Commercial Development in a Complex Environment — MAXIMIZING FUTURE SUCCESS

Future planning defines the destination that will best help the company achieve commercial success and then develop the most effective strategy required to arrive at that destination. Importantly, this strategy is as much about determining what not to do as well as what to do.

Today's biopharma companies recognize the reality of the maxim: pipeline equals lifeline. And, because of the inherent lengths of time involved in the development and bringing to market of pharmaceutical products, they would also recognize the reality that end results invariably rest on successive decisions made over a period of many years. Decisions such as which population to target, what data to collect, and what is the core value proposition made during the development of a product can mean the difference between success and failure.

A Changing World

The importance of decisions made throughout a drug's early life have always significantly impacted both technical and regulatory success. Let's take just one set of figures. For every 5,000 to 10,000 compounds that began early phase research, typically only 250 make it to preclinical testing, out of which only five make it Phase I clinical trials. From this you get just one successful marketed medicine, which equates to less than 0.1% of potential drugs making it from discovery to entry into clinical testing (Pharmaceutical Research & Manufacturers of America [PhRMA] 2010b). The development of a new drug is also a long and expensive process. The estimated time to bring a new drug to market is 10 to 15 years (with clinical testing alone expected to take between six and seven years), and the expected capitalized cost of a new drug is quoted as anywhere between $1.2 billion and $1.5 billion (DiMasi & Grabowski 2007, Office of Health Economics 2012).

However, these same early decisions are impacting the ultimate commercial success of a product more than any time in previous years. Here are some additional figures that are indicative of today's complex environment for drug commercialization:

- 32% of drug candidates are pulled prior to regulatory approval for economic conditions (compared with 20% for safety and 38% for efficacy) (Tufts Center for the Study of Drug Development)
- The rolling average number of applications approved by the U.S. Food and Drug Administration (FDA) in the last five years remains around 35 (Drugs@FDA)
- Only two out of 10 marketed drugs return revenues that match or exceed R&D costs (Vernon, Golec, DiMasi, Health Economics 2010)

These are the result of changing global market dynamics, which have seen increased competition, significant cost pressures, ever-evolving regulatory frameworks, and generic intrusion rates of over 80% post patent expiry.

So, how can we ensure the development of products that will achieve commercial success in the future?

A Changing Future

Anticipating and preparing for the future is clearly a critical determinant in achieving commercial success. But what future? Unfortunately, time travel and predicting exact future worlds remain the property of science fiction, Hollywood, and blockbuster movies, however realistic some of them might seem. Nonetheless, the discipline of planning for different future scenarios based on real-world data, multiple customer perspectives, and the extrapolation of current market trends is an increasingly effective approach. Unlike developing a product to fit a specific, predicted future, planning for different "futures" is about ensuring that what you develop/are developing is fit for whatever future ultimately unfolds. And, as such, offers genuine competitive advantage for those companies that take it seriously and execute it skillfully.

Taking this approach also helps companies understand not just the value of having a clearly defined strategy or direction, but also how this relates to the potential future worlds or scenarios you are anticipating. An oft used analogy in planning for any future scenario is a car journey — you need to know where you want to go in order to make sure you get there. You can then use appropriate tools such as a GPS to guide you to your destination. And while companies may have a clear sense of where they want to go based on today's market dynamics and customer needs, this may not be relevant given the future world(s) that they are heading toward. Treatment approaches and guidelines change, who is bearing the ultimate cost of treatment changes, available medications and diagnostics also change.

Take the example of a pharma company with a promising compound in Phase II to treat a number of potential conditions. What is the optimal path for development and commercialization? Will a competitor with a similar or different mechanism have beaten them to market? How will either generics or biosimilars change the way patients are managed and treatments are reimbursed? Will diagnostics or other technological developments have presented clinicians with very different options, or even rendered the need for the product obsolete? Will the healthcare landscape be such that payers, prescribers and even patients will be able to, or even want to access the product?

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Having a view of how the future is going to change, and the events that have to occur to get there, leads to a number of possible "futures." This approach then provides companies with not only a number of options from which to define the probable future destination but also the likely milestones en route. It is vital to not only have a view of the future but on what has to happen for that "future" to come to fruition. This allows an understanding of the possible deviations from the journey to the probable future should certain events happen or not happen. The equivalent of the map under pinning the GPS analogy above with forks in the road and consequently different destinations.

The Need to Meet Unmet Needs

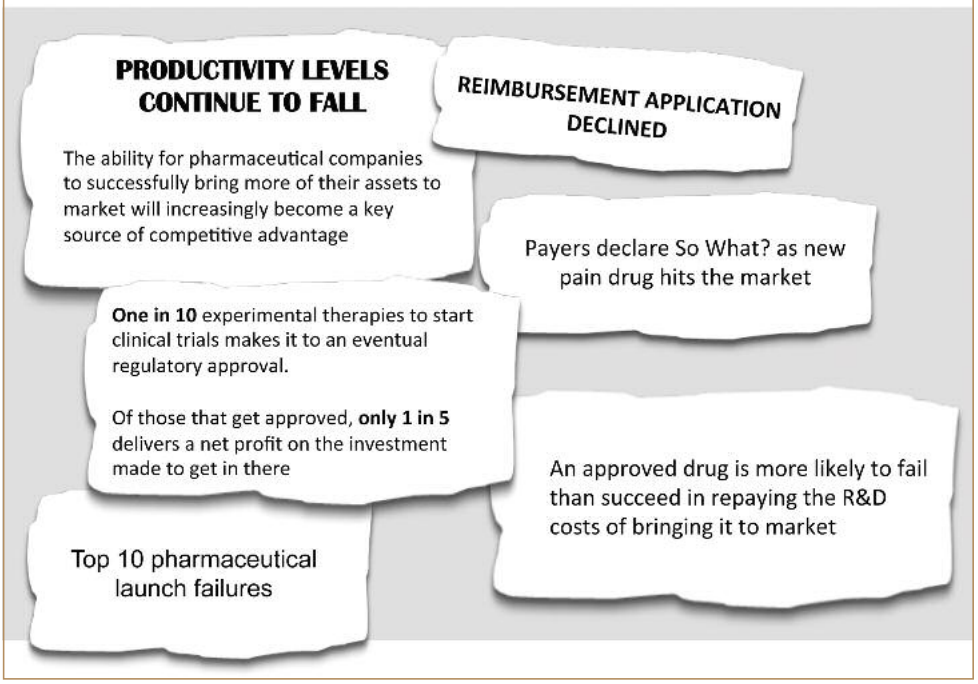
At the heart of this approach is focusing on anticipating the unmet needs of the future and recognizing that they will likely not be the same as the unmet needs of today. To do this well requires understanding multiple stakeholder and market perspectives; understanding where the science is going; seeing things through clinician, patient, and the payer lens; identifying the underlying drivers that may change market dynamics; evaluating potential future competitors. Easier said than done, given the different parts of any business involved in the development process. There is a real requirement to ensure synthesis of all internal views, clinical, commercial, regulatory, access, counterbalanced with objective external assessments of the unmet needs and market drivers. And then developing a fusion of all that different expertise to develop a complete view from a clinical, regulatory, and payer perspective to arrive at a common accepted view of the direction and the journey to get there.

One of the core strengths of adopting this approach is that it is flexible enough to be used at whatever stage a pharma company may be at in its product development cycle.

For example:

- For companies looking for assets in a therapeutic area, "future" planning enables them to answer the questions: "What will drive value in the future?" or "What market problem can we solve?"
- For companies with assets (pre POC) it enables them to answer the question: "Where should we focus development of this asset?"
- For companies with assets (post POC) it enables them to answer the question: "What type and level of evidence will be required and what data will we need to generate?"
- For companies with assets (Phase III) it enables them to answer the question: "How can we best position our product and what can we do now to set the stage for the introduction of our product?"

Commercial Success is Becoming Increasingly Challenging



Preparing for the Future, Today

In each of the above, "future" planning defines the destination that will best help the company achieve commercial success and then develop the most effective strategy required to arrive at that destination. Importantly, this strategy is as much about determining what not to do as well as what to do. For example, a given scenario planning based future destination may necessitate choosing not to continue with the development of certain compounds in a particular direction, or even at all. It may also guide the types of skillsets and relationships a company must develop to successfully commercialize its compound.

We began by talking about pipeline equaling lifeline. Both are fluid and dynamic, and so is the "futures" approach. It allows real-time pressure testing your strategy as you are continually assessing how the marketplace is matching with your range of anticipated futures. For example, by continually engaging with payers and prescribers, you can monitor their actions and beliefs about the future and feed this back into your own strategy. And when anticipated changes in the economic or regulatory climate do, or don't occur, these can be fed back into your strategy, enabling the most effective responses to be made to protect your pipeline and therefore secure your lifeline now, and into the future.

It is not about predicting the future, but rather understanding customer needs and opportunities in a range of potential future scenarios. PV