BY DENISE MYSHKO

# The Growing Influence of GLOBAL PAYERS

**IN THIS PAYER-DOMINATED ERA, GOVERNMENTS OUTSIDE THE UNITED STATES HAVE BEEN INCREASING THEIR DEMANDS FOR DATA ABOUT A PRODUCT'S IMPACT ON THE PATIENT AND THE HEALTHCARE SYSTEM.**

The balance of power is shifting. Global payers are now demanding more data about the cost-effectiveness of prescription drugs. And experts say they will continue to do so. Driving the increasing use of health technology assessments (HTA) by governments to make reimbursement, and sometimes even pricing, decisions is the rising cost of healthcare expenditures around the world, particularly in the European Union countries.

"In line with this growing trend, expenditures on pharmaceuticals also have been increasing in recent years," says Larry Olson, VP and practice leader payer markets, TNS Healthcare. "From a global economic perspective on pricing and reimbursement, the EU market represents the second-largest pharmaceutical market after the United States. And unlike the United States, governments are the major payers in Europe. As a result, the quasi-monopolistic nature of the European healthcare market means that they are powerful drug purchasers with significant leverage, and member countries use extensive pricing, reimbursement, and utilization-management controls to contain spiraling prescription drug costs. Across the EU, governments have not only significantly focused on cost containment, but they also are becoming increasingly restrictive in the extent to which they allow patient choice."

According to Gustav Ando, manager of the healthcare business development unit at Global Insight, the backlash against pricing and increased focus on outcomes is being driven mainly by very expensive oncology drugs where the price increase has significantly exceeded improved outcomes.

The use of economic evaluation tools have allowed authorities to broaden their decision-making roles.

"Decision making for pricing and reimbursement is becoming even more decentralized," says Adam Sohn, principal in the pricing and market access practice at IMS Health. "Much of this is evident by the expanding role of physicians and specialist societies, HTA bodies, policy and advising bodies, and employers. The national payer will still continue to play a critical role but regional and local payers are establishing much more rigorous formulary designs that will shape the true level of access that products have."

LARRY OLSON
TNS HEALTHCARE

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DR. LINUS JONSSON
I3 INNOVUS

*Economic evaluation is a very powerful tool that can have broader uses than supporting a reimbursement application. It can be used both to inform clinical-trial design, addressing patient subgroups or endpoints, as well as informing pricing decisions early in the process.*

## MARKET WATCH

EU countries have different pricing and reimbursement systems, with free pricing in Germany and the United Kingdom, tiered reimbursement in France, and internal reference pricing in France and Germany. According to Mr. Olson, as prescription drug cost containment becomes more critical to EU member countries, there are several key trends to watch in the near term.

"The role of health economics and the emphasis on outcomes research will increase, and there will be restricted reimbursement based on evidence thresholds and patient sub-groups, risk sharing will increase, the OTC market will continue to grow, and supplemental private insurance will rise," he says. "In addition, Europe's most likely future pricing and reimbursement scenario will see pharmacoeconomics, parallel trade, and generic substitution gradually increasing. These trends are very likely to play a more important role in pharmaceutical spend management for all European governments. Furthermore, intensifying regulations and guidelines for drug pricing and reimbursement in the EU will impact future long-term earnings for pharmaceutical companies. And the erosion of long-term revenue for companies in this market region will be affected by lower launch prices, which are as much as 60% less than prices for similar products in the United States."

Leading the way in drug pricing reforms in the EU are the United Kingdom and Germany.

"Everybody watches the United Kingdom and Germany," Mr. Ando says. "The unexpected early reform of Pharmaceutical Price Regulation Scheme (PPRS) and continued jumbo referencing are two of the key trends creating headwind in the pharma sector."

Mr. Olson agrees the UK is a market to watch.

"It's important to note that while the UK accounts for almost 3% of global pharmaceutical sales, it has a disproportionately greater influence internationally, reflecting its importance in research and development, relatively high prices, and methods of scrutiny," he says. "Drug pricing in the UK, like elsewhere in Europe, is tightly regulated. The UK's PPRS, currently being renegotiated, forbids drug price increases, although it permits and even periodically imposes reductions. In the UK there's a growing shift away from free pricing

to value-based pricing mechanisms, where the basis of payment is on the effectiveness of drugs. Pharmaceutical companies in the UK are gradually introducing new drug pricing models, as pressure is mounting to offer better value for money. For example, the Office of Fair Trading (OFT) is considering allowing higher prices for more effective drugs, with the hope of stimulating and rewarding innovation."

In June, Britain proposed a plan to update the PPRS. The plan includes average price cuts of about 5% for existing medicines, as well as an additional price reduction of 2% if growth exceeds an agreed threshold.

The plan also includes a commitment by the National Health Service to take action so that patients have faster access to new medicines that are clinically effective and cost-effective. Under the new five-year deal, the government will work more closely with the pharmaceutical industry to bring new drugs through development faster.

Linus Jonsson, M.D., M.Sc., Ph.D., VP of health economics and outcomes at i3 Innovus, says the impact of the UK's National Institute for Clinical Excellence (NICE), an independent organization responsible for providing national guidance on promoting good health and preventing and treating illnesses, has been tremendous. Likewise, the organization's Centre for Health Technology Evaluation, which develops technology appraisals and interventional procedures guidance, is having an impact. Technology appraisals are recommendations on the use of new and existing medicines and treatments. Interventional procedure guidance evaluates the safety and efficacy of procedures where they are used for diagnosis or treatment.

"The UK has been a leader in applying strict cost utility analysis criteria for recommendations for the use of products in its healthcare system," Dr. Jonsson says. "Many reimbursement agencies in other countries are quite influenced by what is going on in the UK and are evaluating the reports NICE produces. This is both an opportunity and an issue. NICE has been subject to some criticism, and there is a debate around a couple of issues at the moment."

In Germany and other countries, extensive political reforms are creating structural changes in the EU health insurance systems that, according to Mr. Olson, tighten pricing and reimbursement regulation.

"In the case of Germany, eventually compulsory insurance will cover the entire population to obtain more resources for its statutory healthcare system," he says. "Currently in Germany, we can see the beginnings of public-private partnerships. For example, in Germany, public sickness funds are working with private health insurers, and the same now applies in the hospital sector."

Germany's Institute for Quality and Efficiency in Health Care (IQWiG), which is an independent

## KEY GLOBAL PRICING AND REIMBURSEMENT TRENDS

- Regulation is becoming tougher. At the end of October 2007, U.S. Democrats introduced legislation to make government negotiation with the pharmaceutical industry mandatory for medications provided under the Medicare Part D plan. The U.S. elections in 2008 will determine the exact nature of the changes to the government's negotiating power.
- In Mexico, there have been talks about forming a pricing agency for patented drugs. But it is likely that if any changes are to be made they will take place in mid-to-late 2008.
- A major event of 2007 has been the price cuts on erythropoietins (EPOs) in France. Notably, this change affects other countries that use France for reference pricing. In addition, several countries may follow suit and implement similar price cuts on EPOs.
- Reimbursement for oncology drugs has become a controversial topic, with the pharmaceutical industry having taken a more aggressive stance on reimbursement. The risk-sharing agreement between Johnson & Johnson (J&J; U.S.) and the U.K. National Institute for Clinical Excellence (NICE) with regard to multiple myeloma drug Velcade (bortezomib) demonstrates the industry's persistence in negotiating terms of reimbursement.
- Many countries in Central and Eastern Europe have markets that are dominated by big players rather than small, local generics firms. More governments are attempting to take control in negotiating with big pharmaceutical companies over prices. In December 2007, The Ministry of Health in Latvia approached two pharmaceutical companies demanding negotiations over the costs of drugs.
- Brazil has adopted a tough position on HIV/AIDS drugs. Between 2001 and 2005, the Brazilian government made large savings by threatening to forcibly license patented medicines.

Source: Global Insight Inc., London. For more information, visit globalinsight.com.

## STRATEGIES FOR OPTIMIZING GLOBAL REIMBURSEMENT

Today it's critical for pharmaceutical companies to consider global and reimbursement systems when developing a pricing and launch strategy for new products. On a global scale, the economies of many of today's major global pharmaceutical markets are under crippling strain. Consequently, government reforms that focus on limiting drug expenditure and cost containment are gaining increasing momentum. In addition, close monitoring of current reimbursement policy changes and greater cooperation with decision-making authorities are becoming more critical to optimize reimbursement potential.

The reimbursement status of products is a key factor in maximizing return on investment for pharmaceutical products. Accordingly, the importance of achieving a desired reimbursement status for a drug during its entire life cycle should be a primary concern for pharmaceutical companies. Carefully targeted reimbursement strategies are the key to successfully launching new products.

Specifically, pharmaceutical marketers need to integrate pharmacoeconomics more effectively to maximize reimbursement potential, driven by increased use of economic evaluation by payers in reimbursement decision-making. Manufacturers must address reimbursement earlier in the product life cycle to steer product development and enable efficient capital and resource allocation.

It is critical to develop research best practices by assessing the role of pharmacoeconomics in reimbursement throughout product development. It is also crucial to sharpen "product value" communication by understanding the relative importance of various factors on reimbursement decision-makers' thinking. Brand leaders need to ensure that the evidence of product value that supports payer reimbursement decisions is effectively communicated.

**KEY RESEARCH QUESTIONS THAT NEED TO BE ADDRESSED INCLUDE:**

- What strategies best optimize reimbursement potential?
- What are the most significant factors impacting payer decision-making?
- When is the best time to incorporate reimbursement potential into the product life-cycle planning process?
- What are the most compelling payer messages that drive favorable reimbursement and formulary status?

Source: Larry Olson, VP and Practice Leader Payer Markets, TNS Healthcare, New York.
For more information, visit tnsglobal.com.

scientific institute that evaluates the quality and efficiency of healthcare, is developing a methodology for assessing new pharmaceutical products before they reach the market. The Institute's tasks include the evaluation of pharmaceuticals, surgical procedures, diagnostic tests, clinical practice guidelines, and aspects of disease management programs, following the principles of evidence-based medicine.

Mr. Ando says another market to watch is New Zealand.

"The dreaded Kiwi Model of drug tendering is the worst-case scenario, but many countries, from the Netherlands to Belgium, are genuinely looking at this as a viable form of cost containment," he says.

## INCREASING DEMAND FOR PHARMACOECONOMIC DATA

Mr. Ando says the field of pharmacoeconomics is relatively new, and there is little consensus to its applicability in pricing models across Europe as well as internationally.

"Manufacturers and reimbursement authorities rarely, if ever, agree on what model to use in their ICER/QALY assessments," he says. "NICE and IQWiG are often referenced and are being used significantly in practice as the main tool to ensure that even clear innovation has a cost limit."

Interest by payers in pharmacoeconomics continues to grow. Experts says this is being driven by the broader application of HTA.

"HTA bodies are developing in a number of European markets," Mr. Sohn says. "Their role and influence on pricing and reimbursement, however, will likely vary based on mandate and evaluation metrics. The expectation is that some HTA bodies will shift from a placebo-driven model to a head-to-head comparison model as they focus more on outcomes. In other markets, the HTA model may follow the UK and mandate that companies also demonstrate cost per QALY improvement."

According to an IMS report, the key market in Europe in which pharmacoeconomics has developed in recent years is the United Kingdom. This stems from the role of NICE, as well as that of the Scottish Medicines Consortium in Scotland. Both agencies take into account health economic studies presented by the industry (and in the case of NICE, by external agencies) in their assessment of the value of products.

Two additional markets that are viewed as being particularly influential internationally are Australia and Canada. In both countries, the application of health economic data to decision-making by authorities has driven the development of pharmacoeconomics.

Mr. Sohn says where HTAs are not formally institutionalized, such as Italy and Spain, the P&R approach that they have in place will probably continue to remain fairly consistent over the near term.

"But even where HTA bodies do exist, it will be important to understand and contextualize their influence on the overall P&R decision," he says.

## BEST PRACTICES

Pharmaceutical companies can be expected to invest in pharmacoeconomics at earlier stages of development, and in so doing they will be capable of demonstrating the value of innovative products on the basis of extensive data, the IMS study says. Work will also be stepped up on the specific application of pharmacoeconomics to product selection in the early stages of development. Currently, in many companies, the application of pharmacoeconomics following market entry tends to be in the context of sales and marketing support.

IMS experts say companies armed with up-to-date, real-world studies will be in a better position to demonstrate the relative benefits of their products.

"Clearly, there are broader uses of pharmacoeconomic analysis than for the purpose of supporting a reimbursement application," Dr. Jonsson says. "There are examples of companies starting to apply pharmacoeconomics earlier in the product development cycle. There is a lot more that can be done."

He says pharma companies can use these tools in early development to see how the product might resonate with payers.

"By applying health economics, companies can try to predict early on how a product will meet the requirements for reimbursement in different health systems, as well as the likelihood that the product will actually gain market access with a particular outcome that demonstrates efficacy endpoints at a particular price," he says.

Mr. Sohn says spending more time up front on these issues can help pharma better understand payers' needs and improve its relationships with payers.

"When traditional clinical product differentiation becomes more difficult to establish, focusing on other measures that are valuable to each payer in the market will become important," Mr. Sohn says.

Dr. Jonsson says to make HTA tools as useful as possible, companies need to invest in developing knowledge in the therapeutic categories where they have active pipelines.

"In general, companies are very good at running clinical trials and developing programs to meet the regulatory requirements for marketing approval, but I think there is a lot more that can be done to generate other types of data that they can use to support reimbursement applications and to demonstrate the value of their products," he says.

Mr. Ando says companies should consider a "mix the portfolio" strategy.

"A company needs to identify what the key drug is in its portfolio and price it accordingly to ensure that it maintains good margins, even if this comes at the expense of other drugs," he says. ✦

PharmaVOICE welcomes comments about this article. E-mail us at feedback@pharmavoice.com.

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## Experts on this topic

**GUSTAV ANDO.** Manager of the Healthcare Business Development Unit, Global Insight Inc., London; Global Insight provides economic and financial information available on countries, regions, and industries, using a unique combination of expertise, models, data, and software within a common analytical framework to support planning and decision-making. For more information, visit globalinsight.com.

**LINUS JONSSON, M.D., M.SC., PH.D.** VP, Health Economics and Outcomes, i3 Innovus, Medford, Mass.; i3 Innovus delivers the science and solutions to achieve marketplace success. For more information, visit i3global.com.

**LARRY OLSON.** VP and Practice Leader Payer Markets, TNS Healthcare, New York; TNS Healthcare provides globally consistent solutions and custom advisory services to support product introductions; brand, treatment, and sales-performance optimization; and professional and DTC promotional tracking. For more information, visit tnsglobal.com.

**ADAM SOHN.** Principal, Pricing and Market Access Practice, IMS Health, Norwalk, Conn.; IMS Health is a global source for pharmaceutical market intelligence, providing critical information, analysis, and services that drive decisions and shape strategies. For more information, visit imshealth.com.