

# The Fourth Hurdle

## THE CALL FOR PHARMACOECONOMIC DATA

THE NEED TO DEMONSTRATE THE VALUE OF PHARMACEUTICAL PRODUCTS IS NOW UNIVERSAL. EXPERTS SAY A PHARMACOECONOMIC ANALYSIS IS NOT JUST A MARKETING TOOL; IT'S ALSO A PRODUCT LIFE-CYCLE MANAGEMENT TOOL.



REBECCA HYDE  
STRATEGYX

*Pharmacoeconomics is a tool that continuously informs the brand strategy and the development of Phase IV protocols.*



DR. LYNN OKAMOTO  
UNITED BIOSOURCE

*As a new drug comes through the pipeline, it's important to determine two things: what is the unmet need for the product and how will it reduce the burden of disease for patients and the healthcare system.*



DR. BOB MAUCH  
XCENDA

*Pharmacoeconomics, or the need to understand the value products will create in the marketplace, is increasing rather dramatically.*

What began as a movement by government payers in other parts of the world is now making its mark here in the United States. Pharmacoeconomics — the scientific discipline that compares the value of one pharmaceutical drug to another to assess its value and cost-effectiveness — has become the fourth hurdle companies have to address, behind efficacy, safety, and quality.

"Where pharmacoeconomics, as a tool to understand the impact and the value of different treatment decisions, impacts reimbursement decisions or formulary coverage decisions is how well a payer can understand the overall impact and the overall value of using a product," says Bob Mauch, Ph.D., Pharm.D., president of Xcenda. "Given that, pharmacoeconomics, or the need to understand the value products create in the marketplace, is increasing rather dramatically."

In some countries — Australia, Canada, and the United Kingdom, for example — pharmacoeconomic data are a requirement before a reimbursement decision can be made.

Lynn Okamoto, Pharm.D., general manager, healthcare analytics, at United BioSource, says there are two aspects of drug evaluation where pharmacoeconomic outcomes are integrated.

"There is the regulatory component and the payer perspective," Dr. Okamoto says. "As a new drug is coming through the pipeline, it's important

to determine two things in parallel to address the requirements of these different audiences: what is the unmet need for the product and how will it reduce the burden of disease for patients and the healthcare system."

Rebecca Hyde, partner at Strategyx, says pharmacoeconomics is moving into economies where the government is not the only payer.

"This is why it's been somewhat slower to come to the United States," she says. "In our analysis, the more government involvement in healthcare, the greater the demand for pharmacoeconomic evidence."

Europe is far more sophisticated and more comfortable with complicated pharmacoeconomic models, says Cheryl Hankin, Ph.D., founder, president, and chief scientific officer of BioMedEcon.

"Payers in the United States look askance at complicated models," she says. "They're viewed with some suspicion, especially when created in-house by a pharmaceutical company."

Dr. Hankin says it's in a manufacturer's best interest to sponsor an outside organization to conduct pharmacoeconomic analyses — this is more believable than the in-house approach. In general, the simpler and more transparent the models are, the better.

According to Jonathan Tierce, general manager, global health economics outcomes research

(HEOR) and the Center of Excellence Leader at IMS Health, in the United States there is likely to be a stronger call by many people within the health policy arena to have a health technology assessment requirement within Medicare.

"If we did that, managed care would probably follow suit with requirements for health technology assessments," he says. "This macro trend is sitting side by side with another macro trend: evidence-based medicine and economic evaluations of medical technology as a whole."

### DEMONSTRATING VALUE

According to the International Society for Pharmacoeconomics and Outcomes Research, pharmacoeconomics incorporates health economics, clinical evaluations, risk analysis, technology assessment, and health-related quality of life, epidemiology, decision sciences, and health-services research in the examination of drugs, medical devices, diagnostics, biotechnology, surgery, and disease-prevention services. Potential uses for pharmacoeconomic analyses are in pharmaceutical reimbursement, price negotiations, formulary discussions, clinical practice guideline developments, and communications to prescribing physicians.

Mr. Tierce says pharmacoeconomics is all about trying to understand and demonstrate the value of healthcare interventions.

"At times when we talk about pharmacoeconomics, the focus is narrow and addresses just the techniques used to assess drugs for pricing and reimbursement," he says. "My argument is this is too limiting; pharmacoeconomics is about demonstrating the value of healthcare interventions and the value of medicines."

Dr. Mauch says the demand for pharmacoeconomic data is growing every year.

"From a brand standpoint, historically products were differentiated by communicating clinical efficacy to prescribers," he says. "Going forward, the pressure to manage healthcare costs will only increase. The payer component of brand strategy, where pharmacoeconomic value fits in is much more important. It is a critical success factor for any brand to be able to clearly communicate its value to payers."

Ms. Hyde points out that pharmacoeconomics

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is not entirely about saving money as much as it is about how to spend money more wisely. Expenditures, she says, can be evaluated on three levels: societal, institutional, and individual.

"At the societal level, economies of the world's major pharmaceutical markets are under strain, facing both limited budgets and increasing drug costs," Ms. Hyde says. "At the institutional level, managed-care plans have to understand how a new drug is going to impact the long-term budgets for all patients. Hospitals are using pharmacoeconomic data to bolster their decision-making processes. And, increasingly, employers, who bear most of the cost for drug budgets in the United States, are using pharmacoeconomic tools to design the benefits for their employees. At the individual level, we all are using pharmacoeconomic information every time we make a decision on how to allocate our personal resources for healthcare."

**Health economics research should be an early and ongoing part of developing a brand strategy.**

**IMPACT ON BRANDS**

Mr. Tierce says in the future, all brands, especially products that expect to be significant players in the market, will need a health economics research strategy embedded within the marketing plan.

"Health economics research should be an early and ongoing part of developing a brand strategy," he says.

Dr. Hankin says it's in a manufacturer's best interest to do pharmacoeconomic analysis.

"In the absence of providing simple, transparent, and unbiased pharmacoeconomic data to payers, the payers themselves will conduct analyses and they may not use all or the appropriate information in the process," she says. "It's always a good idea for pharmaceutical companies to

make sure that payers have as much information as they can ahead of time by having the pharmacoeconomic analyses available in advance of formulary, medical, or technology review."

Ms. Hyde stresses that pharmacoeconomic data are more than just a marketing tool.

"Companies that are doing pharmacoeconomics right recognize that there is a need for this kind of consideration at every point in the product life cycle," she says. "Pharma companies must address pharmacoeconomics earlier in the product life cycle to steer product development and enable efficient capital and resource allocation. Pharmacoeconomic analyses should begin when a product is first put into man and shouldn't end until the drug goes generic. High-quality PE information can make a

case for a unit price determination and can put the manufacturer in a win-win situation with the payers, facilitating reimbursement and uptake.

"Companies that are doing pharmacoeconomics right understand that a PE dossier must be developed to support the reimbursement evaluation, and that the dossier must be constantly updated and assessed," Ms. Hyde continues. "Companies have to monitor the formulary status of every product and ensure that they are in a position to respond to class review."

They are developing organizational structures that enable coordination across multiple business functions while accounting for global variation in reimbursement policy, she says. This has been a significant change in the last five to seven years.

Dr. Okamoto says the key to building the value story is to align perspectives.

"Companies that are successful in developing

a brand strategy are establishing better studies early on to support the product at launch," she says. "At the same time, they are preparing real-world studies for postlaunch. Payers today are demanding more than just Phase III trials. Using this dual approach, pharma can focus on both the immediate regulatory need to establish clinical and safety endpoints, while meeting payer concerns to demonstrate the value of these products. In the United States, there has often been a disconnect between these two elements. In Europe, by contrast, there is greater emphasis on looking at the total picture: safety, efficacy, and value. NICE is involved in promoting this holistic approach. Other European countries, as well, are planning ahead. Consider, for example, the new IQWiG guidelines in Germany."

Dr. Hankin says it is not always necessary to develop a pharmacoeconomic model, because the value of a pharmaceutical product can be presented in many ways.

"There are other strategies that companies can use to justify coverage and reimbursement," she says. "Those pharmacoeconomic strategies include conducting retrospective claims analyses to show the burden and cost of illness; this technique can then be used to support cost-offsets offered by the pharmaceutical product. Or, meta-analyses can be used to highlight the clinical efficacy or safety profile of the pharmaceutical company's product compared with competitive products. Sometimes, the strategy can include evaluation of patient satisfaction and quality of life with the pharmaceutical product, which can then be quantified in terms of quality-adjusted life years." ♦

PharmaVOICE welcomes comments about this article. E-mail us at [feedback@pharmavoice.com](mailto:feedback@pharmavoice.com).

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