

## **Introduction**

Pharma Design Limited (PhD Limited) is a small, specialised provider of outsourced development services to the pharmaceutical, biotechnology and medical device industries. The company engages in the strategic development and MA approval for medicinal products in EU by means of an integrated approach of multiple functions (R&D strategy, Market Access, Pharmacoepidemiology and Regulatory). Our primary approach is to use a pipeline specialty team, being able to 'design' a broad successful strategy as part of a combined and synchronised work.

## **PhD Limited Market Access**

PHD has a highly experienced Market Access team, with a proven track record of success in health outcomes research, value-based pricing, scenario planning and pricing agency/authority interactions.

PhD can provide support since early phase RCTs through Value Hypothesis Formulation or at later stages through hypothesis verification and optimisation.

## **Payer & KOL research**

We inform our P&R strategy recommendations through primary research with senior current payers. We interview stakeholders which comprises payers, payer advisers, price sensitive customers, health policy-makers and KOLs.

Our team of consultants have a strong understanding of pricing and market access issues in core markets including US, EU5 and other important EU markets. We have developed a strong network of payers and payer influencers at national, regional and local level across more than 40 markets worldwide. Over the past 4 years, we have routinely conducted P&R research in US, EU5 (UK, France, Germany, Spain, Italy), Netherlands, Sweden, Australia, Canada and Japan.

We also occasionally partner with Emerging Markets Centres of Excellence to deliver payer research across Asia-Pacific, Central and Eastern Europe, Latin America and the Middle East and Africa.

## **Pricing research**

We specialise in qualitative & semi-quantitative directional pricing research, typically in Phase II, pre-phase III and at launch with current payers.

## **Price modelling**

Our team includes several members with high levels of price modelling capability and experience. We can use these models to help you test the implications for your product and its uptake of various scenarios, which may cover price, net pricing agreements or patient access schemes, the position of the product within the treatment pathway, payer restrictions, generic or biosimilar competition, international price referencing and parallel trade

## **Value message development**

Payers may refuse to reimburse if they identify significant uncertainty either in the clinical or economic effect of your product. We use our experience of where payers look for uncertainty to inform the value messages that we help our clients craft in the core payer decision-making criteria of target population, unmet need, clinical benefit, economic benefit and price.

We routinely help our clients both in the initial development of an asset value proposition, crafted through payer advisory boards and interviews as well as the formal drafting of global value dossiers.

## **Value message testing, gap analysis and objection handling**

Value propositions need to be refined through testing. We have several methodologies for testing value messaging, both through payer advisory boards or qualitative interviews. This identifies the difference between the importance payers attribute to a particular decision-making criterion and the quality of the evidence supplied to address it. These gaps are graphically demonstrated to provide you with a clear visual of specific issues that may receive a challenge from payers. By following up with payers to test rebuttal statements we can help you understand how additional arguments or evidence is able to mitigate the uncertainty in the minds of payers. We use this methodology to inform the development of objection handlers, which we further test and refine using a limited payer panel.

## **Value dossier development**

Our understanding of payer priorities informs our development of value dossiers. We have developed full global dossiers across a variety of disease areas including auto-inflammatory disorders, oncology and urology. We implement an internal quality control system that combines use of experienced medical writers, edited by experienced market access consultants with medical backgrounds, health economists with 15 years' experience and a Consultant Pharmaceutical Physician to check all content from a medical affairs perspective. Our team of consultants have strong understanding of pricing and market access issues in key markets including US, EU5 and other important EU markets.

## **PHD LIMITED Rates**

### **On Rates & Assumptions**

To ensure the most cost efficient approach to resourcing, PhD is able to deploy a flexible model that only resources experienced regulatory professionals and functional experts as and when required.

Costs are provided for PhD consultants' services on a Daily or Project basis, depending mainly on the contractual duration. VAT and Pass-through costs are not included.