Pharma Trax

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

By Carolyn Gretton

Future of Biotech Lies in

* Collaboration, Managing Outcomes

TREND: With its traditional business model breaking down amid scant financing and lengthy R&D processes, the biotech sector needs to reinvent itself by adopting a more collaborative approach to capitalize on emerging healthcare opportunities.

According to the PricewaterhouseCoopers (PwC) report — Biotech Reinvented: Where do you go from here? — the new biotech business model will likely include more types of cooperation and will focus more on managing outcomes than selling medicines. Under this new model, the largest biopharmaceutical companies will be responsible for coordinating and funding federations and consortia, giving them access to more innovation, reduced costs, and improved productivity.

Meanwhile, smaller biopharmaceutical companies, research institutes, and academic medical centers will be responsible for generating original ideas and providing disease biology and platform technologies on a fee-for-service basis. In return, these smaller organizations will receive more stable, long-term financing; better opportunities for benchmarking the value of their own contributions; and access to critical regulatory and marketing skills.

According to PwC, greater collaboration will be required not only in biotech R&D, but in the rest of the value chain. Because the opportunities for generating value from stand-alone products are getting smaller, biopharma companies will be best served by switching from marketing products to managing patient outcomes. To do this, they'll need more information about how well their medicines work for particular patients — data they can only access and analyze through extensive collaboration.

For more information, visit pwc.com.

BIOTECH MORE LIKELY TO FAIL AT PHASE III

	FDA approvals	% of total FDA approvals	Phase III failures	% of total Phase III failures
Biotech	47	45%	68	74%
Biotech-Pharma Alliances	16	16%	18	21%
Acquisitions/Licenses by Pharma	4	4%	0	0%
Pharma	36	35%	5	5%
Total	103	100%	91	100%

Note: All products were approved for the first time by the FDA between January 2006 and December 2007.

Source: Elizabeth A. Czerepak and Stefan Ryser, "Drug approvals and failures: implications for alliances" (2008); republished by PricewaterhouseCoopers in Biotech reinvented: Where do you go from here? For more information, visit pwc.com.

Regulatory Compliance
REMAINS MAJOR CHALLENGE IN EUROPE


Bill Buzzeo

According to Cegedim Relationship Management's 2010 European Trends in Aggregate Spend, Transparency, and Disclosure Report, 93% of respondents are concerned that regulatory compliance will be a major challenge in Europe over the next three years, and that it is expected to significantly impact the industry's image.

"It came as no surprise to learn that the greatest concern is the changing compliance landscape and how this will affect daily processes and the image of the industry as a whole," says Bill Buzzeo, Cegedim Relationship Management VP and general manager, global compliance.

For more information, visit cegedim.com.

Index Uncovers
HEALTHCARE SAVINGS OPPORTUNITIES


Christopher Parks

With more than 60% of U.S. employers expected to offer a consumer-directed health plan in 2011 as a way to curb costs, employees and their families are increasingly accountable for shopping and paying for their healthcare, making it more critical than ever for them to understand the costs, according to change:healthcare's fourth-quarter 2010 Healthcare Transparency Index (HCTI).

"HCTI was created to highlight the most significant healthcare trends and more importantly, the cost-savings opportunities," says Christopher Parks, CEO of change:healthcare. "Prescription drugs offer the highest opportunity for cost savings: $8 million across the HCTI data set."

For more information, visit changehealthcare.com.

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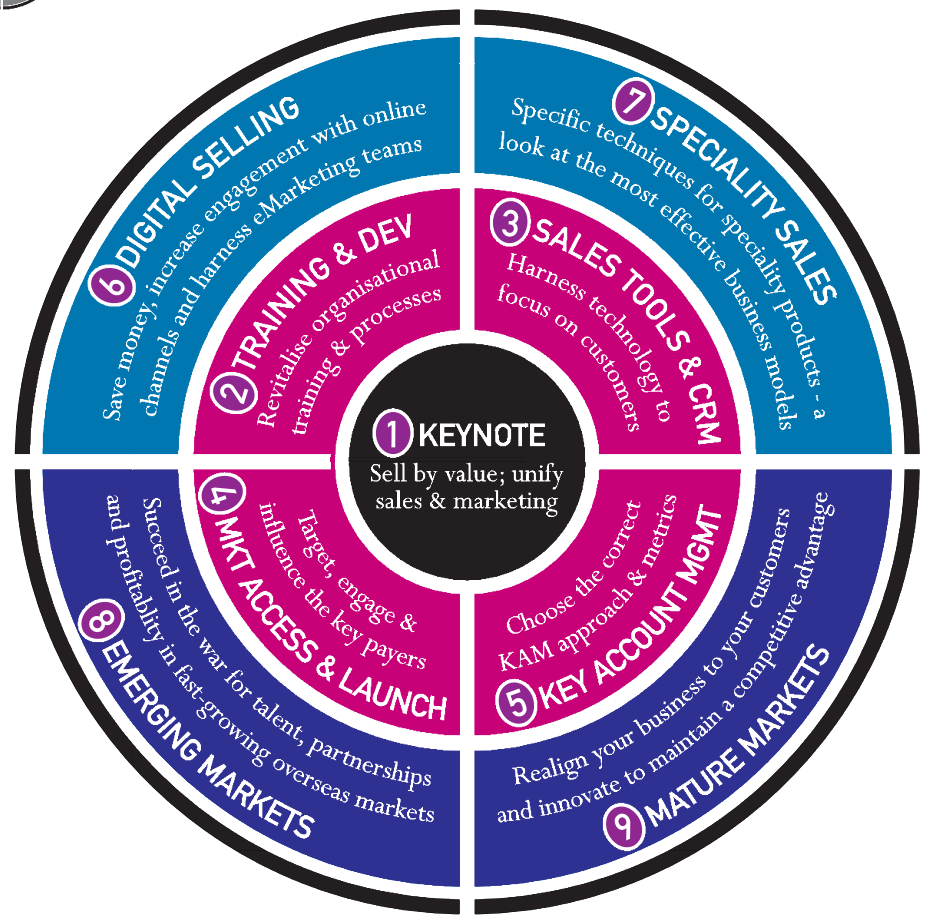

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Pharma VOICE

THERAPEUTIC MARKET FAST TRAX...

ANEMIA

Branded erythropoietin stimulating agents (ESAs) are expected to lose $17.3 billion in combined sales to biosimilar erosion over the 2009-to-2019 period across the seven major pharmaceutical markets of the United States, France, Germany, Italy, Spain, the United Kingdom, and Japan, with $3 billion in lost sales occurring in 2019 alone.

Source: Decision Resources, Biosimilars Advisory Service: Physician Perspectives on Erythropoietin Stimulating Agents, Insulin, and Human Growth Hormone.

For more information, visit decisionresources.com.

The anemia market posted a compound annual growth rate (CAGR) of 7.4% between 2001 and 2009, for an estimated value of $10.4 billion in 2009. But the market is expected to decline during the period from 2009 to 2017 amid safety concerns surrounding the use of erythropoietin stimulating agents (ESAs), as well as the market entry of biosimilar agents in Europe and their impending introduction in the United States.

Source: GlobalData, Anemia - Pipeline Assessment and Market Forecasts to 2017.

For more information, visit globaldata.com.

BIOTECHNOLOGY

Experts predict that an approved oligonucleotide drug based on RNA interference (RNAi) technology may be about one to three years away from approval, with the approval of Quark's systemically delivered kidney-targeting RNAi drug QPI-1002 occurring soon thereafter. Other systemically delivered oligonucleotide drugs that target organs and tissues other than liver or kidney may be a long way off, and the timing of their appearance would be difficult to predict.

Source: Insight Pharma Reports, RNAi Therapeutics: Second-Generation Candidates Build Momentum.

For more information, visit insightpharmareports.com.

Antibodies as a therapeutic modality and technology have matured, and availability of new technologies as well as patent expirations offer a multitude of new options when designing an antibody-based product. As of October 2010, 34 original therapeutic monoclonal antibodies and Fc-fusion proteins are on the market, with 2009 sales exceeding $45.4 billion.

Source: La Merie S.L., Antibody Technology Companies 2010.

For more information, visit marketresearch.com.

CANCER

The oncology market has witnessed a sizeable shift away from cytotoxic and antihormonal therapies toward the more lucrative targeted therapies/immunotherapies class in the last decade. Between 2010 and 2019, conditions in the oncology market will support relatively high growth rates for the targeted therapies and immunotherapies currently on the market, with combined sales in this category growing at a CAGR of 6.6% from $19.5 billion in 2009 to $36.8 billion in 2019.

Source: Datamonitor, Commercial Insight: Cancer Targeted Therapies and Immunotherapies -Top monoclonal antibody brands will resist competitive pressures through to 2019.

For more information, visit datamonitor.com.

CARDIOVASCULAR

The acute ischemic stroke (AIS) drug market is expected to increase from $460 million in 2009 to about $610 million in 2019 in the United States, France, Germany, Italy, Spain, the United Kingdom, and Japan. In the forecasted absence of new therapies, drug-treatment rates in AIS will grow modestly as the use of recombinant tissue plasminogen activator (rt-PA) drugs such as Genentech's Activase gradually increases, aided by a recently extended treatment window.

Source: Decision Resources, Pharmacor 2010 findings on Acute Ischemic Stroke.

For more information, visit decisionresources.com.

The global market for peripheral artery disease (PAD) therapeutics market was valued at about $606 million in 2009 and is expected to reach $1 billion by 2017, for a CAGR of 6.5%. Growth will be driven primarily by an increase in disease incidence and the launch of new, first-in-class PAD therapeutics.

Source: GlobalData, Peripheral Arterial Disease (PAD) - Pipeline Assessment and Market Forecasts to 2017.

For more information, visit globaldata.com.

CENTRAL NERVOUS SYSTEM

The global market value for drugs to treat central nervous system (CNS) disorders is anticipated to reach an estimated $79 billion in 2010 and increase to almost $82 billion in 2015, for a five-year CAGR of 0.7%, as increased sales of epilepsy/convulsion therapeutics help to offset anticipated declines in the two largest CNS segments, psychiatry and depression.

Source: BCC Research, Therapeutic Drugs for Central Nervous System (CNS) Disorders: Technologies and Global Markets.

For more information, visit bccresearch.com.

CONTRACTING

Annual growth in drug sponsor spending for contract clinical services over the last decade has outpaced annual increases in global spending on new drug development, 13.4% versus 9.1%. But researchers note this reliance on CROs has been rewarded, with greater use of CROs associated with faster development at comparable quality to projects with little to no CRO use.

Source: Tufts Center for the Study of Drug Development, Executive Forum Roundtable, Outsourcing Strategies Across the Value Chain.

For more information, visit csdd.tufts.edu.

DRUG DELIVERY

Pharmaceutical companies are increasingly adopting various drug delivery systems to enhance their product efficacy and patient compliance and to extend patent lives through innovative repositioning and reformulations of existing drugs. As a result, the overall drug delivery market is forecast to grow from $101 billion in 2009 to $199 billion in 2016, at a CAGR of 10.3%.

Source: GBI Research, Oral Drug Delivery Market - Controlled and Sustained Release to be Major Revenue Generators.

For more information, visit gbiresearch.com.

As people live longer and advance in age, the incidence of several types of chronic and acute pain are expected to increase significantly, driving growth in transdermal pain drug products at a CAGR of 9.8% over the next five years to $9.2 billion by 2015. Because they possess several features that improve patient safety and compliance, pain drugs formulated for transdermal delivery are well-positioned to capitalize on the growing market for pain management.

Source: Greystone Research Associates, Transdermal Pain Management to 2015.

For more information, visit greystoneassociates.com.

The global top 10 drug delivery technologies market is expected to grow from $43.8 billion in 2009 to $81.5 billion in 2015, at an estimated CAGR of 11%. The time-release technologies category holds the largest share of the overall top 10 drug delivery technologies market, owing to the immense popularity of once-daily formulations.

Source: MarketsandMarkets, Top 10 Drug Delivery Technologies (2010 - 2015).

For more information, visit marketsandmarkets.com.

EMERGING MARKETS

Clinical development executives ranked India as the emerging market with the greatest patient availability for clinical studies, followed closely by China. With regard to patient retention, China — with the largest population of any country — took the top spot, followed by India.

Source: Cutting Edge Information, Emerging Markets Clinical Development Series: BRIC.

For more information, visit cuttingedgeinfo.com.

THERAPEUTIC MARKET FAST TRAX...

INFECTIOUS DISEASE

The leading driver of antibiotic selection in nosocomial pneumonia in the United States is activity against key drug-resistant pathogens. For example, surveyed physicians indicate the excellent bactericidal activity and lung penetration of Pfizer's Zosyn are primary reasons for its success in the nosocomial pneumonia drug market, while Johnson & Johnson's success with Levaquin is driven by a high level of experience among surveyed physicians, as well as relatively high activity against nosocomial pneumonia pathogens, low dosing frequency, and dual IV/oral formulation.

Source: Arlington Medical Resources, Hospital Anti-Infectives Insight Series: Nosocomial Pneumonia.

For more information, visit amr-data.com.

The methicillin-resistant Staphylococcus aureus (MRSA) drug market is projected to increase from $631 million in 2009 to $752 million in 2019 in the United States, France, Germany, Italy, Spain, the United Kingdom, and Japan. Growth will be driven by the uptake of several emerging agents such as Forest/AstraZeneca/Takeda's ceftaroline (Teflaro) and Trius Therapeutics' torezolid, a second-generation oxazolidinone.

Source: Decision Resources, Pharmacor 2010 findings on Methicillin-resistant Staphylococcus aureus (MRSA).

For more information, visit decisionresources.com.

MULTIPLE SCLEROSIS

The global market for multiple sclerosis drugs and biologics was valued at an estimated $11.3 billion in 2010, and is expected to increase to almost $16.7 billion in 2015, for a five-year CAGR of 8.1%. Although the market's largest category, biologics, is only expected to increase at a CAGR of 2.5% over the five-year period, small-molecule compounds are expected to post a five-year CAGR of 17.4%, for a market value of $7.9 billion in 2015.

Source: BCC Research, Multiple Sclerosis (MS) Drugs And Biologics: Technologies And Global Markets.

For more information, visit bccresearch.com.

Both physicians and patients are eagerly anticipating the arrival of new oral therapies for multiple sclerosis (MS), with initial research showing one-third of MS patients are aware that new oral candidates are under development. Physicians are paying particular attention to Novartis's Gilenya, which received FDA approval for relapsing forms of the disease in late September 2010. About 60% of neurologists surveyed expect Gilenya to be very useful as a therapy.

Source: GfK HealthCare, Multiple Sclerosis MD Continuous Tracker and Multiple Sclerosis Patient Continuous Tracker.

For more information, visit gfkhc.com.

PROTEIN THERAPEUTICS

The global protein therapeutics market is expected to grow at a CAGR of around 12% during the period from 2010 to 2013. With the advent of new technologies and genetic and chemical techniques, the protein therapeutics industry has ensured a competitive edge in developing improved protein- and peptide-based therapeutics.

Source: RNCOS, Global Protein Therapeutics Market Analysis.

For more information, visit rncos.com.

PSORIASIS

Four out of five surveyed psoriasis patients in the United States who have requested a brand indicate that physicians are willing to comply with their request to be prescribed a specific drug. But only 20% of surveyed patients indicate that they have asked for a psoriasis drug by name, a finding that suggests marketers of psoriasis therapies could improve their products' uptake by increasing patient awareness of their drugs through physicians, websites, and patient advocacy groups.

Source: Decision Resource, Patient Forum, Underserved Moderate-to-Severe Psoriasis Patients Offer Opportunity for Recently Launched and Emerging Agents.

For more information, visit decisionresources.com.

TECHNOLOGY

The rising demand for healthcare cost containment and need to improve quality of healthcare service are driving the growth of the worldwide electronic medical records (EMR) market. The global market for EMRs is projected to grow from an estimated $4.36 billion in 2009 to $9.96 billion in 2015, for an estimated CAGR of 14.9%.

Source: MarketsandMarkets, Worldwide Electronic Medical Records (EMR) Market, 2010-2015.

For more information, visit marketsandmarkets.com.