

Putting early access on the radar

Peter Mansell talks to Simon Estcourt about Idis' expertise in early market access and innovating the pharma and biotech model

Market access is now an integral component of pharmaceutical product strategy from early R&D through to launch and beyond.

There are many drivers for this trend, from healthcare cost-containment and a broader conception of product value to the proliferation of payers and decision-makers, reduced access to prescribers, and the increasing complexity of biological and/or combination therapies. It is also a global phenomenon with specifically local ramifications, calling for tailored approaches to individual markets.

A key part of this equation is early access: patient and physician demand for medicines where there is an unmet medical need. And as Simon Estcourt, global business director for strategic market access consultancy Idis, points out, the internet and the proliferation of social media are rapidly fuelling interest in new drugs even at the development stage.

That goes both for the growing ranks of 'expert patients' and the doctors who treat them, whose awareness of therapy options is sharpened by global networking. Inevitably this creates opportunities and challenges for industry. With patients even requesting

access to as yet unavailable therapies on YouTube, how can companies respond ethically and responsibly to this kind of demand in a way that ensures genuine needs are met through legal, reliable and properly managed access strategies?

Complete product lifecycle

This is an issue Idis first started addressing over 23 years ago, initially in response to requests for medicines in the UK. Since then, the company has evolved into a global operation with a broad access management approach, extending from clinical development through to product discontinuation.

With around 150 staff and a worldwide business operation spanning Europe, North America and emerging markets in Latin America and South East Asia, Idis dealt with some half a million requests for medicines last year, creating access to products in more than 140 countries. It also opened an office in Princeton, New Jersey, consolidating its relationship with the top-tier pharmaceutical multinationals that operate out of the USA.

While the company's core offering is around strategic access management solutions, which includes the design and implementation of named patient

or expanded access programmes, the timing, circumstances and legal context of these strategies are subject to considerable variation.

The demand may come from clinical trials, where not every patient who stands to benefit from a drug may fit the protocol design or be within geographical reach. In these cases, Idis can establish a parallel access programme or divert qualifying patients into existing trials, bolstering recruitment.

Alternatively, the trigger may be the hiatus between approval and launch, as companies negotiate pricing and reimbursement approval. Or it could be an orphan product designation that limits a product's commercial viability in certain markets. Idis can also help companies discontinue products or optimise their presence geographically in some markets.

Addressing patient demand

This range of scenarios underlines the importance of addressing potential patient demand early enough in the product lifecycle. "We really are talking from Phase II right to the end of the product lifecycle," Estcourt says. The need to improve efficiency in pharmaceutical R&D has reinforced the





Simon Estcourt, global business director

strategic imperative to consider all the available options.

And while the governing principle of early access is a sympathetic response to a request for access for a patient with an unmet medical need, these programmes do offer ancillary benefits that can feed into improved market access further down the line.

Among them is 'real-life' insight into how physicians manage new treatments and how patients respond to them. This could be an opportunity to identify potential key opinion leaders, educate physicians about complex dosing procedures, or collect data of value in informing health technology assessments, Estcourt notes. Early access experience can also help to prepare the ground for pricing and reimbursement negotiations.

Flexible access solutions

The shift towards personalised medicine will further stimulate demand for flexible access solutions, Estcourt believes. This will be a much more limited marketplace, characterised by more unpredictable "pockets of demand" and requiring a very different approach from the marketing muscle employed during the blockbuster era.

As such, Estcourt suggests, early access solutions are a "way to help pharmaceutical and biotechnology companies innovate their model".

The advantage of a consultancy approach, he adds, is that it not only allows customising of programmes to specific products, markets and patients, but leaves companies free to concentrate on what they do best: developing and commercialising innovative drugs.

These companies are not set up to respond to small-scale requests from anywhere in the world, Estcourt notes. The legal procedures for satisfying that demand vary from country to country, even within a nominally harmonised framework such as the EU's directive on named patient use. Within the USA alone, expanded access programmes may follow any one of three treatment Investigational New Drug models.

And while more and more countries are recognising the need for early access mechanisms, the growing use of these channels means a certain "tightening or clarification" of existing procedures, Estcourt observes.

For a pharmaceutical company to address these challenges in-house would mean adding significant resources across several departments or increasing the workload of existing staff. Nor would it suit the essential unpredictability of the early access landscape. "You never know where the demand is going to come from," Estcourt comments.

Partnering with a specialist consultancy that can cover the full range of requirements – from regulatory, legal and customs to stakeholder communications, creating and establishing the access programme, and handling any associated enquiries, data or logistics – offers flexibility, market-to-market insight and cost efficiency.

"As experts in the field, we've been doing this for a long time," Estcourt points out. And with market access "massively on the radar", Idis is ideally positioned to formulate and deliver strategies that ensure new drugs are where they need to be – treating the patients who need them.

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