

# Blue oceans, market access and competition

## Requirements for strategic planning within launch optimisation and market access

**The pharmaceutical industry continues to innovate and stride ahead. However, in today's challenging austere climate, those contemplating new product launches need to navigate many financial and competitive obstacles. Innovation is only as good as the commercialisation strategy behind it. So what does austerity mean for the pharmaceutical industry and how can new product launches survive and achieve success?**

### The impact of austerity measures

In an era of patent cliffs and shrinking pipelines, capturing full value from every product launch is critical. Despite this, only a third of launches actually meet or exceed analyst expectations, meaning successful commercialisation still remains a considerable challenge.

The importance of getting a launch right is critical, however the question that remains for many pharma and biotech firms is how they can consistently optimise the launch process and hence the outcome.

### Patent challenges and payer incentives

In 2014 alone, 10 key brands (worth approximately US \$19.5bn) lost their patent exclusivity. As a result of this and previous patent losses, a multibillion dollar market opportunity for generic manufacturers across key geographic regions has been created.

However, it is not just small molecules which are being affected. Biologics will increasingly feel the impact as more biosimilars enter the market.

### Market access and launch optimisation

As a result of payer pressure in key markets many companies have realised the importance of having more focused market access strategies during clinical development. In many major markets payers have increasingly high negotiating power and unfortunately in most cases pharma is not appropriately prepared to enter discussions.

Experience indicates that companies which strategically plan from the earliest stages of clinical development, and throughout the commercialisation process, are more likely to achieve a successful launch trajectory in the first 6-12 months.

### The concept and reality of Blue Strategy

*"Blue Ocean Strategy is the avoidance of costly competition through innovation with the aim of creating a market where no firms currently operate, leaving the company to expand without competition"*  
W Chan Kim and Renee Maugogne  
Co-authors of Blue Ocean Strategy

Blue Ocean Strategy is based on a study of 150 strategic moves spanning more

than 100 years and 30 industries.

With the combined forces of patent loss, generics and the resultant payer pressure, pharma has looked to 'Blue Oceans' of specialist and orphan indications to both meet high unmet need and replace lost revenue.

Although the rare disease market remains relatively small, orphan drug development is growing at an incredible pace and worldwide orphan drug sales are forecast to total \$176bn by 2020. These previously uncharted waters have been driven by patient demand and the need for alternative revenue streams as the patent cliff for many pharma companies looms closer. In addition regulatory incentives have aided the development of a greater number of orphan drugs.

However, the increased development and licensing of orphan drugs in recent years has now led to greater competition and a change in the market dynamic. The orphan drug market is now starting to more closely resemble the trends and challenges seen within traditional markets. As some rare diseases now introduce second and third entrant orphan drugs the reimbursement challenges and payer demands are increasing. Notably, a greater burden of proof is necessary of unmet medical need.

### Competition-driven access strategies

We know that continuous competition causes disruption. Companies have responded by seeking to develop insight into competitor activity to influence both their market access strategy and subsequent launch. Traditional research methodology focuses on internal assets. For example a market access event may occur and is communicated to your team. Research is scoped and commissioned. The research is then concluded and tactics are implemented. This all occurs in a linear timeframe, offering just a snapshot of one event at one time point. However, during this same period several other market access events may have occurred. As these are not communicated or incorporated into the final tactical plan any conclusion of the research will not be reflective of the changing environment.

Real-time competitive insights are far more valuable than traditional research methodologies. Those companies who



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continually monitor the landscape and competitor events are able to make proactive market access decisions both during clinical development and post launch. This enables them to innovate and shape the market as their tactics are evolved on an ongoing basis. A real-time strategy is flexible and continually adapts to a changing market access landscape.

### Finding land and coming ashore

Ask most airplane passengers and they will tell you that "taking off" and "landing" are what makes them most nervous. The same can almost be said of the pharma and biotech industries. Robust market access and competitive analysis strategies must be considered as a core component of 'launch optimisation' and hence successful commercialisation. Companies who adopt these early will be more likely to achieve commercial success. In a rapidly changing and competitive environment companies reliant on incremental innovation and targeting key customers, will lose out.

The key to striving ahead is to consider and be aware of competitors from the earliest phases of clinical readiness right through to post-launch. Those who ignore their competition, do so at their peril.

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