more information, visit chidb.com.

GOUT

The global gout therapeutics market recorded a CAGR of 13.4% from $527.4 million in 2006 to $988.7 million in 2011 and is predicted to grow further at a CAGR of 12.5% to reach $2.5 billion by 2019. Pharmaceutical companies are scrambling to expand into the gout market, as it is now the most common form of inflammatory joint disease in men and women over 40 years of age, caused by genetic metabolic defects, kidney impairment, alcohol abuse, and meat-heavy diets.

Source: GlobalData, Gout Therapeutics - Pipeline Assessment and Market Forecasts to 2019.

For more information, visit globaldata.com.

INFECTIONS

The global MRSA therapeutics market stood at almost $1.45 billion in 2006 and grew at a CAGR of 12.9% to reach about $2.66 billion in 2011. Forecasts estimate the market will grow at a CAGR of 3.4% over the next eight years to reach $3.47 billion by 2019 as new and improved drug treatment options for serious hospital-acquired infections such as MRSA emerge from the pipeline.

Source: GlobalData, Methicillin-Resistant Staphylococcus Aureus (MRSA) Therapeutics - Pipeline Assessment and Market Forecasts to 2019.

For more information, visit globaldata.com.

KIDNEY TRANSPLANT

The kidney transplantation market was worth almost $2.68 billion in 2011 in the United States, the United Kingdom, France, Germany, Italy, Spain, and Japan and is projected to increase at a CAGR of 5.3% to an estimated $4.04 billion by 2019. The expected launch of promising molecules LCP-Tacro and Voclosporin in 2013 is expected to boost the future market.

Source: GlobalData, Kidney Transplantation Therapeutics - Pipeline Assessment and Market Forecasts to 2019.

For more information, visit globaldata.com.

OPHTHALMIC

The $16.2 billion ophthalmic pharmaceutical market is forecast to expand steadily at a CAGR of 4.6% to 2016. Although glaucoma remains the largest treatment segment, with sales of $5.6 billion in 2010, most future growth likely will come from retinal diseases such as age-related macular degeneration and diabetic retinopathy. The retinal disease segment was valued at $3.5 billion in 2010 and is expected to post CAGR of 14.1% to 2016.

Source: Business Insights, The Ophthalmic Pharmaceutical Market Outlook to 2016.

For more information, visit business-insights.com.

"The FDA recognizes that it can be difficult to recruit kids," says Charli Sanders, M.D., Premier Research's VP, regulatory affairs and pediatric consulting, noting that the agency is receptive to tools like population pharmacokinetic modeling and extrapolation of information from adult studies to help fill in the gaps. In the right hands, Dr. Sanders adds, existing research tools and data can sometimes be used to modify a PREA requirement.

"Studying drugs in children is a scientifically demanding task," she says. "As much as pediatric studies have helped, the reality is that they're harder to conduct than adult studies. Indeed, children's hospitals and care facilities, as well as clinical practices, are being bombarded in the search for pediatric patients to join these studies."

For more information, visit premier-research.com.

KEY FINDINGS ON PREA STRATEGIES BY U.S. COMPANIES

- About 92% of survey respondents said that having an independent analysis of their PREA obligation by a firm that specializes in dealing with PREA could save time and money and might result in the granting of an exemption.
- About 67% of respondents have either had to hire outside consultants or more staff to handle PREA's complex regulatory requirements. Nevertheless, 31% said that PREA has not caused them to change anything, and only 6% have dropped a drug trial because of the PREA expense.
- About 52% of respondents said they have had to increase their R&D budgets because of PREA requirements. Only 23% thought that slashing the cost of running pediatric clinical trials was highly important.

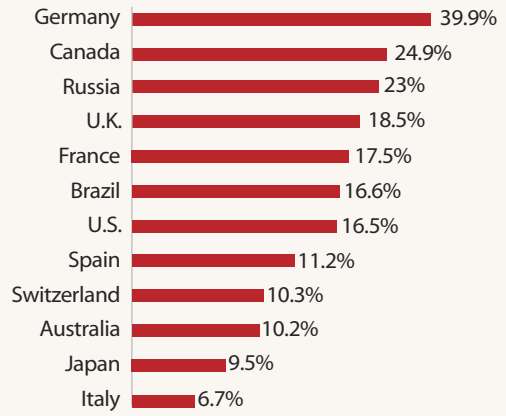
Source: Premier Research
For more information, visit premier-research.com.

Generics Sector Under Pressure to SQUEEZE PRICING MARGINS

Experts predict the global markets for generic drugs will continue to grow despite cost containment pressures from health payers in many markets.

According to The World Generic Market Report from Espicom, the robust U.S. generics market will rise to an estimated $104.1 billion by 2016 amid expiry of patents on major drugs such as Lipitor and Zyprexa, increased pressure for generic use from

GENERIC PHARMACEUTICAL EXPENDITURE AS % OF TOTAL FOR 2011



Source: Espicom, The World Generic Market Report.
For more information, visit espicom.com.

Medicare drug plans, and the gradual emergence of the biosimilars market. In other regions, government efforts to promote and reward expanded generic use should continue to pay off, notably in France and Japan, the report notes. The Swiss market is also performing strongly, although it is limited in size by the country's small population.

But other regions are not expected to fare as well, principally due to price cuts in the face of the global economic downturn. This can be specifically seen in the Eurozone economies, even in Germany, where drug tendering is having a major effect on prices. To a lesser extent, it is also the case in the United Kingdom, which has one of the most competitive generic markets in the world.

Andrew Crofts, senior health analyst at Espicom and the report's co-author, observes that recessionary effects have put pressure on prices that were marginal to begin with.

"In the future, the increasing number of biosimilars losing patent protection will only offer potential to a relatively small number of companies that have the time and resources to leap the regulatory hurdles," Mr. Crofts says. "The trend toward a rationalized market more in step, rather in court, with the branded industry is set to continue."

For more information, visit espicom.com.

Other market insights…

Booming Market FOR DNA SEQUENCING

According to the BCC Research report, DNA Sequencing: Emerging Technologies and Applications, the global market for sequencing products was almost $3 billion in 2011 and it is forecast to record a CAGR of 17.5% to reach $6.6 billion by 2016.

Sequencing instruments and consumables made up the largest market segment in 2011, with revenue of almost $1.6 billion, and BCC expects this market to grow to $2.2 billion by 2016, for a CAGR of 7.3%. Sequencing services comprise the fastest-growing market segment, with revenue expected to post a healthy CAGR of 29% for the 2011-2016 period, reaching $3.5 billion by 2016.

For more information, visit bccresearch.com.

Personalized Medicine DIAGNOSTICS GAIN ACCEPTANCE

Diagnostic tests that can direct a therapy to a specific patient to boost outcomes and lower costs are experiencing faster sales growth than that of the overall in vitro diagnostics (IVD) market.

According to the Kalorama Information report, Personalized Medicine Diagnostics (Biomarkers, Pharmacodiagnostics, Tumor Assays, Cardiac Risk and Other Testing), this particular category of personalized medicine tests has recorded estimated growth of anywhere between 7% and 38% per year, compared with the more modest 2% to 6% growth recorded by IVDs in general. Personalized medicine tests such as fluorescent in situ hybridization (FISH) for cancer screening, CYP450 tests for psychiatric therapy, individual microbiologic assessments to treat infectious disease, and tissue transplant typing, rose to $28.1 billion in 2011.

For more information, visit kaloramainformation.com.

Investigative Sites Remain Cautious ABOUT FUTURE STABILITY

The average site surveyed for CenterWatch's 2012 Study of Global Investigative Sites reported a rebound in operating conditions despite concern about the stability of the clinical research sector.

While small sites — those with five or fewer employees — saw the strongest top-line revenue growth in 2011, up 15%, and the highest profit margin of all site groups, the largest sites are more poised for growth, with 63% reporting expansion plans in 2012, compared with only 36% of small sites.

Younger sites saw the fastest growth and are the most optimistic about the future. More than half of those in business for less than five years expect economic conditions to improve this year, while only 20% of sites with more than 21 years of experience share that optimism.

For more information, visit centerwatch.com.

Biosimilars Market POISED TO EXPLODE

The impending patent expiries of a number of biologics are anticipated to result in the introduction of several new biosimilars and provide impetus to development of the biosimilars manufacturing industry.

Frost & Sullivan's Analysis of European Biosimilars Market finds that the market earned revenue of about $172 million in 2010 and estimates this to reach almost $3.99 billion in 2017, for a CAGR of 56.7% for the period.

For more information, visit frost.com.

Pharma Has Limited Experience in RISK MITIGATION PROGRAMS

One of the outgrowths of increasing regulatory requirements for new products is that pharmaceutical companies must have the capability to develop effective risk evaluation and mitigation strategy (REMS) plans that will both protect the public and ensure access to their products.

According to the Best Practices study, Risk Mitigation Plan Excellence: Innovative Models and Trends in Supporting REMS and RMP Programs, many companies have relatively limited experience in implementing a REMS plan or executing a REMS plan throughout the entire product life cycle.

Companies that participated in the study have only deployed REMS plans for 3.33 products on average since the advent of REMS through federal legislation in 2007. The most total REMS products managed by one company was nine, according to the study.

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

Limited Options to MANAGED SPECIALTY DRUG SPENDING

Health insurers and employers have few tools to control rapidly rising spending on high-cost specialty drugs — typically high-cost biologic medications to treat complex medical conditions, according to a new qualitative study from the Center for Studying Health System Change (HSC).

Unlike conventional prescription drugs, where spending trends have moderated because of patent expiration, generic substitution, and other factors, specialty drugs have persistently high trends, ranging from 14% to 20% annually in recent years.

And spending on specialty drugs is expected to skyrocket over the next decade as some of the hundreds of biologics currently in the pipeline gain market approval.

For more information, visit hschange.com. PV