By Carolyn Gretton

Life-Sciences Companies Face Increased Complexity in

Aggregate Spend Tracking and Reporting

TREND: Aggregate spend mandates within the life-sciences industry are continuing to evolve in 2012 amid ongoing changes to state disclosure laws, the addition of new corporate integrity and deferred prosecution agreements, and institutional requirements compelling disclosure.


Manny Tzavlakis

Huron Consulting Group's Huron Life Sciences practice recently outlined four major aggregate spend issues expected to receive attention in 2012. Manny Tzavlakis, managing director of Huron Life Sciences, cites the implementation of healthcare professional (HCP) and healthcare organization (HCO) relationship management as one key area that life-sciences companies need to address.

"It will be imperative to understand how and if HCP and HCO reactions to transparency may impact a manufacturer's existing business model," Mr. Tzavlakis says. Some actions recommended by Huron include establishing a call center or other response mechanism and potentially increasing specific resources to handle HCP and HCO spend inquiries and disputes.

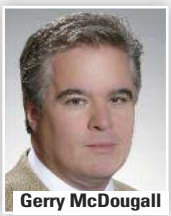
"Preparing a Sunshine Act awareness campaign to educate HCPs and HCOs as well as all corporate functions interacting with HCPs/HCOs is critical; this will enable a consistent, corporatewide response to HCP/HCO inquiries," Mr. Tzavlakis adds.

Other key aggregate spend trends and issues cited by Huron include accurate capture and disclosure of clinical trial data; continuing reporting obligations; and impact on commercial operations and clinical groups.

"Companies must modify their contracts with their CROs, establish appropriate service-level agreements, and ensure CROs are capturing key data," Mr. Tzavlakis says.

For more information, visit huronconsultinggroup.com/lifesciences.

In Vitro Diagnostic Sector Prospects CONTINUE TO SURGE


Gerry McDougall

Investor interest in the global in vitro diagnostics (IVD) market is expected to grow in the 2012-to-2014 period following a surge in M&A deal values, an acceleration of companion diagnostics partnerships, and the emergence of new prospects for early detection testing.

According to Diagnostics 2011, PwC's biennial review of the IVD sector, interest in the IVD market is coming not only from existing players, but also new entrants such as financial investors, life-sciences research groups, clinical laboratories, and medical technology players. PwC expects the IVD competitive landscape to be redefined by new market leaders and larger deals. But analysts note that sustained momentum of companion diagnostics partnerships with pharmaceutical companies depends on actions by governments, regulators, payers, and industry to support diagnostics innovation.


Loic Kubitza

"With science and technology advancing so rapidly, and with in vitro diagnostics offering much promise, pharmaceutical companies can't ignore the role of diagnostics in their future strategies," observes Gerry McDougall, principal, healthcare advisory services, PwC US. "The surge in deal activity and the diversity of buyers highlights a widespread belief in the growth prospects of selected IVD market segments, as well as the potential for cross-industry synergies."

As pharmaceutical companies pursue external partnerships to access diagnostic innovation, the PwC report outlines several business models that have emerged as regards to their in-house diagnostics capability. Development of a stand-alone diagnostics division may provide technology that is relevant for in-house drug-diagnostic cooperation, while creation of a diagnostics business unit within the pharma division may help develop diagnostics primarily to support in-house drug development programs, the report notes.

"The IVD sector has attracted exceptional levels of interest, reflected in the acceleration of com-

IVD MARKET SALES BY SEGMENT

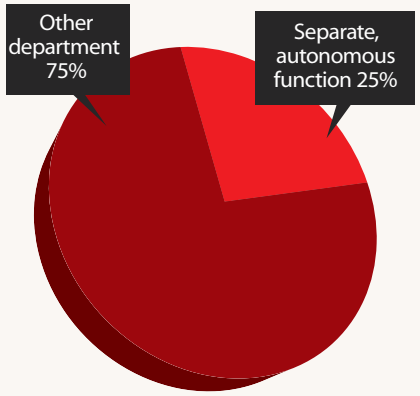
Market Segment	2009 sales (billions)	2014 E sales (billions)	CAGR 2009-2014E	Market Dynamics
Professional Diagnostics	$29	$36	5%	Driven by testing efficiency and unmet medical needs. Serum work area is largest segment.
Diabetes Monitoring	$8	$9.5	3%	Market growth declining due to pricing pressure.
Molecular Diagnostics	$3	$6	11%	Fastest-growing market segment. HPV and other cancer and genetic testing are key growth drivers.
Tissue Diagnostics	$2	$3	9%	Driven by continued lab automation and new cancer tests.
TOTAL	**$42**	**$53**	**5%**	

Source: Roche presentation, as cited in PwC's Diagnostics 2011 report.
For more information, visit pwc.com.

panion diagnostics partnerships with pharmaceutical companies," says Loic Kubitza, director, pharmaceutical and life sciences advisory services, PwC Luxembourg, and author of the report.

For more information, visit pwc.com.

PERCENTAGE OF SURVEYED COMPANIES WITH SEPARATE, AUTONOMOUS MARKET ACCESS FUNCTION



Source: Cutting Edge Information, Market Access Management: Building Teams That Deliver Value to Payers. For more information, visit cuttingedgeinfo.com.

Early Planning Poses Danger to MARKET ACCESS TIMING

As pharmaceutical and biotechnology companies continue moving market access activities to much earlier in the drug development process, they run the risk of growing complacent in their handling of key pricing, reimbursement, and pharmacoeconomic decisions.

According to the Cutting Edge Information study, Market Access Management: Building Teams That Deliver Value to Payers, market access teams have undergone a swift evolution as new product pipelines stumbled and managed markets, payer relationships, and other market access concerns gained in strategic importance. Today, almost every pharmaceutical company sets market access goals starting in Phase II of the clinical development process. At this early stage, however, it can be difficult to outline all the details of market access strategy because even the best forecasting models cannot predict every factor, the study notes.

"Unfortunately, by making market access just one more item on the checklist, companies devalue its purpose," observes Shaylyn Pike, senior research analyst at Cutting Edge Information. "Market access has grown into a proactive strategy, but some companies have become too reliant on starting early rather than starting smart."

The study recommends companies give their market access teams the freedom and flexibility to elevate each brand to its optimal market access position. "Market access might be best viewed like music," Ms. Pike says. "To be proficient requires not only years of technical practice but also instinct, an innate sense of flow and harmony that could never be truly explained in words, statistics, or metrics."

For more information, visit cuttingedgeinfo.com.

More than Momentum SHOULD GUIDE R&D INVESTMENTS IN CHINA

While the global biopharma industry has been grappling with a steady decline in R&D productivity and a long-feared patent cliff, China's R&D environment has been flourishing, prompting industry players to ramp up their China-based R&D activity.

According to the Boston Consulting Group (BCG) report, Biopharma R&D in China: Making Bets Pay Off, China's pharmaceutical market is on track to become the second-largest market in the world by 2015, with more than $100 billion in revenue and annual growth of 20%, driven largely by expanded access to care. An in-country R&D presence provides a good foothold for foreign companies looking to capitalize on this opportunity, the report notes.

Over the next five years China's CRO sector is expected to evolve to include high-quality, one-stop shops, making it easier for multinationals to continue to push the boundaries of R&D in China. BCG advises multinationals to maximize their investments in China through externalizing R&D activities, creating networks to access new sources of innovation, and pursuing new-drug discovery efforts in China.

For more information, visit bcg.com.

E-Prescribing Proves Safe EFFICIENT DESPITE BARRIERS

Physician practices and pharmacies generally view electronic prescribing as an important tool to improve patient safety and save time, but both groups face barriers to realizing the technology's full benefit.

According to a study funded by the U.S. Department of Health and Human Services' (HHS) Agency for Healthcare Research and Quality (AHRQ), e-prescribing has multiple potential benefits, including helping to reduce the risk of medication errors caused by illegible or incomplete handwritten prescriptions.

The study focused on a key aspect of e-prescribing: the electronic exchange of prescription data between physician practices and pharmacies, which can save time and money by streamlining the way in which new prescriptions and renewals are processed.

Physician practices and pharmacies generally were positive about the electronic transmission of new prescriptions, the study found. But prescription renewals, connectivity between physician offices and mail-order pharmacies, and manual entry of certain prescription information by pharmacists — particularly drug name, dosage form, quantity, and patient instructions — continue to pose problems.

"Physicians and pharmacies have come a long way in their use of e-prescribing, and that's a very positive trend for safer patient care and improved efficiency," says AHRQ Director Carolyn Clancy, M.D. "This study identifies issues that need attention to improve e-prescribing for physicians, pharmacies, and patients."

For more information, visit ahrq.gov.

Other market insights…

Monoclonal Antibody Product DEVELOPMENT CONTINUES GROWTH

Developers are steadily increasing the number of monoclonal antibody products (mAbs) for which they are initiating clinical studies, extending a trend that began in the 1990s. According to the Tufts Center for the Study of Drug Development, the number of novel mAbs entering clinical study worldwide annually rose from 19 in 1997 to 53 in 2010, peaking at 54 in 2008. This continues a trend dating back to the mid-1990s when about a dozen mAb candidates entered clinical study each year, a recently completed Tufts CSDD analysis found.

For more information, visit csdd.tufts.edu.

Brazil's Healthcare MARKET STRENGTHENS

The Brazilian healthcare market continues its fast-paced growth backed by several factors, such as strong government support and high healthcare demand as the standard of living continues to rise. According to the RNCOS report, Brazil Healthcare Market Analysis, healthcare spending in the country is expected to record a compound annual growth rate (CAGR) of around 4.5% during the 2011-to-2014 period.

For more information, visit rncos.com.

API Market Expected to EXCEED $159 BILLION BY 2016

The active pharmaceutical ingredient (API) market is facing a period of unprecedented growth as market dynamics continue to shift toward generic drugs with the expiration of U.S. patents for a number of bestselling drugs and the shrinking of R&D pipelines caused by the global economic crisis. The MarketsandMarkets report, Active Pharmaceutical Ingredient (API) Market Trends, Competitive Landscape and Global Forecasts (2011-2016), estimates the overall API market was valued at $101.08 billion in 2010 and projects the sector to record CAGR of 7.9% to reach $159.08 billion in 2016.

For more information, visit marketsandmarkets.com.

Consumers Increasingly ADOPT MOBILE HEALTH

The mobile revolution has already been in full swing among physicians for the past few years, but consumers have lagged behind until just recently. According to Manhattan Research's Cybercitizen Health U.S. 2011 study, as of the third quarter of 2011, 26% of the U.S. adult population is using mobile phones for health information and tools. Still, the report notes, consumer mobile health is fairly early in the game and centers more around information-gathering rather than using devices to support care.

For more information, visit manhattahresearch.com. PV

KEY E-PRESCRIBING STUDY FINDINGS

- **Physician practices and pharmacies used e-prescribing features for electronic renewals much less often than for new prescriptions.** More than a quarter of the community pharmacies reported that they did not send electronic renewal requests to physicians. Similarly, one-third of physician practices had e-prescribing systems that were not set up to receive electronic renewals or only received them infrequently.
- **About three-quarters of physician practices reported problems sending new prescriptions and renewals electronically to mail-order pharmacies.** Many practices were unsure which mail-order pharmacies accepted e-prescriptions and believed that, even when a mail-order company did accept them, the process was unreliable.
- **Nearly half of pharmacies reported that patient instructions typically had to be rewritten for patients to understand them.** Pharmacies also noted the need to sometimes manually edit certain prescription information, such as drug name, dosage, and quantity. One common cause reported by both physicians and pharmacists was that physicians must select medications with more specificity when e-prescribing and make decisions about such factors as packaging and drug form. Such decisions had typically been made by pharmacists for handwritten prescriptions.

Source: Agency for Healthcare Research and Quality, Transmitting and processing electronic prescriptions: Experiences of physician practices and pharmacies. For more information, visit ahrq.gov.

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THERAPEUTIC MARKET FAST TRAX...

ALLERGY

The allergic rhinitis therapeutics market was worth an estimated $4.41 billion in 2010 in the United States, the United Kingdom, France, Germany, Italy, Spain, and Japan. The market is forecast to decline at a compound annual growth rate (CAGR) of 1.3% to slightly more than $3.98 billion by 2018 amid the expected U.S. patent expiries of Astelin (azelastine hydrochloride), Nasonex (mometasone furoate), Nasacort AQ (triamcinolone acetonide), and Rhinocort Aqua (budesonide). Nasacort AQ will lose its patent protection in Europe in 2017.

Source: GlobalData, Allergic Rhinitis Therapeutics - Pipeline Assessment and Market Forecasts to 2018.

For more information, visit globaldata.com.

ANTIBACTERIAL

World revenue for antibacterial drugs is forecast to reach $43.81 billion in 2016, with the global market posting an estimated CAGR of 2.2% between 2010 and 2022. Cephalosporins are expected to remain the largest sector of the market throughout the forecast period, with revenue growing to $11.67 billion by 2016.

Source: visiongain, Antibacterial Drugs: World Market Prospects 2012-2022.

For more information, visit visiongain.com.

ANTIVIRAL

The hepatitis C virus drug market is expected to experience dramatic near-term growth, increasing from $1.7 billion in 2010 to $16 billion in 2015 in the United States, France, Germany, Italy, Spain, the United Kingdom, and Japan. This robust growth will be driven primarily by the launch of novel premium-priced agents that will increase the size of the drug-treated population, mainly as a result of the re-treatment of prior nonresponder patients. After 2015, the market will decrease to an estimated $11.3 billion in 2020, because of a decline in the size of the treatment-eligible population as disease prevalence declines and effective new regimens become available.

Source: Decision Resources, Pharmacor findings on Hepatitis C Virus.

For more information, visit decisionresources.com.

ASTHMA

Despite the uptake of high-priced, once-daily combinations and novel anticytokine agents, generic erosion and increased product competition are predicted to lead to a relatively flat asthma drug market over the next decade. The overall asthma drug market is projected to decrease slightly from $14.6 billion in 2010 to $14.4 billion in 2020 in the United States, France, Germany, Italy, Spain, the United Kingdom, and Japan.

Source: Decision Resources, Pharmacor findings on Asthma.

For more information, visit decisionresources.com.

AUTOIMMUNE

The global market for autoimmune treatments, estimated at $34 billion in 2010, is expected to reach $38.9 billion by 2011 and further expand to $55 billion by 2016 at a CAGR of 7.2%. The United States, the largest market for autoimmune treatments, holds 43% of market share and is expected to sustain its position with 44% of market share in 2016.

Source: BCC Research, Drugs and Treatments for Autoimmune Diseases: Global Markets.

For more information, visit bccresearch.com.

The unmet need for a convenient and safe rheumatoid arthritis (RA) treatment option without adverse side effects has set the stage for a spate of drug launches in the near future. As a result of this demand, some of the current pipeline drugs have the potential to be blockbusters, especially the oral treatments in late-stage development. The market for RA earned estimated revenue of $5.78 billion in 2010 and is expected to increase to $8.34 billion in 2017.

Source: Frost & Sullivan, U.S. Rheumatoid Arthritis Market: Assessment of Biologics and New Treatments.

For more information, visit pharma.frost.com.

The global osteoarthritis therapeutics market was worth an estimated $4.4 billion in 2010 and is forecast to show slow CAGR of 3.8% to reach $5.9 billion by 2018. The current treatment options for osteoarthritis offer only symptomatic relief, and the market is primarily dominated by generics.

Source: GlobalData, Osteoarthritis Therapeutics - Pipeline Assessment and Market Forecasts to 2018.

For more information, visit globaldata.com.

Led by biologic therapies, the market for prescription arthritis treatments is forecast to exceed $20 billion in 2011. Drugs that attack tumor necrosis factor (TNF) led the market to 7.3% revenue growth in 2010, and this type of growth is expected to continue.

Source: Kalorama Information, The World Market for Prescription Arthritis Treatments.

For more information, visit kaloramainformation.com.

Revenue for disease-modifying treatments for multiple sclerosis is forecast to rise to $15.8 billion annually in 2015, with strong revenue growth in established and developing pharmaceutical markets, especially the United States, Japan, and the United Kingdom.

Source: visiongain, Multiple Sclerosis Treatment: World Drug Market 2012-2022.

For more information, visit visiongain.com.

CANCER

As the pharmaceutical industry continues to win new approvals and indications for cancer therapies, the global oncology market is on track to reach $75 billion by 2013. While the United States dominates the oncology market, it is also one of the most daunting countries for new products to penetrate. Faced with an increasingly challenging marketplace, pharmaceutical and biotech companies have come to recognize the value of market education in winning support among the key oncology stakeholders that can help new products gain a foothold.

Source Best Practices, Shaping the Marketplace to Support Successful Oncology Product Launches: Tactics for Educating KOLs, Physicians, Patients and Payers.

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

Specialty pharmaceutical products are often biologically derived and dispensed to treat individuals with chronic or rare diseases. One of the fastest-growing therapeutic areas in the specialty pharmaceutical segment, oncology, comprises 46% of annual sales volume for specialty distributors in this sector, or about $13.3 billion.

Source: Center for Healthcare Supply Chain Research, 2011 Specialty Pharmaceuticals: Facts, Figures and Trends.

For more information, visit hcsupplychainresearch.org.

In 2020, biosimilar versions of monoclonal antibodies for oncology indications will reach more than $4 billion in sales in the United States, France, Germany, Italy, Spain, the United Kingdom, and Japan. Biosimilar versions of rituximab (Biogen Idec/Roche/Chugai/Zenyaku Kogyo's Rituxan/MabThera) could be approved as early as 2013 in Europe, paving the way for biosimilar versions of other monoclonal antibodies including Bristol-Myers Squibb/ImClone/Lilly/Merck Serono's Erbitux and Roche/Genentech/Chugai's Herceptin and Avastin.

Source: Decision Resources, Biosimilars Advisory Service: Physician Perspectives on Biosimilar G-CSFs and MAbs in Oncology.

For more information, visit decisionresources.com.

The acute lymphocytic leukemia therapeutics market, valued at about $1.96 billion in 2010, is expected to reach $3.88 billion by 2020, at a CAGR of 5.21% between 2015 and 2020. In 2010, the market was dominated by Hyper-CVAD regimen; but in 2020 the market is expected to be equally dominated by Hyper-CVAD and Linker regimen.

Source: MarketsandMarkets, Acute Lymphocytic Leukemia Therapeutics Market (Pipeline Forecast & Market Forecast in G8 Countries) (2010 - 2020).

For more information, visit marketsandmarkets.com.

The chronic lymphocytic leukemia therapeutics market in G8 countries was valued at an estimated $437 million in 2010 and is expected to increase at a CAGR of 13% from 2015 to 2020. Campath accounted for the largest share (42.3%) of the chronic lymphocytic leukemia therapeutics market in G8 countries in 2010; but in 2020 the market is expected to be dominated by the drug Arzerrag and the GA101/RG7159 molecule, with sales of $603 million and $994 million, respectively.

Source: MarketsandMarkets, Chronic Lymphocytic Leukemia Therapeutics Market in G8 Countries (2010 - 2020).

For more information, visit marketsandmarkets.com.

The leukemia therapeutics market, valued at about $6.3 billion in 2010, is expected to reach $11.3 billion by 2020, recording a CAGR of about 3.8% between 2015 and 2020. The market was dominated by chronic myeloid leukemia in 2010; but in 2020 the market is expected to be equally dominated by acute lymphocytic leukemia and chronic myeloid leukemia, with sales in these categories amounting to $3.91 billion and $3.58 billion, respectively.

Source: MarketsandMarkets, Leukemia Therapeutics Market (Acute/Chronic Lymphocytic Leukemia & Acute/Chronic Myeloid Leukemia) Pipeline Assessment & Global Market Forecast (2010 - 2020).

For more information, visit marketsandmarkets.com.

The lung cancer drugs market was valued at around $4 billion in 2010 and is expected to reach about $13 billion by 2020, for a CAGR of 13.5% from 2015 to 2020. The market was dominated by drugs such as Avastin, Iressa, Gemzar, and Tarceva in 2010. But by 2020, the market is expected to be dominated by talactoferrin (Agennix), an immunomodulatory drug; followed by Xalkori (Pfizer), and by ARQ 197 (ArQule/Daiichi Sankyo).

Source: MarketsandMarkets, Lung Cancer Drugs Market in G7 Countries (2005 - 2020).

For more information, visit marketsandmarkets.com.

The global prostate cancer therapeutics market was valued at an estimated $2.71 billion in 2010 and is expected to reach almost $6.46 billion by 2020. It is projected that the market will post CAGR of 11.4% from 2010 to 2015, with CAGR slowing to 6.8% from 2015 to 2020.

Source: MarketsandMarkets, Prostate Cancer Therapeutics Market (2010-2020) (Opportunity Analysis, Pipeline Assessment and Global Market Forecast).

For more information, visit marketsandmarkets.com.

The global cancer generics market is anticipated to post a CAGR of around 27% during the period from 2010 to 2014. Growth is likely to be driven by upcoming patent expirations of anticancer blockbuster drugs and the rising bill for oncology drugs encouraging payers to address the barriers to generics access in order to control costs.

Source: RNCOS, Cancer Generics Market Analysis.

For more information, visit rncos.com.

CARDIOVASCULAR

The acute coronary syndrome (ACS) drug market in China is projected to grow from $326 million in 2010 to $448 million in 2015, with AstraZeneca's Brilinta (ticagrelor) exceeding sales of Sanofi's Plavix (clopidogrel) in the treatment of ACS, making Brilinta the top Western brand in the ACS therapeutic market in China in 2015.

Source: Decision Resources, Emerging Markets report, Acute Coronary Syndrome in China.

For more information, visit decisionresources.com.

The drug eluting balloons market is expected to post a CAGR of 8.1% to $127 million by 2017, driven by increased physician adoption as long-term clinical data is released and as the device is adopted for new indications such as peripheral vascular disease.

Source: GlobalData, Drug Eluting Balloons (DEB) - Global Pipeline Analysis, Competitive Landscape and Market Forecasts to 2017.

For more information, visit globaldata.com.

The global market for coronary stents came in at an estimated $6.01 billion in 2011 and is expected to reach $8.29 billion in 2016, for a CAGR of 6.6% over the period from 2010 to 2016. The drug eluting stents segment is the leading market contributor, with a share of around 55% to 60% in 2010.

Source: Transparency Market Research, Global Drug Eluting (DES), Bare Metal (BMS) and Other Coronary Stents Market (2011 - 2016).

For more information, visit transparencymarketresearch.com.

CENTRAL NERVOUS SYSTEM

The global market for drugs to treat central nervous system (CNS) conditions posted an eight-year CAGR of 4.7% to reach $53.1 billion in 2010, from $36.8 billion in 2002. The CNS market — which includes Alzheimer's disease, multiple sclerosis, Parkinson's disease, diabetic neuropathy, major depressive disorder (MDD), bipolar disorder, schizophrenia, insomnia, epilepsy, attention deficit hyperactivity disorder (ADHD), and migraine — is expected to witness fluctuations as a result of patent expiries followed by generic erosion, and it is forecast to experience slow CAGR of 1.4% between 2010 and 2017, when it is projected to reach $58.6 billion.

Source: GBI Research, Central Nervous System Disorders Therapeutics Market to 2017 - Multiple Sclerosis, Major Depressive Disorder and Schizophrenia Accounted for Half the Market Value in 2010.

For more information, visit gbiresearch.com.

GASTROINTESTINAL

A recent survey of U.S. gastroenterologists finds that about two-thirds of the surveyed physicians feel that there is a high unmet need for new agents to treat ulcerative colitis (UC), second only to the need for new therapies for irritable bowel syndrome. Less than 40% percent of the respondents report that they are satisfied with the current treatment options, and about 80% of respondents noted changes in their practice patterns for UC over the past year, with the greatest change related to earlier, more aggressive use of biologic agents.

Source: BioTrends Research Group, TreatmentTrends: Ulcerative Colitis.

For more information, visit bio-trends.com.

RESPIRATORY

The global cystic fibrosis (CF) therapeutics market was valued at $622.9 million in 2005 and expanded at a CAGR of 12% to come in at just under $1.1 billion in 2010. The market is forecast to post a CAGR of 10.7% to an estimated $2.47 billion by 2018, primarily as a result of an increase in the annual cost of treatment due to the expected launch of novel, premium priced therapies VX-770 and Ataluren during the forecast period. VX-770 is expected to be launched in late 2012, and Ataluren in 2014.

Source: GlobalData, Cystic Fibrosis Therapeutics - Pipeline Assessment and Market Forecasts to 2018.

For more information, visit globaldata.com.