It is critical for biotech companies to understand the needs of European payers

There is increasing divergence between the evidence regulators need for approval, and that needed by payers for reimbursement. Whilst ignoring the needs of European payers before entering Phase III imperils the prospects of a drug's success, a clear market access strategy informs development decisions and underpins global partnering discussions.

By Rob Johnson, Partner at Alacrita Consulting LLC

A biotech CEO recently stormed out of negotiations with a pharma partner because there was a 3-5x discrepancy between his and the pharma's view on valuation. Most of that boiled down to pricing and market access assumptions; the pharma had done its homework and brought real world, evidence-based projections to the table, the biotech CEO worked off historic performance and was operating under an illusion of value. Biotech has been slow to catch on to market access considerations, here we try to explain why ignoring payer needs is a grave mistake.

Consider payers in Phase 2

With austerity continuing to bite, healthcare budgets are being squeezed like never before. Payers around the world and particularly in Europe are rejecting high profile drugs and refusing to pay a premium price unless there is compelling evidence of value. In response, pharma is building teams of market access specialists and is designing studies early in development to demonstrate each drug's value proposition. Back in 2008 Sir Andrew Witty announced that GSK would consult with payers on the drugs in their Phase 2 portfolio and focus on reimbursement rather than registration as the ultimate goal[1]. Biotech has been slower to respond and faces significant execution risk as a result.

EU impacts the global price

Europe has been in the vanguard of price pressure and a development program that meets the needs of European payers not only increases the chances of commercial success in Europe, but also builds the value

[1] "Pipeline Dreams: GSK's Witty Outlines Plans to Lower Phase 3 Attrition". The Pink Sheet July 2008

About Alacrita

Alacrita is a transatlantic life science consulting firm specialising in biotech and pharma. We believe that seasoned industry expertise is essential to deliver value to a sophisticated life science client – inexperienced juniors who "borrow your watch to tell you the time" are conspicuously absent from Alacrita.

Our European Market Access team are laser-focussed on helping companies develop their European market access strategies.

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proposition globally. Indeed, the price for a drug in countries like Germany and the UK is used as a direct reference price for more than 20 other countries, and up to 60 different countries when including secondary referencing.

Redefining innovation

In most industries, developing a new product without first finding out whether customers will pay for it is tantamount to corporate folly. Previously, payer research was not necessary - demonstrate a new medicine was safe and efficacious and they would pay. Times have changed, especially in Europe. Payers (and pharma partners) now need to see evidence of value: if a disease is being effectively treated by cheap generics, who cares whether your therapy acts through a novel pharmacologic modality? Innovation for innovation's sake is of no value. When examining novelty, payers aren't asking "has it been patented?", but rather "are you saving us money?".

This calls for a recalibration of the definition of innovation. Value-conscious players are peering into the future to understand the likely future standard of care, then benchmarking their product's performance against that. Obviously, innovative products need to improve patient's lives, but they also need to reduce healthcare costs – less surgery, less recovery time, less time in hospital, fewer readmissions, less time in front of the doctor.

Fragmented EU payer landscape

The onus is firmly on the industry to demonstrate clinical value. But how? Regulators work hard to develop guidelines for industry, setting out advice on clinical endpoints and how to measure them. They engage with industry as a product moves towards the market, providing feedback on a development strategy and other scientific advice. Helpfully, there is usually consistency between US and European regulators, with broad agreement on the choice of primary endpoint or structure of a pivotal trial.

In contrast to the regulator, there is no single European payer. Reimbursement decisions are made on a national, regional or even local level. The payer landscape is fragmented, complex and even inconsistent. There is no common agreement on the definition of 'good' value: NICE in the UK may broadly endorse one drug, only for it to be all but rejected by IQWiG in Germany. This heterogeneity is compounded by political flux (see box).

Questions to ask

There are a number of practical steps that can be taken by companies to help develop their value proposition. First, are you really tackling an unmet need? Traditional market research is no longer the solution: ask a European patient or physician whether intractable constipation is an unmet medical need and the answer is a resounding 'yes'. Payers may not see it that way, especially when standard laxatives cost a few pennies each day. This is a question that needs to be addressed even

The changing EU payer landscape

In 2014, NICE is planning a switch value-based pricing, moving away from PPRS where prices are based on the company's profit from NHS sales. In Germany, the Act to Reform the Market for Medicinal Products (AMNOG) was introduced in 2011, moving the country from a free pricing market to one where drugs are assessed based on their therapeutic benefit versus a chosen comparator. Amendments to AMNOG are expected after the German parliamentary elections in 2014. In the wake of the Mediator scandal, the French HAS (Haute Autorité de Santé) is replacing SMR and ASMR - where drugs are assessed based on medical benefit - with ITR (Index Therapeutique Relatif), where the clinical relevance of comparators and endpoints are considered.

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Cancer therapies – isn't it all about overall survival?

Some people hold the view that in cancer, overall survival is the only endpoint that matters. Not so. NICE, for example, will assess your drug based on Quality Adjusted Life Years (QALY). If you extend a patient's life by 1 year with excellent quality of life, NICE will reward you with a price for one QALY (currently about $50k). If that patient suffers side effects and quality of life is compromised by half, NICE will consider you to only be adding 0.5 years of survival benefit (with a value of $25k). If you don't have QoL data, NICE can't calculate the value of the drug. All oncology drug pivotal trials should, at a minimum, collect quality of life data. Payers may well have different opinions on which QoL instrument is best suited to your scenario.

before a project is started. If there's no market, why bother?

Companies must consider how the healthcare landscape will look when the product reaches the market. What are the unmet medical needs, from a payer perspective? Why will my drug be a better solution than anything else (another drug or other clinical procedure)? How much does it currently cost to treat the disease? Companies must take a long term view of evidence collection, developing a strategy in Phase 2 at the latest.

Check with payers

Then it's important to validate the strategy with payers themselves. CROs and other advisors claim to offer 'payer research', but in reality are unable to access actual payers. One German payer we work with gets 30-40 requests for interviews every week, but only has time for 3-4. He has no interest in speaking with a junior analyst at a consulting firm. Rather, he's after an enriching peer-to-peer engagement, where the interviewer is as much of an expert as him and new ideas and concepts can be brainstormed and jointly formed. Done in this way, many European payers are genuinely interested in engaging with innovators to structure effective clinical trials that generate data they need. The discussion gets to the core of the value proposition: How are current treatments reimbursed? Will the current codes allow the administration of a novel product? What is the minimum clinical performance that would be valuable? What is the value of the improvement I'm offering? How do I demonstrate that value (endpoints, comparator, trial size, patient segmentation etc)? What is the payer's reaction to the proposed clinical trial? What would be the value of a companion diagnostic? Choosing the correct comparator is critical: demonstrating comparative effectiveness is challenging if your comparator is not relevant.

Payer advisory boards

But, in case you hadn't heard, there are differences between each European country. Ask a German payer a question, it'll be different to his French colleague and different again to the Brit. There are national and regional differences in standard of care, complicating the choice of comparator. Quality of life data are crucial to a value proposition, but the preferred instrument can vary by geography. To manage this heterogeneity, Alacrita forms payer advisory boards, bringing together a number of payers from different geographies and perspectives to develop an integrated strategy that best accommodates the broad spectrum of EU payers. For a pivotal trial, this process can be

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iterative, with the target product profile evolving as feedback from payers is incorporated into the trial design, then retested again with the advisory board.

Value of market access strategy

By developing a market access strategy early in development (pre-Phase II), companies are rewarded with a clear roadmap for demonstrating value. Including a value section in the dataroom establishes the company's credibility and negotiations with pharma partners are buttressed by evidence, enabling the biotech to set out a convincing valuation. More and more deals involve milestones tied to market access – you're offered $30m if the drug gets regulatory approval but $100m if the product gets a certain price in key territories. What is the value of those milestones? How likely is it that the drug will get that price?

What's more, the partner, normally accustomed to backfilling market access requirements or even repeating clinical studies, is delighted to see a coherent market access strategy. This further enhances the value of the asset under negotiation.

Your partners need it

Tao Fu, Head of Mergers and Acquisitions at Johnson & Johnson wrote recently "At J&J we do extensive payer research for every significant business development project… we expect [biotech] to thoroughly think through the incremental value their products will bring to medical practice and design their clinical development plans and target product profiles accordingly."

In the words of Louis Pasteur: "Fortune favors the prepared mind".

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