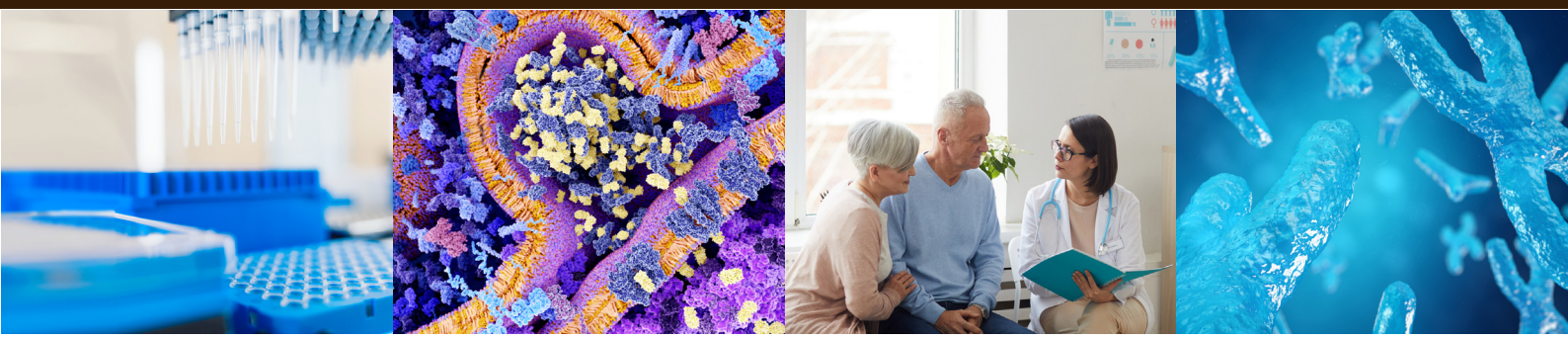
executive insight
HEALTHCARE CONSULTANTS



Rethinking access barriers to innovation

Market access issues don't stop once a product has passed HTA – and this is especially true for disruptive therapies like ATMPs. Experts from Executive Insight discuss how a holistic, multi-stakeholder approach can help companies overcome access barriers at all stages.

The last decade has seen some remarkable advances in medicine, with innovative new products like cell and gene therapies showing efficacy in diseases long thought almost untreatable.

But launching a disruptive product can be a double-edged sword. While the potential patient benefits are huge, these therapies face difficulties in passing health technology assessment (HTA) processes designed for more standard products, and once approved they face other barriers from putting new pressures on health systems.

Michalina Jenkins, who has assessed HTA systems in terms of associated barriers in a number of different countries in her role as a senior consultant at Executive Insight, says that one of the most common HTA barriers companies face is a lack of broad value recognition for innovative products.

"When considering the value of innovation, we know that it should drive benefits to patients – but also, broadly speaking, it should provide cost savings to the healthcare system and improve the wellbeing of society in general," she says.

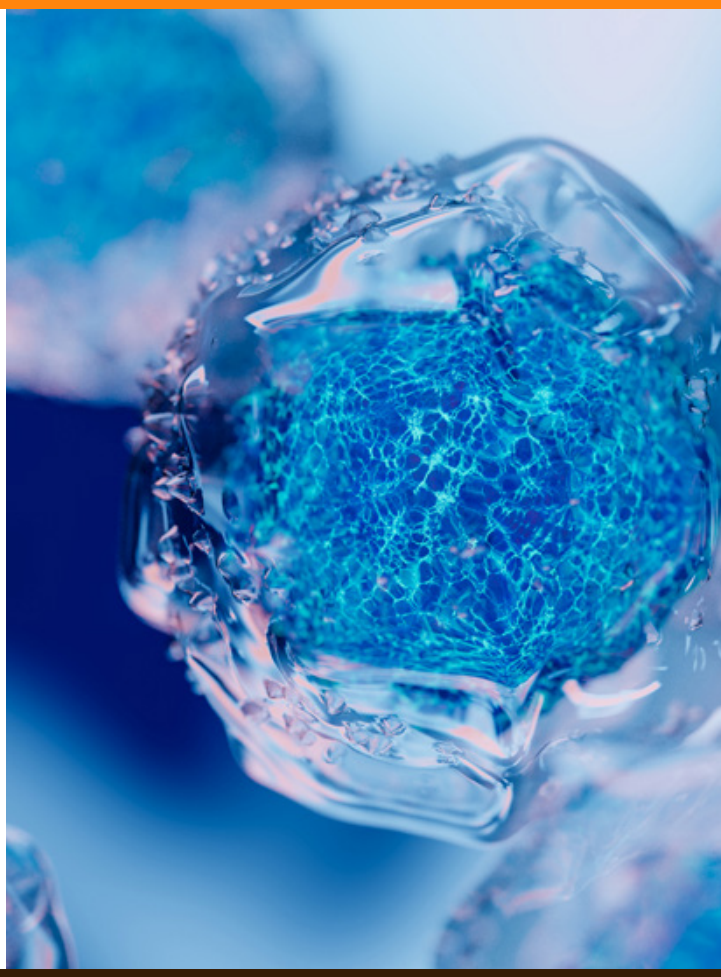
"However, that broader perception of value is often absent in HTA frameworks."

Likewise, she says that HTA processes can lack meaningful contribution from a wide range of stakeholders – especially in countries with newer systems.

A third barrier is that HTA processes, in terms of steps, timelines and assessment criteria, are often still not fully predictable. "This is an issue not only for patients, but also for healthcare providers, and we see it more commonly in countries with younger or emerging HTA systems.

"Meanwhile, access decisions are not always optimal in terms of their timeliness and the breadth of the funding. Often only limited populations of patients can benefit from an innovation when it is approved at the HTA level."

But Jenkins says it's important to remember that market access challenges don't vanish once a drug has been approved. After a product has launched there are often additional systemic barriers beyond the product level to overcome – and this is particularly true for advanced therapy medicinal products (ATMPs).



In the post-launch environment, the effects of not having a broad recognition of value become even sharper, says Luca Lorenzi, manager at Executive Insight.

He notes that, by their nature, these innovative products will often enter an environment that is not ready to support their access and adoption.

"Most importantly, there might be a lack of sufficient funding mechanisms available at launch – and if there is a high burden for healthcare professionals to obtain funding, that will be a major hurdle for adoption of the technology.

"It's important to look at the environment not only from a product angle, but also from an associated services angle – e.g. will the technology cause extra costs because of new procedure, diagnostics or administrative needs that might not receive sufficient funding at launch?"

Additionally, companies may find that there are no optimal care pathways to allow optimal integration of the innovation into the healthcare system.

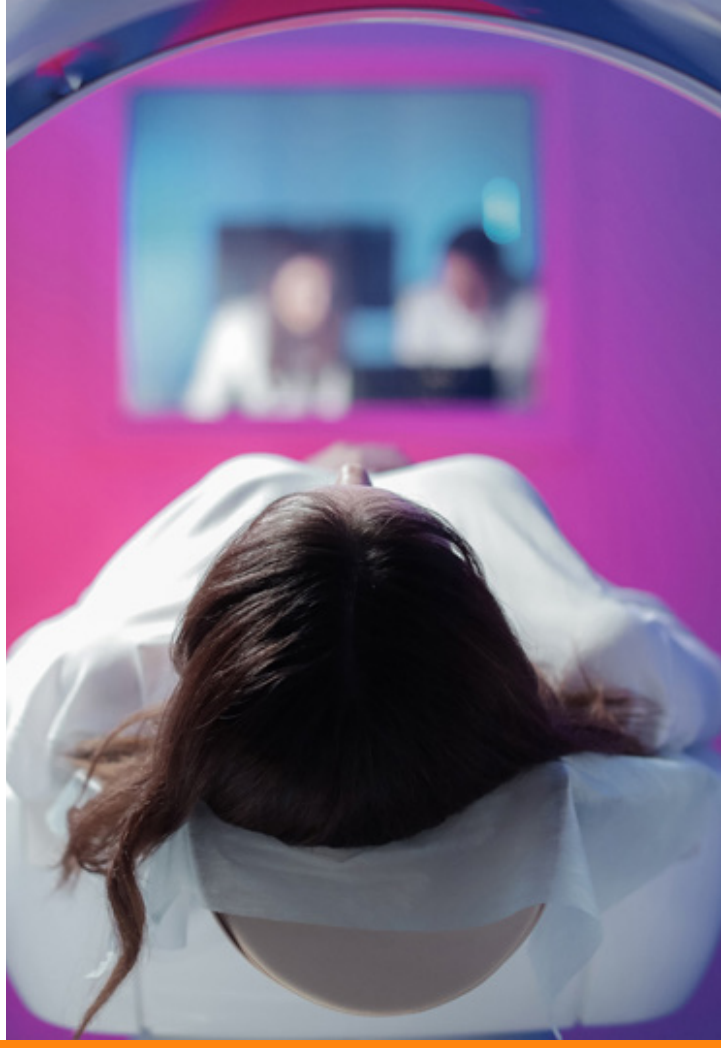
"This all comes down to whether the existing care pathways or process infrastructures are fit for purpose for your innovation, and whether your innovation has a specific complexity in the way it's delivered," says Lorenzi.

"This includes factors like the infrastructure and capacity of treatment sites. We saw with CAR-Ts, for example, that some healthcare systems intentionally limited the number of sites that could deliver this technology to better control its usage."

Similarly, a particularly disruptive product may require behaviour change from HCPs and patients, which can require additional time and cost investment.

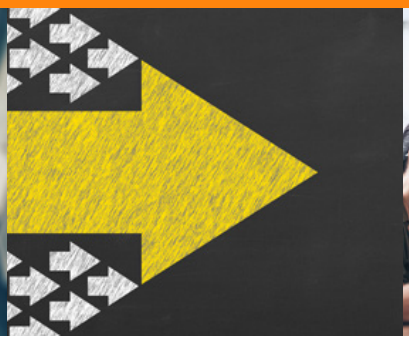
Lorenzi adds that successfully navigating these behaviour challenges again comes down to the broader clinical and economic value proposition of a product.

But often, he says, there can be a lack of awareness or belief in an innovative therapy's value from the healthcare system.



"Initially you might encounter a lack of awareness and understanding of the new therapy and where it fits in the therapeutic landscape. There could also be safety concerns from patients regarding completely new mechanisms of action."






Early planning for access

With such a wide range of factors to consider across the entire access landscape, pharma needs to start planning for potential barriers as early as possible in development – and that means working with key stakeholders systematically and repeatedly to shape the environment before launch.

"The environment won't evolve by itself – and if it does, it will evolve slower than you expect – so pharma needs to act as a catalyst," says Philippe Coune, director at Executive Insight.

"We've seen suboptimal launches of high-profile products that were clearly linked to the fact that the company did not consider potential barriers at an early stage.

"Companies who are specialists in innovative therapies are often okay because they're looking at the world through the prism of their innovation, but that mindset isn't ingrained in big pharma companies who usually work with more standard products."

Mary Rose Ropner, senior consultant at Executive Insight, adds that the process of environment shaping for a particular product can start as early as three to five years before it reaches the market, and can extend beyond launch.

"To start with, the companies can and should comprehensively assess any access barriers their products may face, both at the HTA and post-HTA level."

Jenkins says this begins with bringing together different internal functions within a company.

"Traditionally it was the access team that led a pharma company's efforts to address HTA barriers. But if you want to address issues on a more systemic level, you also need to bring in public affairs, patient affairs, as well as commercial teams.

"It really has to be a collaborative, multi-stakeholder effort on the internal side."

From there, Ropner recommends companies create a broad company position on what they see as the ideal access environment.

"That way, when different countries are trying to shape systems, they will all go in the same direction."

Stakeholder engagement

Companies then need to sit down with a broad group of stakeholders who share common needs and also want to be actors in this change.

All parties can then work together to identify and prioritise key barriers at all levels, and shape the access environment into that ideal position.

"That means you need to identify those stakeholders that have influence over shaping the system, and that may differ from country to country," says Jenkins.

"There are some regions or countries where pharma companies can create strong alliances within trade associations to tackle these barriers together, for example CAEME in Argentina, PhRMA in the US, or EFPIA in Europe. Meanwhile, there are other countries where policymakers are very keen to directly collaborate in shaping HTA systems."

Particularly in countries with emerging HTA environments, doing this means that pharma companies can position themselves as key partners in co-creating such systems, bringing the expertise they have developed in other markets.

"Saudi Arabia is a great example of a country where pharma companies were able to step in and shape an emerging HTA environment," says Jenkins. "The process was initiated by stakeholders building the system. They invited various representatives of access functions from pharma companies to roundtable discussions on what an ideal HTA system should look like, what the key challenges might be, and how they could make sure that the process is predictable from the outset."

Coune says that pharma will often need to widen the scope of the stakeholders it speaks to, so that they match the scope of the challenges a product is likely to face.

"That means going way beyond the usual payer/prescriber stakeholders and looking at all the actors in the system. If you're only interacting with the prescribers and the payers, you are going to miss out on the local level economic complexities associated with your product.

"This is also important because, with the complexities and novelty of some of these therapies, pharma will never be able to address everything themselves. It needs to involve the people who will be able to drive parts of the initiative independently."

Lorenzi adds that it's important to apply the patient perspective throughout all of these discussions.

"A clear advantage of doing that is it allows you to engage stakeholders more effectively. If you assume a patient perspective rather than a product perspective, you are talking to them in their language. That means attempts to shape the environment will be more successful and have more visibility."



Three categories

When it comes to preparing for post-launch barriers with other stakeholders, Ropner says companies need to look for problems across three specific categories.

"First of all, you need to be looking at whether the disease area is actually a priority for different stakeholders, particularly policymakers and payers. More barriers are likely to arise if it is not.

"Secondly, you want to look at the care pathways that are already established, as well as those that are not yet established, and ask how your patient will travel through the healthcare system. If it's a new treatment modality that requires a different administration or manufacturing process, that might impact how patients will receive their care."

US-based Spark Therapeutics, for example, solved this by creating a portal to help patients locate a specialist who can help with genetic testing and assess eligibility for its gene therapy Luxturna.

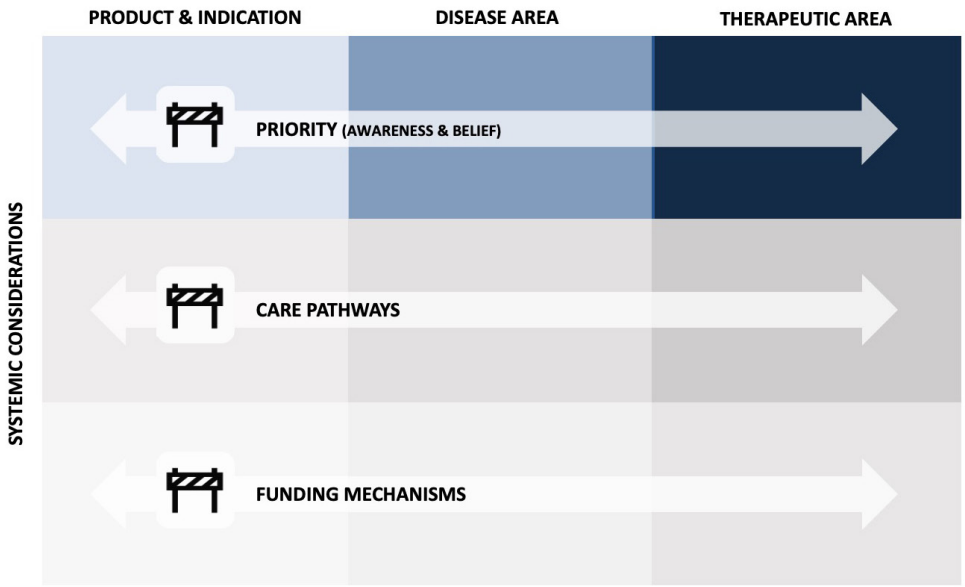
Ropner says that the final category to look at is funding mechanisms.

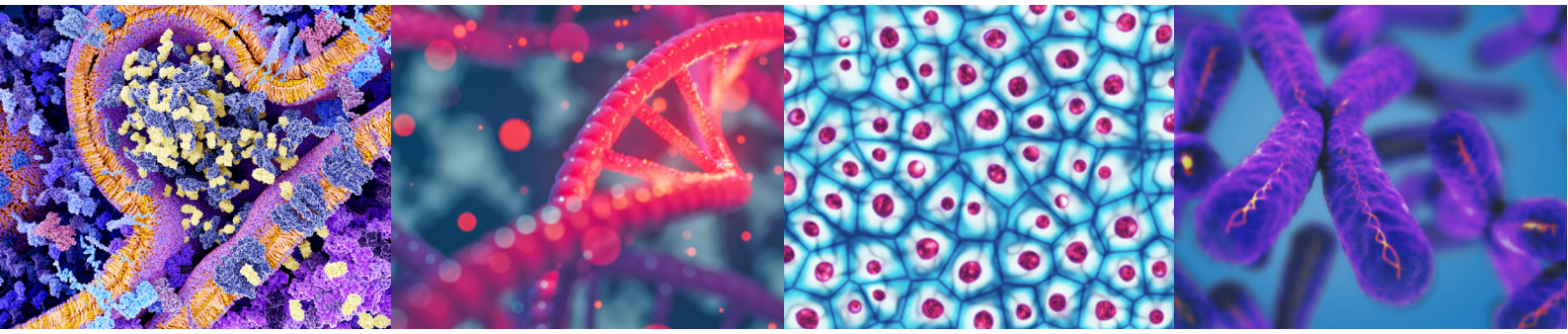
"Those are obviously important at the HTA level, but there might also be post-HTA economic issues – such as whether patients can afford to travel to receive treatment, or whether hospitals can afford wrap-around care and the costs of additional staff, adjuvant therapies etc."

She adds that it's important to consider barriers not just at a product level but also at an indication and disease area level.

"For example, if you have a product in diffuse large B-cell lymphoma (DLBCL) you might want to also look at access issues in lymphoma more generally.

"You essentially need to take a three-by-three matrix view. That means considering disease perceived priority, care pathways, and funding mechanisms, and looking at those three buckets at the product, indication, and disease and therapeutic area level."





Access for CAR-Ts

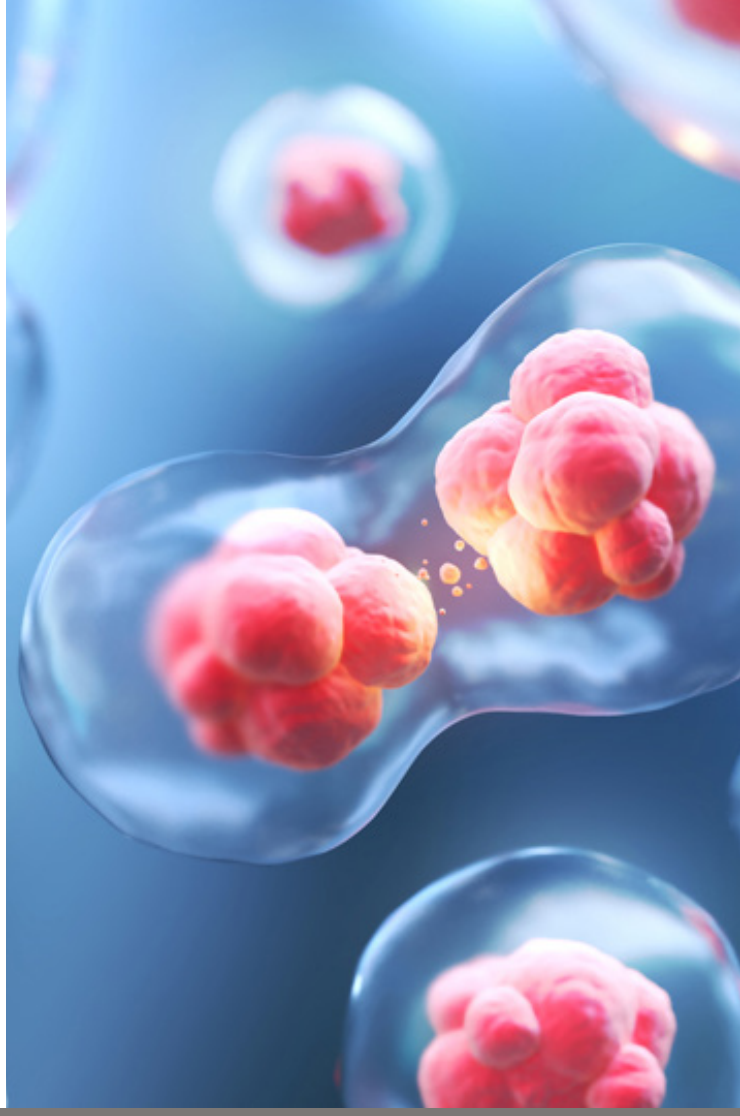
Ropner points out that there are many examples of these strategies paying off for companies – particularly in CAR-T therapies for cancer, which have been among the most anticipated ATMPs to launch over the last five years.

"The markets where CAR-Ts have seen more success are often those where HTA organisations engaged early with companies and healthcare systems and ensured that the system was ready to assess and approve these therapies," she says.

Meanwhile, CAR-T manufacturers across the world had to take broad, multi-stakeholder approaches when reacting to access barriers in different healthcare systems.

In the US, companies addressed financial and patient access barriers by providing a patient support system that covers transportation and hotel costs for CAR-T patients who need to travel to treatment centres. In Germany manufacturers had to devise ways to compensate hospitals for the costs associated with the apheresis required for CAR-T treatment, as the procedure has been excluded from funding by the G-BA.

To address administrative and care pathway burdens in the US and Japan, some of these companies have also provided an online system to help referring haemato-oncologists locate CAR-T treating centres that will assess the potential eligibility of their patients.



"There was a fear at the start that these new therapies would break certain healthcare systems," says Lorenzi. "But by companies engaging stakeholders pre-launch, communicating in a transparent way and helping run assessments, these systems were able to think about what changes were needed."

The overall message, then, is clear: a holistic approach to value and access is needed to drive sustainable adoption of innovation.

That means comprehensively assessing barriers at the product, therapy area, and system level – starting as early as possible – whilst also defining what an ideal environment should look like. To do all this, companies need to identify key stakeholders along the patient journey and build alliances so that together they can co-create solutions to address common needs.

From there, companies need to regularly reassess their approaches and develop corresponding shaping strategies.

"Stakeholders are usually keen to find solutions and build these structures upfront," says Lorenzi, "because in the end it's for the overall good of the patient, healthcare systems and society.

"This can only be a win-win situation for pharma, because ultimately it creates fertile ground for adoption while helping patients."

About the interviewees

Philippe Coune, PhD, is a director at Executive Insight. Phillipe has a background in market access and strategic pricing, with a focus on rare diseases and advanced therapies. His experience includes the assessment of funding options for cell therapies, as well as the development of market access strategies for innovative therapies in the orphan space.

Luca Lorenzi, PhD, is a manager at Executive Insight. He specialises in market access and healthcare policy with a focus on the intricacies of advanced therapies and specialty products. In his role he supports major biopharmaceutical companies in developing access and environment shaping strategies to successfully commercialise their innovations.

Mary Rose Ropner is a senior consultant at Executive Insight, where she specializes in developing pricing and market access strategies for early products, including for oncology therapies. She has provided consulting, market research and competitive intelligence services to major pharmaceutical companies for over five years and continues to support the development of early market access shaping strategies for different products within her current role.

Michalina Jenkins, PhD, is a senior consultant at Executive Insight. She is passionate about driving optimal patient access to innovative medicines. Her experience includes development of market access strategies, including access environment shaping and advocacy, for a variety of assets at different stages of market readiness.

About Executive Insight

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Executive Insight is a specialised healthcare consulting firm supporting biopharmaceutical companies in successfully preparing, launching and commercialising their products. The company was founded in 2000 by a group of industry professionals who recognized the need for specialised healthcare consulting. Today, Executive Insight proudly works for six of the top ten global pharma companies and has about 60 employees located throughout Europe and beyond. The head office is located in Switzerland with a subsidiary in London, UK.

You can contact the company on LinkedIn.

About the author

George Underwood is the editor for pharmaphorum's Deep Dive digital magazine. He has been reporting on the pharma industry since 2014 and has worked at a number of leading publications in the UK.