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Xcenda

Entering the European market

Blind spots are transformed to insights via an in-depth market assessment and global advisory board of local market access experts

Case study

The client situation

The European market represents a significant opportunity for most pharmaceutical manufacturers, yet the barrier to entry can be high given the fragmented regulatory and market access environment. Successfully commercializing a new product in the European market requires knowledge of the many unique standards and preferences when it comes to local market access requirements, pricing, and reimbursement. Predicting how country-specific Health Technology Assessments (HTAs) will respond to the value proposition of new therapies has become increasingly difficult.

Not surprisingly, many pharmaceutical executives have more questions than answers when it comes time to develop a global market access plan for a new product. It's equivalent to flying a plane with large black circles on the cockpit window. The likelihood that you will miss a key component of your product launch is unacceptably high.

This is precisely where a pharmaceutical company with an innovative new orphan drug found itself. They knew that HTAs were the primary influencers on market access. But they also knew that they did not have the time, expertise, or resources to quickly tap into the minds of European key opinion leaders in health economics, the local market experts whose guidance would reduce their blind spots.

So, this company turned to Xcenda for help.

"I didn't know who else to call who could give us this kind of help, especially this quickly."

–Commercial Director

The Xcenda solution

At the first meeting with Xcenda, the pharmaceutical company's executives described their concerns over the complexities facing a brand entering the European market. According to the International Network of Agencies for Health Technology Assessment, there are more than 30 HTA agencies operating in Europe at any given time.

While most of these agencies make market access, pricing, and reimbursement decisions independently, they tend to monitor and influence each other. This is why it is critical to understand who the major influencers are within the European continent. A decision by one leading HTA agency can greatly influence HTA decisions throughout Europe.

What's more, most of these agencies are part of the nationalized healthcare system of their given governments. This means the health economists, clinicians, and other professionals who serve on the HTA and make market access, pricing, and reimbursement decisions are government employees. As such, the company could not conduct formal market research or traditional advisory boards with the actual HTA members since they are usually prohibited from participating in such manufacturer sponsored activities.

Herein lies the conundrum. As the old saying goes, you never get a second chance to make a good first impression. In Europe, if you make the wrong impression on a leading HTA agency, the repercussions could reverberate throughout the entire European market, substantially limiting patient access. But without guidance on the specific clinical information, health economic evidence, comparator data, and unmet needs that each HTA views as a priority, the risks are very high that the HTA will not find your product value story sufficiently compelling.

To mitigate these risks and to ensure the pharmaceutical company's orphan drug made a solid first impression, Xcenda consultants recommended 2 key strategies: an in-depth European market assessment, and the development of a global advisory board made up of local market access experts.

The service package

This pharmaceutical company had a unique product and specific market access goals. So Xcenda consultants developed a strategic solution to help find the blind spots and determine the best way to eliminate them.

Xcenda recommended that the engagement begin with a customized market assessment to uncover the current landscape for this orphan drug.

Consultants also recommended a global advisory board made up of country-specific experts and influencers. After the market assessment was complete, the global advisory board's insights would guide the development of a strategic action plan for the product's launch in key European markets.

The market assessment began with a clear articulation of the goals of the engagement. Xcenda consultants wanted to:

- Gauge payer perceptions of access and reimbursement challenges for orphan products
- Assess current perceptions of unmet needs for this specific orphan therapy area
- Rationalize payer price expectations for this specific orphan therapy area
- Determine potential current and future payer access hurdles
- Recommend additional clinical or health economic data that could help overcome these hurdles

To accomplish these goals, Xcenda consultants conducted secondary market research. The market access team analyzed historical decisions made by influential HTA agencies about products that treat orphan or rare diseases.

Then the consultants conducted primary market research with key decision influencers from 7 European nations. While the EU Market Assessment helped determine the landscape, the next step included primary research to discover specific variables within key countries.

Xcenda consultants expedited the next phase of the engagement by leveraging a ready-to-deploy resource unique to Xcenda – the Global Market Access Network, or GMAN. This standing panel is comprised of health economists, health technology assessment experts, and market access experts from major and emerging markets across the world.

While these individuals typically are not government employees who are restricted from participating in market research, they often advise HTAs and deeply understand the decision-making processes within the most influential HTA agencies.

More importantly, they have all agreed to participate in the GMAN advisory panel, which means Xcenda can quickly and efficiently tap into their insights.

Xcenda brought together a panel of local market experts for detailed discussion on specific topics:

- Current treatment landscape
- Current market access landscape
- Future expected market access landscape and expected changes
- Outcomes research requirements
- Clinical evidence requirements
- Opinions about product profiles
- Expectations of pricing potential

By following Xcenda's recommended approach for the global advisory board, the pharmaceutical company engaged in highly qualitative discussions between the experts and the moderators and also among the experts themselves.

This generated more in-depth information that would inform the company's market access strategy. The advisory board format allowed the pharmaceutical company's executives to take part in meetings as co-moderators, presenters, and observers.

This level of access to local experts from key European markets allowed differing stakeholders within a pharmaceutical company to hear firsthand how those expert opinions could and should influence their area of responsibility.

Best of all, Xcenda handled all aspects of the GMAN process including recruitment, materials development, logistics, and meeting facilitation.

The outcome

The insights generated by the global advisory board, along with Xcenda's analyses and strategic guidance, transformed blind spots into a path forward. Through a mix of comprehensive secondary research, qualitative insights from credible advisors, and analyses from Xcenda's market access consultants, this pharmaceutical company gained a clear vision for how to articulate its orphan product's value proposition.

With a better understanding of how it addressed unmet needs for patient populations in various countries, they knew how to price the product in key markets across Europe. And because Xcenda helped the pharmaceutical company identify the reimbursement challenges it was likely to encounter with differing HTA agencies, the company was then in a stronger position to shore up both economic and clinical evidence to tell a stronger story to HTA agencies when it launched in Europe.

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