Regulatory approval and reimbursement are two completely different worlds, but are they?

Q&A with Paul Bridges, Senior Vice President, Regulatory & Access

REGULATORY & ACCESS

If regulatory and payer landscapes are so different, then why is Parexel bringing two completely different worlds together? Paul Bridges, SVP of Parexel's newly formed business explains.

1 Today, Parexel have launched a new consulting business 'Regulatory & Access'. How will this impact Parexel's customers?

Parexel's Regulatory & Access solution is designed to help our clients chart the best course through complex regulatory and market access landscapes. By holistically considering the requirements of all stakeholders and aligning these insights with clinical development, companies can optimize their plans to drive more efficient, smarter and faster development. Our goal is to help companies identify every action possible to reduce the time that a patient must wait for their innovative new therapy.

2 Parexel began as a regulatory consulting firm more than 35 years ago, how do you and your colleagues see that the industry has changed?

In the early days of our consulting practice, small molecules targeting common disease areas drove success – the blockbuster era. Market authorization from regulators was usually enough to secure market access and drug pricing was often unchallenged. Today's landscape is very different. In today's highly competitive or niche target markets, companies must have a cast-iron value proposition to be successful. Budgets are under pressure, there is greater scrutiny from regulators and a greater exchange between global regulatory agencies. The HTA assessment process has naturally raised the bar for demonstrating value and with greater pressure on pricing, companies are under huge pressure to obtain the first-to-market advantage in order to secure favourable return on investment.

3 How does bringing together regulatory and market access expertise benefit your customers

Traditionally, our clients would have separate conversations with multiple vendors about their commercial strategy, clinical development planning, their regulatory and compliance issues and then engage with market access providers about reimbursement. Now, our customers can engage with a single provider for all their needs, with a more seamless, integrated experience. But its not just about simplifying the business model for our clients – by working with an integrated provider companies can achieve significant competitive advantage. By integrating our world-class regulatory and market access consultants we can give our clients access to a greater depth and breadth of expertise. We can provide integrated insights that help companies develop a compelling value proposition, competitively position their products, and rapidly navigate through regulatory and market access hurdles.

Additionally, with highly innovative therapies coming through for rare diseases, cell & gene therapies and precision medicines, highly specialist expertise is valued

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by pioneering companies to help navigate uncharted territory without the cost and challenge of hiring expert resources across multiple functions to the payroll.

4 Are customers buying in this integrated way today?

Yes! And if they aren't, they are likely to be seriously considering it because siloed drug development is no longer fit for purpose and few companies can afford to take such an inefficient route.

In particular, we've seen a sharp demand for integrated advisory from Biotech companies who don't always take their products to market and end up partnering with other, larger companies, for the later stages of development. Having Parexel input into the strategy and the earlier stages of development, I would argue positions those conversations with external partners well and helps maximize opportunities. Additionally, the ability for Biotech companies to go it alone and bring a product to market globally has been traditionally constrained, but we see that changing. Being able to tap into a global clinical research organization with integrated consulting capabilities which allows them to get expert input into early stages of development in a way which is flexible and cost-effective, provides the expert resources and bandwidth they might not have had before.

5 Why is it so important for companies to understand the different stakeholders needs at each stage of development?

Understanding the distinct requirements of key stakeholders – regulators, payers, physicians and patients - helps companies develop and optimize their clinical development program to address diverse stakeholder requirements sooner. Taking a product successfully to the end of phase III and gaining successful negotiation with the regulatory authorities, means nothing if you can't command an appropriate price or achieve reimbursement. Companies can end up scrambling and adding peri-approval studies to demonstrate value. This makes designing studies more and more important, ensuring the design includes the inputs and requirements of all stakeholders and generating evidence of value alongside safety and efficacy data for improved efficiency.

It is critical that companies that have a clear proposition from the outset. Companies that can determine that a product is safe, efficacious and equally demonstrate value offers significant competitive advantage in this crowded marketplace. It can be the difference of being first to market or falling behind the pack.

6 Where do patients fit into your business model?

At Parexel, our mission is to put the patient at the heart of everything we do. After all, we are all patients. Our consultants are focused on identifying every possible action to reduce the burden on patients throughout clinical trials, for example highlighting unnecessary inclusions within clinical protocols. Without patients supporting clinical trials and development, products are at risk of being misaligned with patient needs in the end. This is why it is more important than ever to engage patients as early as possible and ensure they are being heard at each valuable stage of development.

Regulators and payers are also making sure patients have a voice and are getting a seat at the table. Patients are more empowered than ever, through advocacy groups, social media, availability of data and improved access to trials and treatment.

7 Why should companies choose to work with Parexel?

Quite simply, I believe we have the best talent. We have over 1000 consultants on staff, including ~100 former regulators and HTA assessors. Our integrated approach gives 360-degree insights that help companies make better decisions and plan "with the end in mind". What's more, our colleagues from Health Advances fully supplement this expertise with tremendous strategic consulting capability. In this way, we can fully mitigate risks, optimize investments and maximize probability of success.

Additionally, our patient-first ethos not only aligns with our customer's values but also helps us to attract and retain the best talent. People want to work for Parexel because we've taken our traditional heritage of quality delivery and infused that with our commitment to the patient – and this is exciting!