By Carolyn Gretton

Compliance Programs

Make Room for Integrity Agreements

TREND: Pharmaceutical, medical device, and biotech companies of all sizes are entering into the complex world of corporate integrity agreements.


Paul Silver


Tracy Mastro

While 2011 was considered a slow year for new corporate integrity agreements (CIAs), a recent Huron Life Sciences white paper predicts that based on the number of government inquiries that have been announced in the last several years, it is likely that there will be an increasing number of new CIAs announced in the near future.

Companies enter into CIAs, and accept their obligations, in exchange for an agreement by the Office of the Inspector General (OIG) of the U.S. Department of Health and Human Services (HHS) that it will not seek the company's exclusion from participating in Medicare, Medicaid, and other federal healthcare programs. After a CIA is signed, there are typically 120 days to implement.

According to the Huron white paper, Understanding the Key Challenges when Entering into a Corporate Integrity Agreement, companies should be proactive by making changes even before the CIA is signed in order to avoid a potentially agonizing four-month implementation period.

"While most companies have a general understanding of CIAs, some companies might be surprised to learn how monumental the task is of incorporating all their requirements into daily operations," says Paul Silver, managing director, Huron Life Sciences. "Implementation of a CIA can be a significant change management effort."

"Companies should enter into a CIA with the advanced planning and preparation that will position them for success and should begin by benchmarking their compliance programs against the most recent CIAs to determine where current policies, procedures, processes, and systems could be improved," adds Tracy Mastro, senior director, Huron Life Sciences.

For more information, visit huronconsultinggroup.com.

Use of PROs in PRODUCT EVALUATIONS ON THE RISE


Dr. Yin Ho

Experts believe increased use of patient-reported outcomes (PROs) may deepen available evidence in regulatory and reimbursement decision-making.

Context Matters' recent global analysis of product evaluations for health technology assessments (HTAs), which are often influential in decision-making for approving and/or providing reimbursement for pharmaceuticals and other medical technology, found that the use of PROs increased between 2005 and 2011. The study also showed substantial variation across both nations and treatment areas in applying HTAs to such decisions.

The study suggests that increased use of PROs in product evaluations in the healthcare industry may provide additional insight as to how regulatory agencies and even manufacturers themselves decide what products to make available to the public. Ultimately, this more expansive approach may influence the availability of new treatment approaches.

"Physicians are increasingly advocating a patient-centered approach to practicing medicine, but once products are approved, reimbursement decisions tend to be more economically based," says Yin Ho, M.D., CEO of Context Matters and co-author of the study."While there has been progress in changing that paradigm, it has been very slow. Increased inclusion of PROs in analyses of things like length of treatment, appropriate comparators, and optimal launch windows may balance the patient-centered approach with economic analysis, all of which support a more robust evidence-based approach to decision-making."

The study examined the prevalence of PRO use in reviews of nine regulatory agencies worldwide from 2005 to 2011 across 19 disease areas. Among the 424 reviews examined, only 29% reported PROs, but the use of PROs did increase from 25% in 2005 to 38% in 2011. The study also demonstrated that generally, anemia in cancer, ovarian cancer,

and Parkinson's disease reviews utilize PROs at least 75% of the time, but that use by agencies varies from about 10% to about 67%.

Dr. Ho also observes that PROs were never used in any pediatric indications, even in those disease states where both adults and children were affected.

For more information, visit contextmattersinc.com.

Other market insights…

Patent Cliff Hits GLOBAL PHARMA MARKET GROWTH

According to the EvaluatePharma report, World Preview 2018: Embracing the Patent Cliff, prescription drug sales are forecast to increase by 3.1% per year between 2011 and 2018, compared with year-earlier forecasts for 4% growth per year between 2010 and 2016. The reduction in forecast growth is mainly due to the decline in the euro and the translated value of sales into U.S. dollars, the report says.

The report's geographic analysis notes that growth in the major markets of the United States, Europe, and Japan has flatlined in 2011, with projections of 0.8% U.S. growth, 3% growth in Japan, and a decline of 2.8% in Europe.

For more information, visit evaluatepharma.com.

Declining R&D Budgets Drive Drug DISCOVERY OUTSOURCING

Once an activity kept in-house at global pharmaceutical companies, the discovery of new compounds with a possible pharmacological effect is now increasingly handled by outside firms.

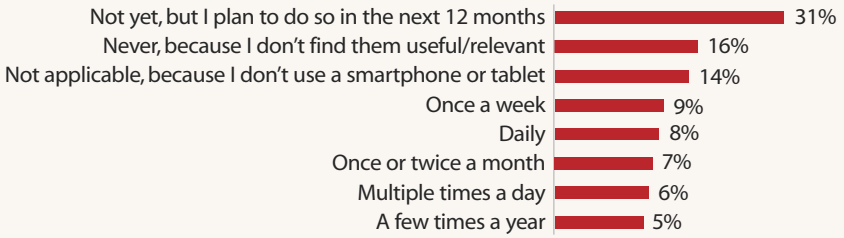
According to the Kalorama Information report, Outsourcing in Drug Discovery, the global market for outsourced drug discovery services was valued at an estimated $9.4 billion in 2011, up 15% from a year earlier. Despite the current unsettled economic environment, the drug discovery outsourcing category remains robust, with an optimistic outlook going forward.

For more information, visit kaloramainformation.com.

Chiral Technology Market is BOOMING

Experts say chiral technology is becoming an important element of rational drug design, aiding in the conception and discovery of new receptor-based or enzyme-inhibiting small molecule drugs, particularly those with high selectivity of action.

Q: HOW FREQUENTLY DO YOU USE AN APPLICATION ON A SMARTPHONE OR TABLET SPECIFICALLY DESIGNED TO SUPPORT LIFE-SCIENCES RESEARCH?



Source: BioInformatics, Ask-A-Scientist survey from June 1, 2012 . For more information, visit gene2drug.com.

According to the BCC Research report, Global Markets for Chiral Technology, the global chiral technology market was worth almost $5.3 billion in 2011 and is expected to approach $7.2 billion in 2016, for a compound annual growth rate (CAGR) of 6.5% for the forecast period.

Chiral synthesis products accounted for the majority of the chiral technology market, with estimated revenue of $4.2 billion in 2011 and projected revenue of $5.7 billion in 2016, for a CAGR of 6.4%.

For more information, visit bccresearch.com.

BRIC Markets Present Ripe Opportunity for MEDICAL DEVICE GROWTH

In its report, The Outlook for Medical Devices in Brazil, Russia, India & China, Espicom notes the impact of economic downturn on the BRIC markets has been varied. For example, the report says the Brazilian import market may be affected by disadvantageous U.S. dollar exchange rates, but China is affected more by a weak economy in the United States, its major market.

Brazil has the largest medical device market in the Latin America region, with the medical equipment and supplies market valued at about $4 billion and has a well-established medical industry comprised of local and multinational companies.

By comparison, while Russia's medical market was valued at an estimated $5.96 billion in 2011, Russian medical device manufacturers are generally small and undercapitalized, and tend to produce obsolete products that can only compete with Western products in terms of cost. The country has a strong scientific research base but has no experience of commercializing new products, the Espicom report notes.

For more information, visit espicom.com.

Funded CER Lacks PATIENT-CENTRIC FOCUS

A recent Avalere Health analysis of funded comparative effectiveness research (CER) shows that patients, caregivers, consumers, and patient advocates are eager to find ways to contribute to the prioritization, conceptualization, execution, and dissemination of CER.

But about 57% of the CER analyzed by Avalere included patient-centered outcomes such as survival, function, symptoms, and quality of life. The analysis notes that future funding has an opportunity to advance CER that is patient-centered and improves the evidence base in areas of prevention, diagnosis, and treatment.

Interviews performed as part of the analysis revealed that patients favor disease prevention over diagnosis and treatment; but only 18% of the CER evidence featured prevention as a primary focus.

For more information, visit avalerehealth.net.

Antibody Sales Forecast to SURPASS $50 BILLION MARK

The antibody therapeutics category remains a shining star of pharma, yet there is a constant push to explore new approaches as pipelines become glutted with "me-too" products.

According to the Insight Pharma Reports study, The New Generation of Antibody Therapeutics: Current Status and Future Prospects, sales of currently approved antibodies are expected to grow from an estimated $32 billion in 2008 to roughly $58 billion by 2014.

The report observes that the success of biologics, especially antibodies, has been accompanied by increasing concerns over their cost and whether it is sustainable in the long run, especially given the push toward healthcare reform.

Not only do antibodies have a high unit cost, they are frequently employed in the treatment of chronic conditions and may require dosing for years. For small-molecule drugs, costs run from pennies to as much as a dollar per day, yet biopharmaceuticals average $22 per day.

For more information, visit insightpharmareports.com. PV