

The Growing Importance Of An Integrated Market Access Strategy To Battle The Recession

Contributed by GfK

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It's All About Return On Investment (ROI)

In the past few years, the pharmaceutical and biotech sector has faced many challenges with the patent-expiry of big blockbuster drugs, shrinking pipelines and fewer drugs entering the market.

With respect to the latter, the role of the payer in determining market access success has become significantly more pronounced.

The economic downturn has taken its toll on the life science industry. The lack of freely-available credit has significantly affected smaller- to mid-size life science companies, and even large companies are not immune.

Most notably, the current economic crisis has forced some companies to focus resources solely on development, at the expense of basic research, with the aim of bringing drugs in clinical development to the market as quickly and efficiently as possible.

For example:

BioNovo has made a strategic decision to defer work on pre-clinical drug candidates to focus on their clinical pipeline. The current difficulties in obtaining financing has also forced EpiCept Corporation to discontinue all drug discovery operations, in order to direct resources towards its clinical programs and registration of Celplene.

Telik Inc is also restructuring and downsizing its workforce primarily in early-stage drug discovery, enabling the company to focus on the clinical development of its lead compound, Telintra, which is currently in phase II development. Even the largest pharmaceutical company in the world, Pfizer, announced in early January that it was downsizing its R&D program.

You can all agree, then, that bringing a drug to market has become increasingly challenging for pharmaceutical and biotechnology companies. Traditionally, pharmaceutical companies were required to demonstrate product safety, efficacy and quality for purposes of registration (the so-called "three hurdles"). Starting from approval, the licensed drug is patent-protected for a specified number of years.

It is during these years that a drug needs to maximize its return on investment (ROI). In the past, drug companies were largely unopposed in charging what they believed was the "right" price for their product. In recent times, a fourth hurdle has emerged which requires that companies demonstrate to payers the economic value of a product to be reimbursed. This fourth hurdle not only has pricing implications but also influences the period of patent protection.

On the one hand, registration requires data obtained in the clinical trial setting (mandated in the traditional clinical development plan); but payers require data from the "real world" for their decision making.

Payers want clear evidence that the new drug offers significant benefit over current standard of care, and not placebo, and are increasingly requiring cost-effective data (incremental to current therapies) to assist them in their decision making. There is thus clearly a disjoint between the data required for registration and that for reimbursement of a product.

The key to success for market access today is to define what evidence is required for both registration and reimbursement of a product as early as possible during clinical development. As early as phase 2, it is imperative to develop a robust and comprehensive market access strategy that complements the clinical development plan.

Development of market access strategy may include positioning studies and assessments of unmet needs, forecasting and early economic modelling. Ultimately, it is a critical exercise in determining what data need to be collected in clinical trials from a regulatory and reimbursement perspective, and what additional studies and analyses need to be performed to ensure successful market access.

The bottom line for companies is that planning ahead and thinking about market access during the early stages of clinical development makes financial sense. It has become increasingly important to get it right the first time around and maximize ROI in any environment, but especially in a period of economic downturn.

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