# CRA Insights:
## Life Sciences

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## How can pharmaceutical companies anticipate and address payer resistance to expensive, but cost-effective new therapies?

It is a paradox that new and effective treatments can be as much a problem for health services as the diseases themselves which were once incurable. The emergence of high-cost new therapies which are assessed to be cost effective for diseases with large patient populations has potentially damaging financial implications for the healthcare systems which are expected to fund them. The downstream implications for the pharmaceutical industry of payers, other stakeholders and the media focusing on pharmaceutical prices and total patient numbers in isolation can be very serious, especially when one considers the future beneficial impact of emerging new and costly therapies. Regrettably, the pharmaceutical industry becomes identified as the cause of problems regarding the perceived high cost of healthcare rather than a key player in solving those problems by providing cost-effective new therapies. Patients lose out as a result of being denied access to therapies that are proven to be effective in treating particular conditions.

To secure access to drugs at lower prices that are deemed acceptable, there is a danger that health systems will adopt ever more draconian forms of cost containment to the disadvantage of innovative pharma companies, such as:

- Cross border procurement of drugs, for example across Europe
- Bespoke taxes on pharmaceutical companies, such as the recent threats regarding hepatitis C therapies in France
- Compulsory licensing
- A shift in attitudes in the US leading to either price caps by individual payers or the introduction of a Health Technology Assessment (HTA) body which could significantly restrict access to high cost therapies

## Pharma can avoid the abyss by adopting creative strategies for pricing, access and reimbursement

Pharmaceutical companies need to secure approval for patient access at fair prices that deliver reasonable margins. To pre-empt the emotive and apparently contradictory decisions being made by policy makers and payers that go against them, pharmaceutical companies must act early in the development process to anticipate and manage the likely reaction to a new, high-cost therapy:

- Initiate and take control of the dialogue with all relevant stakeholders
- Clearly communicate the cost/benefit situation with reference to the real numbers of patients likely to be affected
- Be creative with payment mechanisms that will help alleviate the challenge for payers.

This is about working to ensure that healthcare systems are not overly restrictive and that decision makers and their influencers all understand the context for the pricing strategy and the true cost burden of treating patients effectively. At the same time, pharmaceutical companies need to demonstrate their understanding of the constraints faced by payers and a commitment to helping them manage the impact of the new products. They must also build relationships and genuinely engage with stakeholders from early in the development process, eventually working with them to create contractual structures that make patient access appropriate and achievable.

## How does an efficacious treatment become a problem, not a success?

At a time when proven efficacious but high cost, new therapies are being questioned in terms of funding viability, it is an anomaly that there are cases where payers fund drugs that deliver lower value for money. For instance in England, the Cancer Drugs Fund exists to fund treatments which are not regarded as cost effective. The new advanced breast cancer drug Kadcyla (ado-trastuzumab emtansine), for example, is funded in England at its full list price of more than £90,000 per patient via the Cancer Drugs Fund despite the fact that the cost per QALY was estimated by the National Institute for Health and Care Excellence (NICE) to be around £166,000 and therefore not within NICE's limit of £30,000 to be classed as cost effective. For treatments that are assessed to be cost effective, there is inevitably less resistance to funding them when patient numbers are lower because of the much reduced overall impact on healthcare budgets. But when patient numbers are high, payers and commissioning groups take a different stance.

In theory, finding a cure for every cancer at a cost of say $50,000, rather than incur the long-term costs of treatment and related care for patients who live with their condition, often for many years, would be seen as a triumph. But in the short term, funding such treatments across large patient populations would threaten to bring the system to its knees. Payers are therefore balking at the prospects facing them. High-cost drugs may have a significant short-term impact on their budgets and their ability to fund care for patients with other conditions. The prospect of funding shortfalls has become part of an intense public dialogue, primarily because the situation is misunderstood. In reality many patients were already being treated using therapies which have a significant cost, with the added problem of long-term societal costs associated with management of the sickest patients. So, refusing to fund a new therapy at a higher initial cost may be a false economy.

At the same time, it is only right that payers adopt a robust negotiating stance when considering the budgetary impact of a wide scale uptake of a high-cost new treatment. Not only do they have to balance the books from year to year, but also they are entitled to challenge the price tag put on new drugs.

## Pharma must understand, engage and collaborate with stakeholders

This is a complex situation, where both payers and the industry have valid but seemingly opposing stances and yet they share the goal of providing patients with access to effective therapies. While pharmaceutical companies can appear to be deploying brinkmanship in holding out for higher prices, it does not need to be like that: they need to invest time and effort in understanding and building relationships with all of the stakeholders involved, from early in the development process and then work towards pricing, access and reimbursement strategies that deliver value for both sides. Success is about preparing the ground effectively, well in advance of the product reaching the market, while recognising the political and financial constraints.

Taking the engagement concept even further, a company's reputation among the wider stakeholder community, including patient groups, media and politicians, has a significant impact on how price will be perceived by that community and on how price negotiations will be anticipated by payers. Thus, the combination of close relationships, ongoing engagement and effective communication tailored to key groups, makes for a better chance of achieving a "fair" price that results in appropriate access for patients rather than becoming embroiled in a debate within the court of public opinion.

From their side, payers value constructive interaction with pharmaceutical companies and put much store by how well their needs and constraints are understood by them. To avoid drug pricing appearing arbitrary and excessive, it is vital that payers and other policy influencers have clarity regarding the holistic implications of the various treatment options, including patient benefits, costs and societal impact. In addition, payers appreciate a degree of flexibility in how pharmaceutical companies help them manage demand and provide an economically rational and viable regime for access to medicines. Where there is a potentially high volume/cost implication of an effective new therapy, payers will appreciate innovative schemes that help them to manage annual budgets, especially in the early days of access to a new therapy.

Every case is different, so pharmaceutical companies need to find ways to create bespoke solutions or to more effectively deploy commonly applied approaches such as:

- Patient Access Schemes that improve overall value for payers
- Linking price to outcomes
- Segmentation of the patient population to focus treatment on priority groups
- Monitoring adherence to the treatment regime and restricting access accordingly
- Phasing payment for drugs over a multi-year horizon to mitigate the short-term impact of introducing a new therapy.

Ultimately the biggest costs for health systems are associated with the long-term management of patients with chronic conditions. While the short-term financial impact of effective new treatments often attracts negative headlines, pharmaceutical companies have an opportunity to ensure that the good news associated with innovation drowns out the negative media coverage regarding the price tag and budget impact. The message — healthier patients and a lower long-term cost burden — is strong but it needs professional, empathetic and two-way dialogue to ensure that it resonates among relevant stakeholders. The main challenge for pharmaceutical companies therefore is to change the mind-set both internally to drive smarter commercial strategies, and externally to make more of their relationships with all of the stakeholders concerned.

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