Denise Myshko

Addressing REIMBURSEMENT During Development

Pharma companies are experiencing greater scrutiny from government, private payers, and consumers. Creating a comprehensive reimbursement plan that begins at early phases of product development is essential in successfully obtaining coverage.

Increasingly in the United States and in Europe, payers and stakeholders are making a more rigorous assessment of the value new pharmaceutical products bring to the table; therefore, pharmaceutical companies are under increasing pressure to demonstrate a product's benefit to justify reimbursement.

"There is a growing tension between the data requirements for regulatory purposes of clinical trial data and what payers and other stakeholders want to see to support funding decisions," says Timothy Fitzgerald, CEO of GfK Bridgehead. "Instead of absolute efficacy data from controlled clinical trials, payers would much prefer to see more relative effectiveness data, which requires two key areas of attention: comparative effectiveness in the United States and value-based pricing in Europe."

Susan Capps, executive director, global pricing and payer planning, Amgen, says payers want to know the product's relative value compared with what's already available on the market.

"Value is the total package of the clinical value, including patient reported outcomes and economic value," she says. "Economic reviews are being developed at different rates in different countries. Countries are struggling with how to construct cost-effectiveness ratios."

Stephanie Dyson, senior director, government affairs, Genentech, says product differentiation before it reaches the market is critical.

Global Health Trends

- Health spending growth will continue to be strong in the emerging market economies while weakening in the developed market economies going forward.
- A slow economy and high unemployment — plus reform initiatives — are among the factors expected to affect U.S. health spending adversely in the short and medium term, while Medicare expenditure will be a major factor in the long term.
- The French government is aiming at containing health-spending growth below a 3% threshold and has cut reimbursement for 200 drugs to 15% (down from 35%).
- The German healthcare system has undergone considerable reform over the past decade as the government seeks to contain spiraling costs, particularly in terms of expenditure on pharmaceuticals.
- The Italian government's austerity measures — cutting spending for healthcare access, imposing high co-payments, and reducing drug prices — will raise out-of-pocket (OOP) expenses while lowering health spending and drug sales.
- Spain made substantial reductions to generic and off-patent brand prices in order to encourage higher generic utilization and lower health-system costs.
- Unlike most of its European neighbors, the United Kingdom is actively seeking to bring expenditure levels up to be more in line with European norms.
- Cost-containment measures in the Czech Republic, Hungary, and Slovakia — introducing fixed co-payments while cutting reference prices and drug reimbursement expenditure — will raise OOP expenses and lower growth in drug sales and health spending going forward.
- India and China's healthcare reforms — including expanding medical insurance coverage — should translate into stronger growth in drug sales and health spending.
- The Brazilian government's efforts — boosting domestic manufacturers' drug production, hence shrinking the share of more expensive imported drugs; and reducing drug prices through direct negotiation with multinational drugmakers — will decrease drug prices.

Source: IHS Global Insight. For more information, visit ihs.com.

"We understand that payers look at the totality and the value of a product," she says. "We understand that our role is to make sure that we show not only patients and physicians, but also payers, why our products are different. We look at the clinical value of a product; we also think about the humanistic value of products and what are we doing for patients. Then there is the third rung, which is economic value."

Mr. Fitzpatrick says companies are adapting their structures and policies to build in payer insights earlier in development.

"Companies have to account for all key data to make sure decisions around business, licensing, and portfolio management appropriately shape clinical trial plans to ensure that comparators, end points, and patients selected for clinical trials will result in reimbursement further down the line," Ms. Fitzpatrich says.

Ms. Capps suggests that Phase I is not too early to begin to think about a reimbursement strategy.

"By the time a product enters into Phase II, there should be a preliminary reimbursement and pricing strategy in place, and certainly before going into Phase III trials," she says.

Jim Furniss, director of market access at GfK Bridgehead, says payers are interested in improved outcomes.

"Payers want to see clinically relevant outcomes," he says. "This is a challenge for companies because these require longer-term trials. Clinical end points are important to payers because they are interested in long-term outcomes — not the 12-week outcomes required for regulatory purposes."

Global Reimbursement Trends

In January 2011, Germany introduced health reform — AMNOG — which links pharmaceutical pricing to added therapeutic benefit scores. Under AMNOG, the level of added therapeutic benefit granted to newly approved drugs is based on a scoring system ranging from 1 (major added benefit over comparator) to 6 (less than comparator). This score impacts the reimbursement of new drugs.

> "Phase I is not too early to begin gathering evidence for a pricing and reimbursement strategy."
>
> **SUSAN CAPPS** / Amgen

> "Regulatory success doesn't equate with commercial success."
>
> **STEPHANIE DYSON**
> Genentech

Mr. Fitzgerald says the new laws in Germany have been very explicit in terms of what data regulators are looking for: mortality and significant reduction in morbidity.

"Products that only offer small marginal incremental gains versus the current standard of care, especially if they use surrogate end points, are going to face significant challenges if they are seeking any meaningful premium in terms of price," he says.

Additionally, in February 2012, the European Medicines Agency (EMA) released its first batch of good pharmacovigilance practices (GVP) modules for public consultation. These modules will eventually serve as guidance for how the EMA wants to see pharmacovigilance activities conducted in the EU, in light of the new pharmacovigilance legislation passed in July 2011 that goes into effect July 2012.

At the end of last year, France passed its own pharmacovigilance reform. One key component of this reform is the ability of the French regulatory agency to now request active comparator trials for marketing authorization.

Mr. Furniss also points out that health economics has been a critical part of product assessment in the United Kingdom and with the Scottish Medicines Consortium.

"It's important in other markets as well, for example, in Sweden and the Netherlands and some regions in Spain," he says. "In addition to clinical evidence, manufacturers need to look at costs and benefits in a more monetized way and they need to look at the benefits in terms of quality of life."

Best Practices

Experts say early engagement of payers to gain insight is absolutely critical. A recent study by IHS Global Insight found that partnering with payers is actually a necessity, especially for small biotechs, to secure market access for products.

The IHS survey found that both industry and payers are broadly open to partnering, although payer willingness varies by market. In each market, the organization of the health insurance system, healthcare delivery, and the pricing and reimbursement decision-making process determines the key influential stakeholders for industry-payer partnerships.

In the majority of countries analyzed, public payers dominate the industry-payer partnership landscape, although private payers are expected to play an increasing role.

Pharmaceutical and biotechnology companies are adapting to a more complex healthcare landscape by better demonstrating the value of their products to private payers, government payers, and other stakeholders.

According to a recent series of market access studies from Cutting Edge Information, the shake-up is accelerating and becoming more formal. The health economics and outcomes research (HEOR) function is leading the way in this conversation. Two-thirds of companies are expected to increase their spending in this area in 2012, with average growth of 14%.

Most companies do not currently measure ROI for their HEOR teams. But executives interviewed by Cutting Edge Information suggest that as the immediate urgency of expiring patents and an epidemic of austerity policies recedes, these groups will be called upon to deliver clearer ROI metrics.

Ms. Dyson says there are three basic pillars of reimbursement: coverage, coding, and reimbursement.

"In general, in order for Medicare to cover an item or service, it must be reasonable and necessary," she says.

Ms. Dyson says pharmaceutical companies have to challenge this traditional assumption. She says Genentech works to ensure payers understand the value of their products and work to commercialize only those medicines and diagnostic tests that improve the length and quality of patients' lives and that bring clear medical and economic benefit to the healthcare system and society.

"We are at a stage where it isn't business as usual," she says. "It's about determining what's best for patients, and we need to understand how payers will react to new products. Companies are focusing on the totality of the medical value of a product from the earliest stage of development, which includes a focus on pharmacoeconomics." PV

Ensuring Market Access

Questions remain about how payers and governments will assess clinical trial data for pricing and reimbursement considerations, including:

- **Clinical trial design:** Will payers consider indirect comparison or will they require head-to-head clinical trials between the new product and its comparator?
- **End points:** Will payers consider surrogate endpoints or will they require clinical end points?
- **Appropriate comparator:** Will the appropriate comparator be selected based on legal, pharmacological, evidence, utilization, or economic criteria? Will it be the standard of care or any suitable therapeutic alternative? What if the appropriate comparator differs across markets?
- **Target patient population selection:** What is the optimal target patient population? (as relative efficacy varies across patient subpopulations)
- **National data:** Will payers consider international clinical trials or will they require market-specific data?

Source: IHS Global Insight. For more information, visit ihs.com.

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