2017 IN REVIEW

LEARNING LESSONS IN MARKET ACCESS

As we enter the last busy period of the year, time and resources are highly constrained. Current projects are finishing up before the Christmas break and new ones are coming in as client budgets get their final flow. It's a time of non-stop action, when focus is on delivering value at fast pace, and in the here and now.

And that's why this is the perfect time to put our heads above the trenches for a moment, see where we have come in the last year, and start looking ahead so that we can greet the new year, not exhausted from our efforts, but energised by our outlook.

Reviewing our business this year, it's possible to categorise our engagements into clusters and identify not only common themes, but lessons on how our clients can avoid some of the challenges they highlight. We outline two of these themes below (though there is certainly many more).

Moving From Price to Value

We have written previously on the different mechanisms that payers use to control prices and limit access for both new and generic medicines. But many of our clients are facing access challenges a few years down the line from launch, when the buzz of innovation has begun to wear off, but the drug still offers strong clinical value.

The first question to ask is how did the company get themselves in this position. Doing so raises several possibilities: perhaps they got the initial pricing strategy wrong and are now suffering as payers start to question the true value added; or, maybe the value and access plans for the post-launch period were not fully considered prior to launch.

Considering the case that both of these might be partially true points to a lack of cross-functional communication in the peri-launch period. Commercial has set a price based on research and revenue projections, market access has focused its energies on getting the right access strategy, and now local teams are at the mercy of increasing payer pushback with an inadequate in-market evidence and communications strategy – the 'fifth hurdle' of market access.

The obvious, and most unhelpful, solution is to think much earlier about the challenges that an innovative drug will face post-launch. Yes, the company will have done a competitive pipeline analysis, assessed market threats, and have a vague idea about lifecycle management, but this is insufficient. Earlier thinking is nothing without earlier engagement and action.

And so, what is really needed is a continuous plan for market access excellence, which, needs to proactively factor in opportunities for value-adding evidence collection and its dissemination. The silver bullet of real-world evidence? Not quite, but leaving it as an afterthought is no longer possible.

Lesson 1: Start planning post-launch evidence generation and value communication seriously and as early as possible.

This is all very suitable advice for companies in the appropriate planning stage, but what if they find themselves in the mire without an effective plan. Well, it's not too late to salvage success, though it won't be easy.

Companies that find themselves in this position are likely to have limited and disparate evidence of clinical efficacy in the real world. The aspirational value propositions that so wooed payers at launch are wearing thin, and without any mandate on either side for continuing access, the value of the drug remains unsupported. At this point, companies begin to consider some kind of contracting solution that will help to maintain access at, or very close to, the initial launch price. But, when the product has the feel of being in a commoditised area, it can be difficult to persuade payers that additional administrative burdens are worthwhile when simple discounts are offered by competitors.

The upshot here is that contracting solutions that continue from the point of market access, where so-called managed entry agreements (MEAs) typically focus, through the mire of commoditisation are needed. Even if the focus, appropriately so, remains on the launch phase, at least having a precedent in place makes the renewal or redesign of such an access scheme more palatable.

That said, we still haven't provided a solution to the original problem: how to demonstrate the value of best-in-class therapeutics in price-driven markets. It's tricky, because it is not primarily a technical problem, that can be solved just through evidence generation and innovative contracting. It is, instead a strategic problem, which requires a re-alignment in the business objectives given the current state of play.

Lesson 2: Ensure that managed entry agreements factor in the changing clinical and economic environment to future-proof product value and access.

We have learnt this the hard way by helping clients with what appears to be the most pressing problem, be that a consolidated value proposition, or innovative contracting scheme. However, often along the process of mutually probing the issues, it becomes clear that the crux runs deeper down than the surface. This process is not always easy, because the client is not always cognisant of the problem or, if they are, they are not in a position to admit it (perhaps because of internal political reasons).

What is required is an honest account of what is known and what is not. A consultancy is able to provide a better, more insightful process when they are aware of all the contingent factors.

A brainstorming phase, followed by filtering, is a good idea to narrow down the many priorities so as not to become overwhelmed in trying to solve all the client's problems at once.

Once these core issues have been identified, an in-depth re-analysis of the therapeutic environment should be conducted in several key markets. What has changed in the clinical and economic marketplace since launch? What is the direction of travel in the marketplace? What solutions have worked in the past? These steps can add several weeks to the programme of work, but the results produced at the end, which will then also include the more technical and tactical aspects, will produce a much better response to the business objectives.

Lesson 3: Take time to get to the heart of the problem by re-assessing the current and future landscape from a global business objective point of view.

Disrupting the Treatment Paradigm

Another challenge that we have helped numerous clients with over the last year (and beforehand) is one that begins with a treatment landscape that has either (i) a well-entrenched but sub-optimal standard of care or (ii) a multitude of therapeutic approaches defined largely by individual clinical preferences. Though at opposite ends of the spectrum, and seemingly providing divergent marketplace dynamics, the common root between them is that new treatments can face particularly strong access challenges.

Typically, the therapeutic innovations that face this additional hurdle fall within what we refer to as 'cold' indications. Often, they are acute interventions, which, given the prevailing focus of health systems on chronic conditions, already places them at a perceptual disadvantage in the payer's eye. They are not a top healthcare priority and, incredibly, sometimes they are not taken seriously. Such therapies include those that are administered in critical care. Here, incumbent treatments may have been the same for decades and are usually supportive rather than disease modifying, so there is almost always a clear clinical unmet need. They may also be generic off-label products and hence make for inexpensive pricing comparators.

However, while the disease areas will be low on the payer radar, any new treatment cost is likely to have an immediate additional budget impact because they are not replacing an existing therapy, and therefore costs are still an issue. Additionally, because the disease aetiologies are less well understood and, most of the time, are multi-factorial, there is a perceived credibility gap and less appetite on the payer side for adopting risk. Further complications can be an ill-defined treatment duration, which, if there is a change in treatment setting, has implications on the funding pathway in some markets.

The best approach to this problem is to map out in detail the current treatment approaches and, importantly, the associated costs. Overlaying the new management strategy should enable identification of improvements in the treatment pathway and tangible cost-savings that can be used to offset the price of the new intervention. Now the client is in a position to draft a value story around this impact and accurately assess payer willingness to pay. Evidence generation plans can then be tested for feasibility internally, which will also serve to align separate business units (e.g. medical, commercial and market access) around the clinical strategy.

Lesson 4: Creating a compelling payer-centric value proposition should include detailed mapping of the treatment landscape and costs.

When there are a number of indications under consideration, it is important not to get overwhelmed by the amount of information available and over-do the depth of research. Conversely, spread the investigation too thinly and insights will not be robust enough to adequately inform commercial decisions. Therefore, a systematic approach is hugely beneficial, not only because then all recommendations will rest on an equal footing. There are several useful methodologies that can help, particularly in early asset identification and business development activities, when time is usually of the essence.

Using decision matrices, plotting critical needs against each other, is the easiest and most easily understandable methodology. And sometimes, simplicity has its benefits, particularly when the results of these early assessments will likely need to be communicated quickly and clearly to senior business leaders for rapid decision-making. Of course, having simple outputs doesn't mean that complex thinking doesn't underpin their meaning.

Critical here, therefore, is defining what are the critical needs in the first place. Do assets need some functional or therapeutic alignment with in-house pipeline products? Is the goal incremental value in a wide patient population or game-changing efficacy in a sub-set of patients?

Alternative methodologies might leverage multi-criteria decision analysis-style frameworks or target product profile scenario models, as appropriate. Each one has its benefits and drawbacks. However, one major failing we have observed in some assessments has been too much focus on either the clinical or the commercial aspects, which produces a skewed viewpoint. Sure, an asset hitting the target outcomes in a particular oncology indication, say, may satisfy an undeniable unmet need, but is there a viable cost model that can pay overall commercial dividends?

Lesson 5: Early business development opportunities should be systematically assessed along defined business needs from both clinical and commercial perspectives.

Once the primary target indication has been agreed upon, an important consideration in situations like this is the need for developing advocacy in favour of the disruptive technology, across stakeholder archetypes. This is critical given that if the intervention is going above and beyond current political, technical, or financial boundaries, additional buy-in and support will be needed. Typically, a successful market access strategy is based around alignment of three dimensions: the product (and its associated value proposition), the organisation (and its launch and marketing capabilities), and the marketplace (with its associated drivers and barriers).

Concerning the latter, and learning from some of the lessons discussed earlier, understanding how the business goals are embedded within the external environment is a necessary first step. Then it is a case of shifting the market in favour of the goals. Not exactly an easy proposition. But, with a clearly identified stakeholder engagement strategy, not an insurmountable problem.

Clearly, understanding current stakeholder mindsets is fundamental. Only when the needs and drivers of certain behaviours are mapped can steps be made to change those behaviours. Belief-shift models here can help to align tactical engagements around core business goals. Planning for long-term partnerships is also much more preferable than capricious and irregular communication and will help build trust towards

collaboration, whether that is developing bespoke contracting solutions with payers, or updating guidelines with physicians, just for example. It is a lot more efficient to bring stakeholders along for the journey than to have to backtrack to pick them up later on.

Lesson 6: Leveraging wide stakeholder advocates to make the case for change will help in understanding and overcoming market access barriers.

In Summary

It's a sad reality that personal resolutions made at New Year seldom make it through January, often because they are unrealistic and not evidence-based. The same can be said of our professional goals. However, by considering both the mistakes and success stories over the last year, and continually re-evaluating our clients' needs within what is a continually evolving marketplace, we hope to welcome 2018 with clear sight and the ability to put our lessons learned into practice.

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