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Value-based Pricing

Lessons to Learn from the UK Experience

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This article is reproduced with permission from eyeforpharma, which hosted the Oncology Summit Europe conference in January, 2008. The original title was "Market access: obstacles and opportunities (Part II)." Please read part I of this article, in which, Uday Bose, European marketing director for GlaxoSmithKline Oncology, spoke about the EU environment for oncology pharma. Bose gave his opinion on the reality of pharma costs to get drugs to market, market-access pressures and the particulars of pricing across Europe. This article summarizes the second half of Bose's presentation, which focuses on reform attempts within European countries and pharma's reactions, the benefits and perils of risk-sharing agreements and how pharma might best meet the challenges of the marketplace now and into the future. Since this topic has relevance for global pharmaceutical marketing and sales, it is with pleasure that I offer it to subscribers of Pharma Marketing News.
– **John Mack**, *PMN Editor*

One attempt to regulate drug pricing in the UK is the Pharma Price Regulation Scheme (PPRS). This plan, says Bose, was both innovative and positive in that it would allow pharma and the government of the UK to work together to determine what was fair value for money. The plan was intended to guarantee pharma sufficient compensation for its efforts at a level that would encourage further innovation while ensuring the government got reasonable value for its money. And the agreement did help maintain relative stability of pricing in the UK—no small achievement, since about 10% of the UK government's total spend (around £8 billion or $15.8 billion per year) is on branded medicines.

The scheme has two main components: profit controls that cap the amount of profit a company can earn selling branded medicines to the National Health Service (NHS), and price controls that impose restrictions on raising the price of branded drugs and set agreed price cuts. This ensures that the price of branded drugs stays within defined limits.

Price Regulation and Innovation

In 2007, the Office of Fair Trading (OFT) released a study it had conducted on the success of the PPRS over the previous two years. Had the PPRS delivered? Was the NHS getting value for its money, and had the scheme encouraged innovation from pharma?

Some of the OFT's findings were a little shocking—the variance of pricing between branded meds and very similar generics was as much as 500% in some cases. In 2005, the study found, one drug was very badly overvalued. Had the drug been priced commensurate with its benefits, the NHS would have saved £350 ($691) million. The use of generics alone would have saved the NHS £65 ($128) million, and cholesterol and blood pressure meds were grossly overpriced for the results they achieved. Based on its findings, the OFT recommended that the PPRS shift its focus to a "value-based approach to pricing." Value-based pricing would provide both incentive for innovation and quick access to medicines for those patients who need them, according to the OFT.

Office of Fair Trading

The UK's Office of Fair Trading (OFT) is a non-ministerial government department of the United Kingdom, established by the Fair Trading Act 1973, which enforces both consumer protection and competition law, acting as the UK's economic regulator.

Similar to the Federal Trade Commission (FTC) in the U.S., the OFT's goal is to make markets work well for consumers, ensuring vigorous competition between fair-dealing businesses and prohibiting unfair practices such as rogue trading, scams and cartels. Its role was modified and its powers changed with the Enterprise Act 2002.

The industry's reaction was provided in an article by Sir Richard Barker, Director General of the Association of the British Pharmaceutical Industry (ABPI), the British equivalent of PhRMA. The current PPRS, he said, has resulted in a savings of £1.2 ($2.4) billion for the NHS. UK drug prices are 21% lower than they were a decade ago, and new medicines are often priced lower in the UK than in other parts of the EU. Most importantly, Barker warned, any reforms done to the existing PPRS must not discourage innovation or produce delays in patients' access to therapies.

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UK Market Small But Packs International Clout

The London *Financial Times* reports: While the UK represents only 3-4 per cent of the global market for medicines, it punches above its weight, in part because the National Institute for Health and Clinical Excellence's (NICE's) assessments are closely followed internationally. Price reductions in the UK would likely trigger copycat actions by purchasers elsewhere and encourage "parallel trade", by which medicines sold in countries at lower prices are exported by arbitrageurs to higher priced ones.

Drug pricing in the UK, like elsewhere in Europe, is tightly regulated. The UK's Pharmaceutical Price Regulation Scheme, currently being renegotiated, forbids increases—although it permits and even periodically imposes reductions.

Belen Garijo, senior vice-president for Europe and Canada for **Sanofi-Aventis**, said: "Pressure to keep costs under control is forcing us more and more to document the value of new products. These are times of unprecedented change. The UK has almost invented pay for performance."

Bose suggests we look carefully at the inherent weaknesses of value-based pricing. Such pricing can only be subjective, he says. How is the threshold for cost-effectiveness determined? An "inappropriate pricing structure could lead to overall inefficient resource allocation." After all, benefits gained in one area (saving money on more appropriately priced cholesterol lowering drugs, for example) is not necessarily going to mean more money for breast cancer research. The system simply doesn't work that way. And how does one account for uncertainty?

To "correct" the problems with PPRS, the OFT offers two options: the first, ex post value-based pricing, would involve companies setting the prices for the drugs prior to the launch. After the drug has been on the market awhile, the company takes data gathered on that drug and submits it for review. Based on the results of the review, a maximum price is set that takes into account the clinical benefits as well as any potential major impacts, such as new entrants or a comparator losing its patent.

The second option is ex ante value-based pricing. Here the pharma company works with the government during licensing. The drug's cost effectiveness is given a "fast-track assessment," and the company goes to launch with a clear idea of the maximum price it can charge and whether or not it will receive reimbursement.

The OFT, says Bose, favors the second arrangement, citing a role for risk sharing agreements.

Risk sharing, pros, cons and possibilities

According to Bose, risk sharing propositions can be placed in two categories. The first are financial agreements in which there is a target financial outcome. There may be, for example, a cap on expenditure. Any amount over the agreed-upon figure must be paid by the pharma company.

The second type of risk sharing agreement is outcome based. In this arrangement, the government agrees to participate financially only if the drug achieves certain target patient outcomes, such as a specific clinical response.

US Example of Risk Sharing

One example of a financial-based risk sharing agreement in the U.S. was with Genentech. In order to overcome the negative publicity generated by the high price of the drug Avastin, Genentech agreed on a price cap — patients below a certain income level would have a maximum spend for treatment of $55,000. Anything above that would be picked up by Genentech.

An outcome- or performance-based agreement was devised between Janssen-Cilag and NICE (National Institute for Health and Clinical Excellence) in the UK. Initially, NICE determined that a drug, Velcade, was not cost-effective. Janssen-Cilag proposed that they be allowed to treat eligible patients for four months. At the end of that time, if they achieved a specific response (marker of disease activity in the blood), patients would continue the therapy at the NHS's expense. If not, Janssen-Cilag agreed to reimburse the NHS for its expenses.

Outcome-based agreements, however, are not without challenges, Bose says. It can be difficult to agree on a definition of the desired outcome. What is the target response? Is it quality of life? Survival? What's an outcome both parties can agree on? And getting an accurate measurement of the response can be tricky — such measurements are difficult to get even in clinical studies, much less in the "real world."

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And where is the line between achievement and failure? If the target is a 50% response, what happens to the patient who showed a 48% response? Some patients simply take longer to respond to medications than the agreement may allow. Logistical concerns are also no small matter when patients have to travel hundreds of miles to get to a clinic with the facilities to measure their response accurately.

Payer concerns

Risk-sharing is ultimately a balancing act of pros and cons. Payers have to balance the risks of budget impact uncertainty; uncertainty around outcomes, evidence and utilization; the expectations of other companies to enter into similar agreements, etc. with the possible benefits. Additionally, payers have implementation concerns: expenditures of time, effort and financing, setting up data systems that can collect the information, determining a termination procedure.

Potential benefits, according to Bose, include "immediate launch of new products for patients with unmet needs and no substitutes." This is crucial as no health care trust wants to be seen as barring access to needed drugs. Also, such a system would allow the health care body to control how the drugs are used. Says Bose, oncology drugs are notorious for off-label usage, but with risk sharing, the payers are in control.

Pharma concerns

The problems aren't limited to the payers. As Bose says, "the long-term risk to pharma may often outweigh any short term uptake and PR benefits." Risks include not breaking even on a drug or getting revenue beyond the break-even point, reluctance from senior management to accept significant financial risk, payer skepticism on innovative pricing agreements, significant investment time, effort and financing and the difficulties of measuring compliance with the agreement.

There are, of course, real benefits to pharma—market access without delays, and access to relevant patient groups, increased use of the drug, patient and physician good will as the drug becomes accessible, and at least initial acceptance of (high) prices.

It's not just efficacy anymore

According to Bose, it's not just payers who are looking more closely at value returns. Regulatory bodies are also taking notice. One example involves Amgen's 3rd line colorectal cancer drug, Vectibix. Initial assessment by the CHMP (Committee for Medicinal Products for Human Use) led the body to not recommend the drug. The effect of the drug was minimal and not sufficient to overcome side effects. Amgen at that point could have walked away, but because the drug was the only treatment available for some patients, the company decided to take another look.

Fortunately, 95% of the patients in clinical trials had provided tissue samples. Amgen discovered

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Big Progress In Government And Industry Drug Price Deal

ABPI Press Release (http://tinyurl.com/5kvo3v)

The UK government and the pharmaceutical industry announced on June 18, 2008, a significant deal on parts of the new Pharmaceutical Price Regulation Scheme.

"The package agreed between Government and industry strikes a reasonable balance," says the Association of the British Pharmaceutical Industry (ABPI). "Pledges to support uptake of new medicines—ensuring that patients benefit from access to innovative treatments as well as industry—helped secure a deal that will also deliver stability and predictability for the industry and achieve better value for money for the taxpayer."

The headline agreements with industry include:

- a saving of 5% in the cost of drugs sold to the NHS : In addition, a further price reduction of 2% will be available if growth in the drugs bill exceeds an agreed threshold. The 5% savings will be made up of a base price cut for all branded medicines of 2%, combined with measures to reduce the price of out of patent drugs (where a generic equivalent exists) and a further variable price cut to deliver 5% overall.
- action to support innovation so patients have faster access to new medicines that are clinically and cost-effective.
- a new non-contractual voluntary scheme providing stability and predictability in Pharmaceutical Pricing for the next 5 years.

that a particular biomarker indicated a group of people who would receive no benefit from the treatment. People who did not have the particular mutation received significant benefit. The new data was enough to get CHMP to change its mind and recommend the drug for patients without the biomarker. Clearly, there is a benefit to working with regulatory agencies to find value for all.

So what is the future for oncology? Says Bose, the future is already here. Biomarkers are making it possible to "identify the right patient with the right treatment at the right dose at the right time with the right outcome." They key, according to Bose, is innovation. Generally, the mechanisms are in place to ensure that innovation will be rewarded, and if pharma can bring innovative ideas and therapies to the table, it can justify the premium prices.

Innovation depends on R&D, at all stages of a drug's development. In the early stages, it's crucial to identify unmet needs and to choose the right comparator to put your drug up against and differentiate from. In later stages of development, it's crucial to continue finding those differentiating factors and to undertake health economic studies which will inform both "stop-go" and pricing decisions. Finally, R&D must be prepared to provide data that will support pricing decisions in reimbursement negotiations.

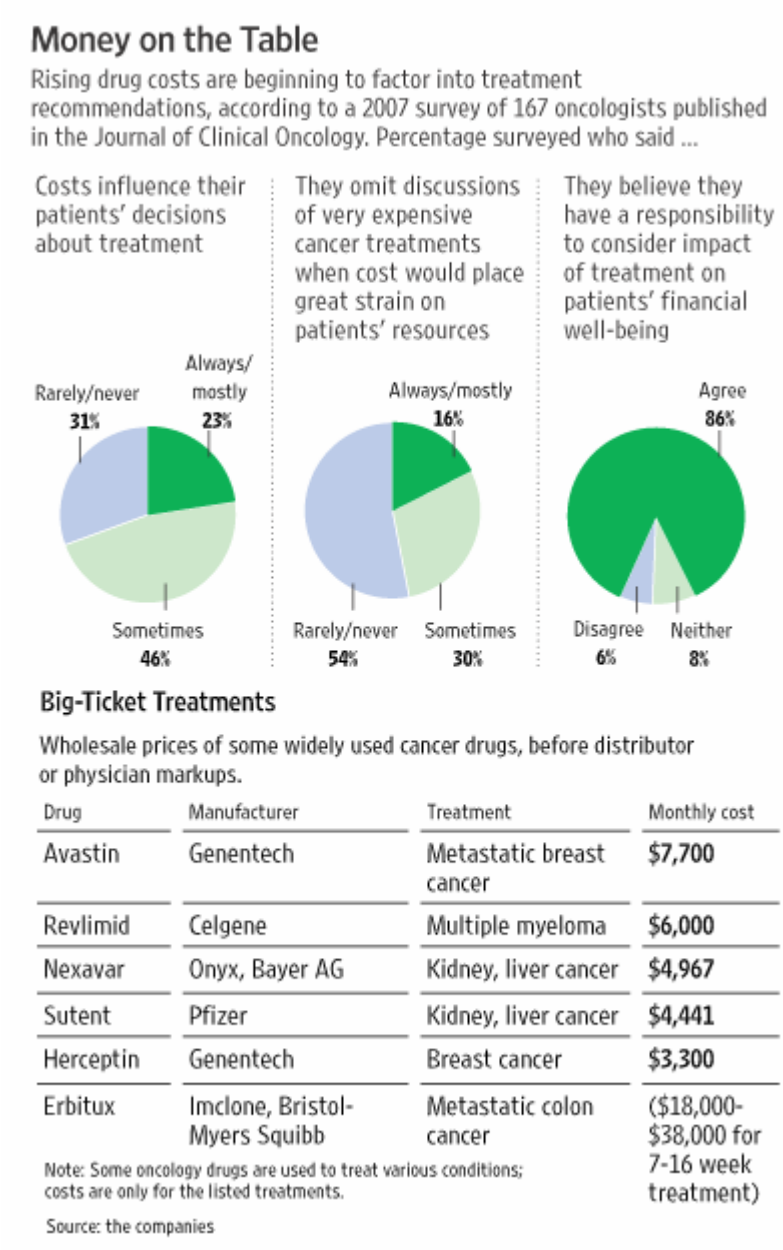

Figure 1: Drug Costs are Beginning to be Factored into Treatment in the US Too! Source: Wall Street Journal, July 8, 2008. http://tinyurl.com/6dfka2

Optimal pricing can only be achieved by an integrated approach with an eye to R&D strategies, pricing strategies and portfolio management strategies. In Phase I, for example, the company must "identify key benefits over gold standard treatment," says Bose, and prioritize potentially high priced projects. Phase II is time to choose a comparator—one with the best reimbursement and the best price. In Phase III, the developing drug and the comparator can go head to head to highlight the new drug's key benefits and cost effectiveness. At launch, a company may decide to negotiate the price, launch at a high price but forgo reimbursement or not launch at all. It may be useful to prioritize the launch order from high-priced to low-priced countries. Post-launch, companies may opt to promote their most innovative products, those that meet unmet needs, to optimize profit margin.

A best-case scenario, according to Bose, is one in which reference pricing drives prices toward the high end of the pricing range, where government reimbursement encourages innovation and where generics have little impact. A more realistic view is one in which reference pricing and parallel trade

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drive prices toward the middle of the range, where differentials promote innovative drugs and there is a greater impact from health economics, parallel trade and generic substitutes.

Says Bose, there is an obvious trend in EU pricing and regulation to prioritize innovation, and the increasing use of risk-sharing agreements demanding evidence of real-world efficacy is one indicator of the push toward greater innovation. Pharma's response, according to Bose, is to be innovative, to ensure pricing reflects both brand positioning and economic value. The only way to do this, Bose says, is to have close collaboration with R&D from Phase I all the way to launch. Those companies reluctant to adopt this strategy will be left behind.

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Pharma Marketing News

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