

Mundipharma International: staying fleet of foot

Peter Mansell talks to Mundipharma International's Tom Rowland about the need for convergence in European market access conditions, and how moving fast on opportunities is key in a difficult marketplace

Photos by *Magnus Rew*

Market access is increasingly a regional, if not global, preoccupation for the pharmaceutical industry.

Market access authority, though, is exercised both nationally and locally. So while companies are seeking a more level playing field to help optimise R&D efforts and recalibrate their sales and marketing to new conceptions of value, they must generate and communicate that value in ways that can be tailored to local requirements.

Tom Rowland, European head of market access at Mundipharma International, sees a “strong desire” across the industry for better harmonised market access conditions, particularly around health technology assessment. Reimbursement authorities “just assume pharma, big and small, has almost unlimited resources” to put together national dossiers, he contends. There is growing recognition that companies “continually struggle” with the relationship between different prices and value propositions in different European markets, says Rowland. As such, “some kind of convergence is absolutely going to happen”. The question, though, is how quickly, given the continuing divergence in European healthcare systems.

Industry groups have an opportunity to help shape the course of HTA over



Tom Rowland



the next few years. Otherwise, Rowland warns, “we’ve only got ourselves to blame if the result is something that’s still incredibly fragmented”.

In common with the industry trend, the Mundipharma independent associated companies are taking a top down approach to market access where practical while recognising the local nature of reimbursement decisions. Responsibility “for really delivering that value proposition, and tailoring it to different authorities, rests with the country itself”, Rowland points out.

Much of the impetus for future developments is coming from the UK and Germany. The UK has been “out in front for a very long time from an HTA perspective”, Rowland notes. Now these effects are being felt in Germany, where the latest batch of healthcare reforms includes “a clear pathway where HTA is activated”. Indeed, the German

model is moving in a similar direction to the value-based pricing system now under discussion in the UK. “Rather than looking at the price and saying, the quality-adjusted life year threshold doesn’t match, it’ll be turned on its head,” Rowland explains. Whether or not Germany opts for QALYs, the basic principle will be “this is the threshold, so based on current evidence what should the price be?”

Another area in which the UK has led the field is in offering scientific advice on drugs in development. The German HTA agency, IQWiG, will be following suit. Yet uptake of the NICE service has been “very variable”, Rowland says. The problem is the advice is specific to the UK and, “when you’re talking about a drug in Phase II or III, clearly the UK is an important market but you’ve got other considerations in Europe and worldwide”.

Feeling the sharp end

The Mundipharma independent associated companies have felt the sharp end of varying national requirements with one of their recent pain products. “The way pain treatments are assessed is very different across Europe,” Rowland notes. For example, one HTA agency may ask for comparators that do not reflect clinical practice in other European markets.

“The real challenge is resources, not just in producing a reimbursement dossier but in conducting studies relevant to local markets,” Rowland says. Industry is “excellent at running studies that get us a marketing authorisation”, but it cannot handle “20 studies across 20 different countries in Europe” to fulfil national HTA requirements. As a result, “there are always trade-offs. There are certain studies you’d like to run but you can’t necessarily justify”. And this stands in the way of industry’s ultimate objective – providing medicines to the patients who need them.

One way companies can help themselves is by making sure their value proposition includes well-established and clinically valid endpoints. If a proposition with unfamiliar elements “just lands in a payer’s lap it’s going to lead to problems”, Rowland comments. This is why companies need to think about market access from an early stage.

“It starts at Phase II and it builds from there,” Rowland says. “Market access has to be fully integrated both in the way it cascades down into countries and the way it operates through R&D into product commercialisation.”

In terms of its own positioning, one thing the Mundipharma independent associated companies have resisted is the strong industry trend in recent years towards orphan drug development. Rowland questions the logic of a strategy that has witnessed “creep in the system from orphan diseases to ultra-orphan diseases”. Clearly one incentive is “lower thresholds in terms of how these areas are assessed”. But reimbursement authorities will eventually “get wise” to situations where orphan status has been bent out of shape, Rowland believes.

Going against the grain

The Mundipharma independent associated companies are going against the grain by focusing on primary care through a strong heritage in pain management and with new products such as a novel combination for the treatment of asthma that they plan to launch in Europe next year. The philosophy is to offer “very important steps forward” in options for clinicians, but at a price that makes the whole package a compelling value proposition for payers as well, Rowland says. He relates this to an evolving conception of incremental innovation.

Traditionally, payers have been “more than slightly reticent” about embracing advances such as a new delivery mechanism or formulations without very clear benefits. But industry needs to “work harder and prove those innovations really do translate into not just convenience but also demonstrable value to patients and the broader healthcare systems”, Rowland argues.

With healthcare systems in rapid flux, “having the ability to move fast on opportunities is absolutely key” – the Mundipharma independent associated companies “really have that autonomy to capitalise on local country situations”, Rowland says. “And they’re proving themselves very agile in a difficult marketplace.”

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