THEN & NOW

PharmaVOICE asked experts who participated in last year's issue to review their predictions for 2007 and evaluate whether their forecasts came to fruition and why or why not.

(Editor's Note: Predictions are presented in alphabetical order by contributor's last name.)

SEPARATING PHARMA AND BIOTECH

Joseph Brindisi
VP, Business Development and General Counsel
Kyowa Pharmaceutical Inc.

"The numerous acquisitions by big pharma of biotech capabilities especially in the protein and antibody space have proven out my prediction from 2007."

THEN: One of the biggest trends in 2007 will be the continuing separation between pharmaceutical companies as the developers and biotech companies as the drivers of discovery efforts for development. This symbiotic relationship will enable companies, such as Kyowa, to develop more drug candidates from their science-driven discovery pipelines. This is achieved by conserving development resources and reducing business risk by using the capabilities of other leading pharmaceutical developers and manufacturers for the costly clinical development process.

Perhaps one of the biggest opportunities for 2007 is for pharmaceutical companies to acquire biotechnology and other drug-discovery capabilities from the many promising companies that exist today.

NOW: My statement that "perhaps one of the biggest opportunities for 2007 is for pharmaceutical companies to acquire biotechnology and other drug-discovery capabilities from the many promising companies that exist today" has been proven out by the numerous acquisitions by big pharma of biotech capabilities especially in the protein and antibody space with a prime example being the acquisition of MedImmune by AstraZeneca.

Kyowa Pharmaceutical Inc., Princeton, N.J., focuses on the development of innovative, internationally accepted pharmaceuticals that contribute to people's well-being and enhance the quality of life worldwide. For more information, visit kyowa-kpi.com.

INTERNET MARKETING

Stephen E. Gerard
Managing Partner
TGaS Advisors

"For Internet mareketing, we predict that more will be spent on online video content in 2008. This may be balanced by marketers spending less on sponsorships of third-party consumer health content, which, at more than $1 million per brand, has the highest average spend of any online consumer tactic."

THEN: Pharma companies will spend more on Internet marketing to reach consumers in 2007, while Internet marketing budgets to reach physicians will remain flat. Benchmark results have shown there are demonstrated performance results in using the Internet in both consumer acquisition and retention, but brands are still struggling to find a clear high-performing Internet program to reach physicians.

NOW: We were half right. Internet marketing did indeed stay flat for physicians, but it was flat for consumers as well. Within each brand, TGaS benchmark data often show large changes, but the changes even out across data for the industry. The tactical mix for consumers had one new component: online video content, although this was on a relatively small scale in 2007. We predict that more will be spent on online video content in 2008. This may be balanced by marketers spending less on sponsorships of third-party consumer health content, which, at more than $1 million, has the highest average spend of any online consumer tactic. Costs may go down with increased competition among these venues, but marketers still question how to measure ROI. Many brands are interested in social networking, but the "first mover disadvantage" of increased regulatory scrutiny will dissuade most from doing more than using these sites to place consumer media.

On the professional side, brands are still struggling to find as many outlets as possible to reach physicians via the Internet. Further restrictions in honoraria reduce the ability of brand marketers to offer as many e-details as they wanted to, although e-detailing is still the largest and most important portion of their online spend for physicians.

Many brands are talking about enterprise portals for their physicians, but most have not answered the question of the advantage over their current physician sites. Social networking for physicians will receive increased scrutiny, especially with the announcement of the Pfizer-Sermo deal. Although physician opinion monitoring remains a strong value of this channel, we have not yet witnessed a strong promotional return. Tune in next year.

TGaS Advisors, East Norriton, Pa., improves the strategy and effectiveness of pharmaceutical commercial operations through collaborative benchmarking. For more information, visit tgas.com.

REALITY-BASED MARKETING

Matt Giegerich
CEO and President
CommonHealth

"The notion of brand storytelling helps stitch the various aspects of a brand into a more meaningfully cohesive whole."

THEN: We are organizing the full network of creative talent around the principles of reality-based marketing, which is a unique approach that highlights real brand drivers across patient, provider, and payer dynamics. We are approaching all assignments from an integrated, idea-centric, and media-neutral perspective. Also, we are leveraging technology and the basic tenets of permission-based marketing across all audiences.

NOW: We are increasingly leveraging our insight tools and techniques and taking a multifaceted creative approach. We added powerful new dimensions as well, including the notion of brand storytelling, which helps stitch the various aspects of a brand into a more meaningfully cohesive whole.

CommonHealth, Parsippany, N.J., is a healthcare communications resource and a WPP Group company. For more information, visit commonhealth.com.

POSTAPPROVAL ISSUES

Richard Gliklich, M.D.
CEO
Outcome

"Once surveillance systems and safety nets for drugs and devices become more common, the groundwork for moving toward conditional approval periods will be in place and the economic benefits to the drug-development process should finally come to fruition."

THEN: One of the biggest trends that will impact drug development will come from outside development, for example postapproval. The idea of "conditional approval" periods will be much more seriously looked at in 2007. This concept would allow earlier approvals of some drugs and biologics with a conditional approval phase where the drug would be monitored closely through registries and other surveillance mechanisms.

We are seeing a tremendous growth in the number of patient registries during the drug-development phase during which companies are seeking to understand the background safety signal before they introduce a product in a particular disease area, as well as the impact on safety and effectiveness after the product is launched.

NOW: Last year, I predicted that one of the biggest trends that would impact drug development would come from postapproval and the concept of conditional approval periods would start to be more seriously looked at in 2007. With the PDUFA reauthorization, the impact of postapproval has certainly become clear; Europe is even further ahead. Furthermore, the creation of resources at the FDA to focus on postapproval through PDUFA, coupled with the significant increase in risk-management plans and requirements that have come from the FDA to sponsors in 2007 suggest that this path will continue.

Looking to 2008, I think there will continue to be incremental changes in that direction through increasing postmarket RiskMAPs and safety registries required with approvals.

Once these surveillance systems and safety nets for drugs and devices become more common, the groundwork for moving toward conditional approval periods will be in place and the economic benefits to the drug-development process should finally come to fruition. This will take several years, but we definitely expect there will be many more risk minimization plans put into place in 2008, and the FDA will require increasing structure and objective measurability.

My second prediction was that there would be a significant rise in the number of patient registries, and they would be requested earlier in the product life cycle for safety and effectiveness purposes. Since the release of the Agency for Healthcare Research and Quality (AHRQ) handbook, "Registries for Evaluating Patient Outcomes: A Users Guide" in May, for which I had the honor of serving as principal investigator, there has been a remarkable surge in the number of sponsors seeking registries for meeting risk-management safety concerns or evidence needs for reimbursement. We are also witnessing more calls for registries in national coverage determinations by the Center for Medicare and Medicaid Services.

In 2008, I expect this trend to continue to grow both nationally and internationally, as there is now a set of principles to guide good registry practices and there is clearer understanding of the role of observational research in the evidence hierarchy.

Outcome, Cambridge, Mass., is a provider of patient registries, postapproval studies, quality improvement programs, and integrated technologies for evaluating real-world outcomes. For more information, visit outcome.com.

GLOBAL ISSUES

John Hudak
President and Founder
Criterium Inc.

"If I were starting my career now, I would become a regulatory specialist for the emerging nations. They will be the MVPs of the coming year."

THEN: There will be a continued trend for big pharma consolidation as companies look for economies of scale and greater ability to compete globally; this is no surprise as many other industries have already gone through this. Also, because big pharma companies have the financial resources, they will develop more partnerships with small discovery firms, and the trend will extend to them buying many of these smaller, more successful innovators. The line between drugs and devices will blur as more devices incorporate drugs into their systems for better effect.

There will continue to be new small pharma companies developing and conducting studies on better formulations or delivery of older drugs, either under license or when the drugs become generic; the financial resources will come from venture companies while others will come from generic companies that wish to develop their own brands, as well as some of the more difficult to evaluate generics — intranasal, transdermal, inhalation products — and biosimilars — biotech products coming off patent. Overall, there will be increased concentration on, and sophistication of, generic drug development.

NOW: Increasing price pressure in the largest pharmaceutical market in the world continues to take its toll on the pharmaceutical industry, which is changing from the NIH (not invented here) philosophy to foraging for products to incorporate into their product lines. Companies are looking for new molecules and these take years to develop at great risk. The more targeted approach — monoclonal antibodies — to disease treatment means companies need more products to meet their annual revenue needs. With luck, these products, such as Genentech's Herceptin, will occasionally reap benefits. In fact, they are extending product lines and developing new formulations that extend the product life well after the molecule loses its patent protection.

The majority of our inquiries and almost every new clinical project we started in 2007 came about as a result of smaller discovery firms that were not funded by larger pharma. Their strategy is to conduct their studies outside of the United States where the costs are perceived to be less expensive, eligible patients more plentiful, and the timelines more manageable. Once they have sufficient data they are then in the position to either raise more private money, thereby retaining control of the development of their molecule, or to get funding from big pharma, which in turn may take over the development of the compound. We have been involved with smaller pharma and biotech companies that get swallowed up by the larger pharma's development processes. Is that their reward for taking risks in clinical development outside the United States or Europe? That's up to each company to decide, but it's a trend to be emphasized for the coming year.

Half of the small pharma companies we work with are reformulating known molecules into trademarked products using the 505 b 2 FDA processes that give some exclusivity at a lower risk. Large pharma companies are doing the same thing with their innovative products to extend their products' lives. It is possible that in 2008 more than half of the RFPs will involve both a known molecule with a unique delivery system, and I would expect that percentage will continue to rise over time.

Like other industries where the discount department store tries to become more high end, the more successful generic companies are moving to products with higher barriers to entry — intranasal, inhalation, and dermatological drugs that act locally in the GI tract — while offshore API

suppliers are starting to develop products that are approved based on traditional bioequivalence studies in healthy volunteers and sell these products at prices that the established generic companies cannot match. Products with higher barriers to entry mean higher risk and require bioequivalence studies with clinical endpoints.

A few generic giants have developed reformulation divisions and even espouse new molecule discovery, but each step in complexity introduces more risk and the requirement to become a fully integrated pharmaceutical company.

In last year's Year in Preview issue, I wrote about the challenge of staying on top of individual nation's unique regulatory requirements and cultural norms, and I think that this is a trend that will continue to be important in 2008.

The demands of clinical trials are shifting the focus to other parts of the globe as companies look to developing countries' patients to meet their enrollment timelines.

Criterium Inc., Saratoga Springs, N.Y., is a full-service, global CRO that offers a mix of high-quality clinical research services, real-time data acquisition, and personalized communication processes to manage a clinical trial from initial planning to approval, on time and on budget. For more information, visit criteriuminc.com.

ELECTRONIC SUBMISSIONS

John Lawrie
VP, Process Solutions
Octagon Research Solutions Inc.

"A renewed focus on core process management and improvement will be critical in the new year."

THEN: 2007 will be a transition year for many sponsor organizations as these companies move toward eCTD submission formats. In a draft proposed final rule, the FDA recently announced the withdrawal of three electronic submission guidances and has identified eCTD as the preferred format for electronic submissions. This means that as of Jan. 1, 2008, all electronic regulatory submissions to the FDA's CDER will have to be in eCTD format.

Implementation of eCTD requires process and technology changes and affects all functions that are contributing data and documentation across the drug-development life cycle.

NOW: As predicted, 2007 has indeed been a year of transition for many sponsor organizations as they have prepared for eCTD come Jan. 1, 2008. Not surprisingly, as companies began to peel back the onion of becoming ready, they found that the eCTD preparation process does not solely include the implementation of software.

The metadata and life-cycle management requirements necessitate the definition of standards to ensure regulatory submission quality and consistency and process changes for how regulatory builds submissions as well as how the upstream areas produce their documents and data. The scope of these changes has some companies looking to outsource the submission preparation efforts associated with their first eCTD while they continue to establish their capabilities.

Because of the complexity of intersecting processes, technologies, and evolving standards, we expect 2008 to be another year of transition. Competitive organizations not only want to submit in eCTD format, but they also want to do it well. A renewed focus on core process management and improvement will be critical in the new year.

Octagon Research Solutions Inc., Wayne, Pa., offers a suite of regulatory, clinical, process, and information technology solutions to the life-sciences industry to electronically transform clinical R&D. For more information, visit octagonresearch.com.

CME AND THE INTERNET

Barbara Winkelman
VP, Marketing and Multimedia
CME LLC

"Our industry needs to focus on developing more exciting, interesting, and useful formats for online education."

THEN: Many live CME programs in 2006 incorporated an online component, and we saw most clinicians taking advantage of online resources for one of two reasons: to acquire more detail than was presented in the meeting or when a clinician was unable to attend a live meeting. Clinicians continue to report an overwhelming preference for live CME events; so we expect this type of growth to continue into and beyond 2007.

The Internet's role will also expand in 2007 thanks to established annual offline events. High-quality programming from annual CME conferences and congresses is being adapted for the Internet to reach more clinicians. In 2007, expect the same and more from the Internet with regard to CME.

The Internet's growing roles in outcomes measurement and self-directed education will emerge as huge growth engines for online learning in 2007 as more providers and clinicians acknowledge and embrace the Web for its convenience and data collection strengths.

NOW: As predicted last year, the use of CME online events continued to flourish in 2007, with most CME providers expanding their offerings to include some online version. Most online activities resulted from live events and favored similar formats — video, audio, slides, and/or text. A clinician's virtual mailbox is now as crowded as his or her physical mailbox, as providers use the Internet for e-communications, e-lerts, e-newsletters, outcomes measurements, and so much more. Today, our industry needs to focus on developing more exciting, interesting, and useful formats for online education.

We have all become dependent on the Internet for immediate information and purchases, and this is no different for clinicians. As clinicians become more comfortable with using the Internet as a reliable resource for information and education, CME providers must meet their needs. Because of the very nature of their field, clinicians require accurate and trusted information, and that's where CME providers can help. Since more practices now incorporate Internet access in every exam room, the need for "trusted" information becomes greater. But the virtual classroom should do more than satisfy the demand for information — it should provide other personal features. That's where blogs and other Web 2.0 features come into play.

New ACCME regulations are not the only area CME providers are challenged with; finding the best online offering and successfully communicating with clinicians continue to be just as challenging.

Live meetings will continue to be a favorite format for learning in 2008, but cost, time, and need will strengthen the Internet's position as a strong alternative.

CME LLC, Irvine, Calif., provides lifelong learning opportunities for clinicians through a variety of convenient learning formats. For more information, visit cmellc.com. ✦

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E-mail us at feedback@pharmavoice.com.