Synchronising brand and market-shaping activities for disruptive therapies: the importance of policy and brand alignment (PDG8)



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Introduction

Significant innovations in healthcare often require new ways of thinking to recognise their true value. It is the responsibility of the pharmaceutical industry to help drive change that can match healthcare spending to the most valuable innovations. Here we assesses the challenges facing industry in preparing for innovation by synchronising long-term investment in the broad policy environment with shorter-term market access strategy ahead of brand launch. This is especially important for disruptive therapies because the policy environment needs to be ready for a paradigm shift. To understand what drives success in brand, policy and market alignment for innovative new therapies, we conducted discussions with experts in the field (n=12). The aim was to identify common themes, examples of good practice, and lessons for companies as they bring new generation innovations to market. We have distilled our findings into 10 lessons for aligning policy and branding in market-shaping activities for breakthrough technologies. We propose strategically integrating within the drug development process additional key steps that will ensure synchronisation of market-shaping activities. Early in the process, researchers, developers and marketers will need to form a consensus of what is possible and how much time and investment it may take.



Current healthcare systems are not ready to adequately value breakthrough innovation

Current healthcare systems have evolved to value incremental improvements in therapeutic outcomes. These systems have proved less flexible at responding to increasingly complex, personalised medicines that offer game-changing solutions. The first gene therapy approved by the European Medicines Agency (EMA), uniQure's Glybera, launched in 2012 and attracted headlines as the "world's first million dollar drug". It was withdrawn after allegedly recording just one commercial sale. Payers were extremely cautious in their assessments of Glybera and could not see beyond the immediate financial burden – despite comparing the one-time administration of Glybera with comparators that required continuous administration.



Traditional launch readiness models are unfit for taking breakthrough products to market

Stakeholders and systems are not prepared for potential step-changes in outcomes, such as cures. The onus is therefore on manufacturers to develop and prepare the market in new ways ahead of launch – not just shape the brand in anticipation of its arrival, e.g., Spark Therapeutics engaged with policy and pricing stakeholders pre-launch of Luxturna to overcome the financial burden and secure funding. An innovative contract with Express Scripts to use their distribution capabilities helped to secure market access.



Breakthrough innovations need a more concerted change in the ecosystem

Manufacturers must invest in advance to make the market more receptive to the full value of disruptive innovations but in the knowledge this must be brand agnostic. For example the IO class achieved success through education on the mean of the Kaplan-Meier Survival Estimate, rather than median, which was previously the benchmark in oncology. This effort was led by BMS in support of Opdivo, but also supported Merck's Keytruda, which was generally considered by analysts as relatively low-priority until Opdivo's results changed the market.



There are multiple options and examples for macro market development

In the traditional pharma model for non-targeted therapies, payers bear the financial risk for non-respondents, leading to potential frictions at launch. Novartis considered an outcomes-based contract to overcome resistance from payers to fund Kymriah, in which the payer does not pay for (or is rebated) the drug if the patient fails. The situation was complicated by Medicaid best price rules under which Medicaid pays the lower of either a 23.1% discount from list price, or the lowest commercial rebate/discount. For failing patients, that is effectively a 100% discount, which will influence the Medicaid best price.



The current paradigm to appraise value will need to evolve

If disruptive technologies launch for mass-market conditions like sarcopenia and NASH, then attitudes and priorities in public health and policy will change. Expectations (and demand) will change if there are potential solutions to long-term chronic diseases such as early cognitive impairment and obesity. However, the market will need significant prior investment to change the way it perceives and values potentially disruptive changes to established paradigms.

Sync and disrupt



The need for change in value frameworks is clear but how and where to invest is uncertain

In areas such as antibiotic resistance and rare diseases, there is acknowledgement of the need for investment but uncertainty over incentives. In the case of antibiotic resistance, the high cost of bringing new drugs to market, low volumes required by antimicrobial stewardship, and low prices of generic benchmarks mean that normal commercial incentives are insufficient. An international task force, for example, is calling for a \$1 billion reward for new antibiotics with the amount linked to potential sales of the product.



Traditional med affairs or advocacy are unlikely to obtain step change in the market

Disruptive innovations may raise new questions about low patient numbers, lack of clinical data and the high cost of therapies for teams within pharma companies. While their processes and work flows work for incremental advances, they are not always set up to change the ecosystem for disruptive innovation. One way around this is to engage earlier and more collaboratively with patient advocacy groups (PAGs). This can help make a big difference in understanding and representing patients' interests across stakeholders within a company.



Policy and corporate teams are more likely disrupters than brand teams

Policy and corporate teams are more brand agnostic and have greater freedom to focus on developing the macro environment – not just the brand. But budgets are smaller making it more challenging to make longer term investments in changing the ecosystem. Pharmacia's launch of Zyvox for MRSA is a good example. Pharmacia (now part of Pfizer) prefaced its launch with many years of public relations work, helping raise both public and healthcare professionals' awareness of Zyvox, and securing near nationwide coverage from day one.



Adopt a portfolio approach to macro market development to help drive success

While the brand approach to micro market development is a well-oiled machine in which results are relatively fast and metrics well-defined, a portfolio-based approach can also pave the way for successive, multiple launches. When Yervoy (ipilumab) was the first IO to be approved in melanoma in 2011, BMS invested in payer education of the relevance of the mean of the Kaplan-Meier Survival Estimate. When BMS came to launch Opdivo in 2014 in the same indication and with better results, payers were more receptive to the additional benefit.



Long-term investment in a range of solutions is needed for disruptive technologies

With disruptive therapies, it is important to take a long-term view of the overarching 'story' behind the new technology to give time and space to prepare the market for launch. Roche strategically acted ahead of the launch of its breakthrough medicine Herceptin for the treatment of early-stage breast cancer in England, sponsoring hospitals to establish HER2 testing, as well as running a public awareness campaign that brought public attention to Herceptin, leading to fast-track assessment and approval by NICE.

Conclusions

The pharmaceutical industry is still learning how to prepare existing healthcare systems for the arrival of the latest generation of more personalised medicines with the potential to disrupt current concepts of value. The best advice is to synchronise brand, franchise and policy initiatives early, work collaboratively across industry, patients and healthcare stakeholders, and follow a few simple best practices to prepare the market in advance for what promises to be the arrival of a new set of disruptive game-changers.



