BY ROBIN ROBINSON

LAUNCH: Safety Counts

Once a drug is approved, companies also have to consider postmarketing safety requirements.

"Approval is no longer the final step," says Anne Tomalin, president of i3 CanReg. "Companies need to consider the possibility that their product may have to be removed from the market one to two years down the road because a safety signal develops."

In addition to collecting data and managing a difficult registration process, companies must also take into consideration the new Section 905 of the FDAAA that calls for HHS to develop methods to obtain access to disparate data sources and to establish a postmarket risk identification and analysis system to link and analyze healthcare data from multiple sources. The law sets a goal to access data from 25 million patients by July 1, 2010, and 100 million patients by July 1, 2012. The law also requires the FDA to work closely with partners from public, academic, and private entities.

The FDA's focus on safety has repercussions on three levels, Ms. Tomalin says.

"Drugs, especially those taken long term, are required to have even more long-term safety data available for review: for example, recent guidelines on the development of diabetic drugs," she says. "In making the risk/benefit decision for drugs that are submitted, a more cautious approach is being taken which is resulting in fewer submissions being approved and more review cycles. And once the approval is issued there are now frequent risk management plans that require additional safety monitoring and clinical work."

Companies are being driven by the FDA's enhanced focus to employ standards, such as CDISC's SDTM, in the pooling of safety data, says Nancy Smerkanich, executive VP, global regulatory affairs, Octagon Research Solutions.

"Data standards enable the agency to take a broader view of safety, not only within studies, but also across studies and across applications," she says. "Regulatory submissions will also be scrutinized by this increased focus on safety."

"Probably the biggest current regulatory issue is the global nature of drug development and the challenge of maintaining a core repository of information that can be accessed to satisfy the requirements of multiple regions," Ms. Smerkanich adds.

The challenges don't stop there. The use of placebo-controlled trials will continue to be challenged by IRBs and some regulatory agencies as a result of the safety focus, Ms. Tomalin says.

"There is also increasing interest in comparing the 'value' of drugs against what is already on the market, similar to what has been required in Europe for some time," she adds.

Pharmacogenomics will continue to define specific subgroups of patients who are most likely to respond to a therapy through the use of diagnostic tests that identify specific genetic markers.

"Drug companies will need to partner or learn to develop such tests to be sold simultaneously with their drug launch," Ms. Tomalin says. "Biosimilars and processes that are established for their registration will open a new field of regulatory activity, and second-entry biologics will put pressure on the pricing of successful biologics whose patents are expiring."

Launch: Safety Communications

Sales reps must also be able to provide healthcare professionals with up-to-date, relevant, and nonbiased customer-focused communications. In order for this to happen, sales reps must be provided with comprehensive scientific and clinical training that will transform them into a lean and elite team of experts, says Ed Damp, chief operating officer, BioPath Consulting.

"We know that sales reps need to fix their broken relationships with physicians by proving that they can deliver comprehensive, valuable, and unbiased information," Mr. Damp says.

This type of training can come from MSLs, says Robin Winter-Sperry, M.D., president and CEO of Scientific Advantage and Science Oriented Solutions (SOS).

"There is no 'golden shield' for MSLs or anyone else in the company with regard to compliance, but MSLs' mission of scientific exchange positions them to be the company's internal educators of the external scholars," she says. "MSLs can provide clinical training to sales representatives that contributes to their understanding of the local issues, regional practice dynamics, and current medical literature."

DR. ROBIN WINTER-SPERRY ■ *Scientific Advantage and Science Oriented Solutions (SOS)*

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This will help teams to begin building strong relationships with healthcare providers, which is critical these days, our experts say. MSLs will also have an important role as key purveyors of information to the medical community and should represent the voice of the thought leader back to their company.

"Gaining physician access is certainly a big challenge; about 25% of physicians have closed their doors to sales reps," Mr. Damp says. "Additionally, almost 87% of physicians are dissatisfied with sales reps not being able to provide relevant, valuable, and trustworthy customer-focused interactions that offer physician and patient benefits."

"Providing value and building relationships early on are essential to a successful launch," Dr. Winter-Sperry says. "Physicians want to do what is best for their patients, and being informed and/or involved with new therapeutic agents contributes to their education, and the feedback assists the company in the agent's clinical development." ✦

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