



U.S. Pharmaceuticals Market Is Improving

TRENDING NOW: Patient access is broadening with implementation of the Affordable Care Act and the expansion of Medicaid.

The outlook for the pharmaceutical market in the United States is becoming more favorable, as the size of the insured population is expanding and opportunities for specialty pharmaceutical products support premium pricing and better profitability, according to a new report by Decision Resources Group. The implementation of the Affordable Care Act appears to be expanding patient access, as mandated enrollment through the state and federal health insurance exchanges has outpaced government estimates. In addition, the majority of states have expanded their Medicaid programs according to this law (or are proposing alternative programs).

“Government and private payers are exploring new models that put greater emphasis on disease prevention and improving the quality of healthcare services,” says Decision Resources Group Analyst Michael Latwis. “This shift could be an advantage for the pharmaceutical industry if companies can demonstrate that their products can improve outcomes and reduce overall healthcare expenditures.”



Michael Latwis

- Other key findings from the United States Market Access Tracker advisory service include:
- » The Affordable Care Act exceeded government expectations with the enrollment of 8 million people through federal and state health insurance exchanges. The expansion of Medicaid coverage at the state level has further reduced the ranks of the uninsured with 26 states (and the District of Columbia) expanding coverage, while 21 states have decided not to expand this program, and four states remain undecided or are proposing alternative plans.
 - » Accountable care organizations (ACOs) were established to better align patient, provider and payer interests with financial incentives for meeting performance standards and specific levels of savings. The number of Medicare and commercial ACOs has greatly exceeded expectations in terms of both number of plans and covered lives.
 - » Comparative effectiveness research will play an increasingly important role in reimbursement decisions in the United States. AMCP's Format for Formulary Submissions includes CER guidelines in its standards for formulary submissions, and the Patient-Centered Outcomes Research Institute was established under the Affordable Care Act to promote CER in evaluating new drugs.

▼ For more information, visit DecisionResourcesGroup.com.

Managed Care Predicts BIOLOGICS COSTS TO INCREASE

Managed care organizations (MCOs) anticipate that their costs of covering biologic treatments of autoimmune diseases will increase by double-digit rates each year for the next two years, according to a survey by Decision Resources Group.



Chris Lewis

The cost trend for rheumatoid arthritis (RA), which MCOs expect to average 19%, is a major concern for more than two-thirds of the 40 surveyed MCO pharmacy and medical directors. As a result, payers have increased cost controls on biologics, which has affected prescribing by

Managed Care and Biologics

- » Close to 60% of surveyed rheumatologists said their patients treated for RA, PsA and AS are prescribed a biologic agent, typically after an initial trial and failure of conventional disease modifying anti-rheumatic drugs.
- » Among all the restrictions and strategies to control the use of high-cost biologics, MCOs overwhelmingly apply utilization management controls, most commonly prior authorization and step therapy, to steer to preferred agents.
- » In response to increased payer controls, more than half of surveyed rheumatologists reported they adhere more closely to preferred drug lists and plan to do so in the next 12 months.
- » About half of MCOs reported a specialty pharmacy is commonly used to acquire biologic drugs for members with RA — a trend that may accelerate with the launch of more self-administered therapies, thus increasing the ability of payers to control costs.

Source: Decision Resources Group

specialists. The survey, which also included 103 rheumatologists, indicates that 80% of the specialists encounter moderate-to-strong control by payers when prescribing biologic agents for RA and psoriatic arthritis (PsA), while 74% of specialists note this level of control for ankylosing spondylitis (AS).

“Considering prescribers intend to adhere more closely to preferred drug lists as a result of increased payer control on biologics, drug marketers need to find ways to obtain preferred brand coverage on MCO formularies or risk losing patient share to competitors that achieve favorable coverage,” says Decision Resources Group Analyst Chris Lewis.

▼ For more information, visit DecisionResourcesGroup.com.


Anti-counterfeiting**MARKET TO GROW**

The global anti-tampering, authentication and anti-counterfeit packaging market is projected to grow at a CAGR of 14.1% between 2014 and 2019, according to MarketsandMarkets. Authentication

technologies are projected to grow at the highest CAGR of 16.3%, because of the increasing awareness about counterfeit products.

In 2014, North America is identified as the largest market supporting anti-counterfeit, anti-tampering, and authentication technologies fol-

lowed by Europe. Asia-Pacific is the fastest growing market for anti-counterfeit technologies with increasing awareness about counterfeit products penetrating regional markets.

▼ For more information, visit marketsandmarkets.com. 

THERAPEUTIC TRAX... ▶▶**CANCER**

The mantle cell lymphoma (MCL) market will experience the strongest growth in the six major markets during the forecast period from \$445 million in 2013 to \$660 million in 2018 at a CAGR of 8.2%. Despite being the indication with the lowest incidence, revenues in the MCL market will be driven by a strong uptake of the premium-priced Imbruvica in the relapsed/refractory setting, beginning in the US in 2013, and in the 5EU (France, Italy, Germany, Spain, and UK) in 2014.

Source: GlobalData, OpportunityAnalyzer: Non-Hodgkin's B-Cell Lymphoma - Opportunity Analysis and Forecast to 2018

▼ For more information, visit globaldata.com.

CNS

By 2023, total major-market sales for unipolar depression will reach under \$10 billion. The expanding use of two recently approved therapies — Lundbeck/Takeda Pharmaceutical's Brintellix (vortioxetine), Actavis/Pierre Fabre's Fetzima (levomefiprazole ER) — together with the forecasted launch of Otsuka Pharmaceutical/Lundbeck's brexpiprazole in the major pharmaceutical markets will offset a steep near-term decline in sales resulting from the loss of market exclusivity for the two key drugs prescribed for unipolar depression: duloxetine (Lilly/Shionogi's Cymbalta/Xeristar generic) and the atypical antipsychotic Abilify (Bristol-Myers Squibb/Otsuka Pharmaceutical's aripiprazole).

Source: Decision Resources Group, Pharmacor: Unipolar Depression

▼ For more information, visit decisionresourcesgroup.com.

INFECTIONS

Thanks to patent expirations of several key therapies, the HIV treatment market value will increase at a slow pace in the coming years, from \$14.3 billion in 2012 to \$16.3 billion by 2019, at a CAGR of 1.9%. The first-line antiretroviral therapies Atripla and Truvada will lose patent protection during the forecast period, which will hurt their markets in Europe and Canada. The HIV pipeline is strong and displays a high degree of novelty and diver-

sity, consisting of therapies that address the unmet needs of drug resistance and toxicity.

Source: GBI Research, HIV Therapeutics in Major Developed Market to 2019

▼ For more information, visit gbiresearch.com.

RARE DISEASE

The graft-versus-host disease (GVHD) market, was valued at \$297.0 million across the six major markets (US, France, Germany, Italy, Spain, and UK) in 2013, and is expected to increase to \$407 million in 2018, at a CAGR of 6.59%. Growth is anticipated to be slowest in the US, as there are fewer market changes expected during the five-year forecast period. Six new products are expected to enter the market by 2018. Osiris Therapeutics/Mesoblast's Prochymal is expected to launch in 2014 (US) and 2015 (5EU), reaching \$12.2 million in sales from the six major markets in 2018.

Source: GlobalData, OpportunityAnalyzer: Graft-Versus-Host Disease - Opportunity Analysis and Forecasts to 2018

▼ For more information, visit globaldata.com.

VACCINES

The global market for DNA vaccines is expected to grow to \$2.7 billion by 2019, with a five-year CAGR of 54.8%. The clinical vaccines category, the largest and fastest-growing segment of this market, is surging at 81.2% CAGR. Key to this growth is emerging delivery technologies that are demonstrating the higher efficacy in humans required for commercialization of DNA vaccines. Consequently, research tools and animal health play a vital role in the development of the large, human vaccine applications. This segment is expected to reach \$308 million by 2019, registering a significant CAGR of 11.1%.

Source: BCC Research, DNA Vaccines: Technologies and Global Markets

▼ For more information, visit bccresearch.com

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