Overcoming quantitative pricing limitations with payer insights

Choosing an accurate price for a product without a therapeutic equivalent can feel like a leap in the dark

Pricing pharmaceutical products is not an exact science. There are many elements that pharmaceutical companies must consider when making this judgement, not all of which can be exactly quantified. Recouping the large investment in research and development is always going to be the priority, but other considerations such as product life cycle, patent protection, innovation, government controls, and corporate philosophy all have an influence in the pricing decision thus making pricing one of the most complex economic decisions.

One of the main benchmarks for pricing decisions is of course the competition - but what about when there are no comparable therapies? You may have a first-to-market treatment, a new innovative targeted therapy, or an orphan drug - these scenarios raise different questions and, in the case of the latter, represent a burgeoning trend in the industry. The pharmaceutical blockbuster model has been diminishing for years, leading to increased interest in more targeted, personalised therapies, and in rarer diseases where there is often no therapeutic alternative. Orphan drugs - pharmaceutical treatments for rare diseases or disorders - have proven themselves as viable money-makers.

Indeed, EvaluatePharma's 2014 *Orphan Drug Report* reveals that orphan drugs are now associated with a greater return on investment than products aimed at larger groups of patients. According to the report, orphan drug sales will make up 19% of the total share of prescription drug sales by 2020, totalling $176bn.

And they'll grow at an annual rate of nearly 11% per year through the end of the decade, compared with about 4% for drugs treating larger populations. As well as the lack of competition, the orphan drug designation offers a fast-tracked regulatory review process and lower cost late-stage development.

But while there is more freedom in pricing for treatments without a therapeutic alternative, and while potentially these can be very lucrative, it is certainly possible to get the pricing strategy wrong. For example, in 2011, a company called KV Pharmaceuticals received orphan drugs status - and seven years of market exclusivity - for Makena, its own version of progesterone, used to reduce the risk of pre-term birth. The company set a price of $1,500 per dose for Makena, compared to $10-$20 for compounded versions, and sent cease-and-desist letter to pharmacies to stop compounding the medicine. A social media-led public outcry followed; in the backlash, KV Pharmaceutical's non-profit partner March of Dimes cut all ties, the FDA issued a press release saying they would take no action against pharmacies which produced compounded versions, and the company's stock subsequently tumbled by 60%. In 2012, the company filed for bankruptcy.

Choosing the right model

Companies launching new treatments which don't have any therapeutic equivalent on the market often base their pricing strategy either on a 'value-added' pricing model, based on replacement or enhancement of current treatments in the same category, even if they are a different class, or a 'cost plus' pricing model, based on the development costs and return on

investment before newer products or generics are likely to be available.

These strategic decisions tend to happen relatively early in the clinical development process (eg during indication sequencing or clinical trial design), in the context of asset evaluations for in-licensing, or during the pre-launch phase to inform commercial price decisions. While they are valuable tools, such models can be complex, time-consuming and expensive, and often require a significant amount of input data, which isn't always available.

A new approach

'Comparable value' pricing models can compare the characteristics or benefits of drugs in different clinical categories. For example, disease areas that have seen therapeutic innovation in recent years may provide points of reference for assessing the value of new interventions in areas where there has been a longstanding lack of innovation.

We have developed a new analogue value analysis, which leverages secondary data for an eligible set of products, providing an alternative to other traditional market research-based methods.

The unique methodology looks at the cost of drugs approved in the past. We select potential analogues for a new product based on one or more shared characteristics. These could include characteristics such as the type of clinical benefit - for example reduced mortality, symptom control, cure and disease control - route of administration or treatment duration.

For these analogues we calculate the size of the patient population that would be eligible for treatment based on the wording of the indication statement at the time of first marketing authorisation. Similarly, we look at the cost per day of therapy (DOT) based on the drug prices at the time of launch. Finally, in order to compare the efficacy of analogues, we calculate the Number Needed to Treat (NNT) for any of the appropriate primary or secondary endpoints in the pivotal registration studies.

The relationship between the size of the patient population eligible for treatment, the cost of treatment and clinical efficacy is then explored further.

'A social media outcry about a firm's price-hike eventually saw it go bankrupt'

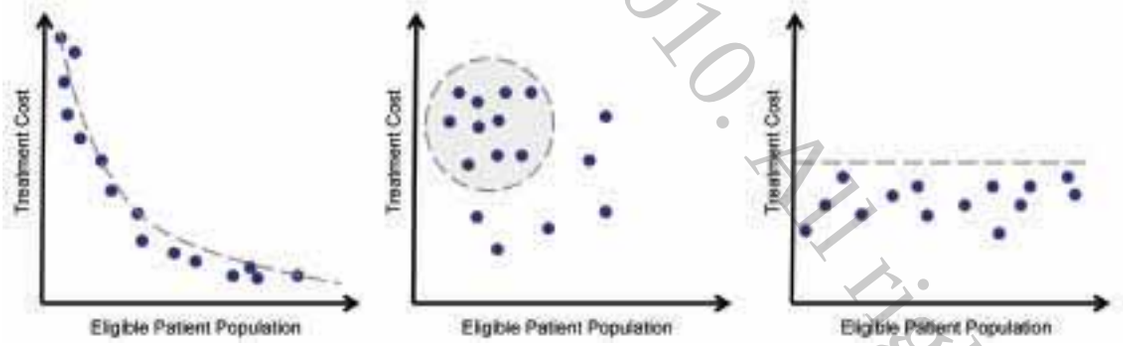
Clear patterns emerge

In analyses conducted to date, this method of assessing previous market performance produces critical insights that can inform pricing decisions. We have seen clear patterns emerge, the most common of which are a strong correlation between greater efficacy and higher price and, on the other hand, a strong correlation between bigger eligible patient populations and lower price (see Graph 1). In this scenario, most of the variation in the prices of the analogues is explained by these two variables.

While patterns such as these are relatively predictable, if the data is available on the actual or expected efficacy of a new drug and the expected size of the patient population, these correlations can be extrapolated to identify the likely price corridor for the new drug, with the upper boundary usually set by the efficacy and the lower by the population size.

A second clear pattern to emerge is where prices clustered around a single point (see Graph 2). In this case it is likely that the price will need to be anchored to the

'Pricing is never an exact science, but new methodologies can help'



price of these existing analogues. Finally, we have seen a third pattern (see Graph 3) where clear price ceilings exist in certain markets and groups of analogues.

When to use this methodology

In our experience to date, this methodology delivers insights into likely price scenarios that are comparable to other systems, but also has some advantages. First, it can be conducted using relatively simple, and usually readily available, information about a new treatment, such as the indication, patient population size, efficacy, proposed route of administration and duration of treatment. As a result, this type of analysis is particularly useful in situations where the company is facing time pressures, budget constraints or limited availability of market research information.

Examples of where it can be most usefully applied include the rapid evaluation of drug in-licensing candidates, price evaluation of assets (and different potential indications) that are still in early phase drug development, and as a complement and a verification tool to other price research methodologies when phase III results are available.

Finding the price corridor

While the pricing of a pharmaceutical product without a therapeutic equivalent is never an exact science, we believe this methodology can complement other approaches and, in specific situations - such as when time, money or market research are lacking - can provide an ideal solution for simply but accurately calculating the right price corridor for a new product.

Andrea Sobrio, managing partner, Executive Insight AG: a.sobrio@executiveinsight.ch

Dr. Clifford Hall, MD/subject matter expert, Executive Insight AG: c.hall@executiveinsight.ch