After years of drug development, your product stands on the doorstep of regulatory approval, poised to launch across Europe. Meanwhile, a team of experts has devised a robust global revenue-maximizing pricing, reimbursement and market access strategy, targeted and sequenced by country. Now it’s time for the country affiliates to hit the trenches and execute the plan, right?

Not so fast. Even the perfect global market access strategy will fail if it’s not communicated effectively and flexibly. Country affiliate companies must be empowered, agile, battle-tested, armed with data and staffed with skilled communicators. This is easier said than done.
will accept indirect comparisons, but the German market is important and broadly influential.

The pace of medical innovation and its associated costs creates a high level of uncertainty around the evaluation of novel treatments and potential new contractual requirements for their reimbursement across markets. Country affiliates are best positioned to take the pulse of the situation in their own markets and thereby use the product value communication strategically to maximize local market access.

Recently, The Italian pharmaceutical agency AIFA granted reimbursement of a new Janssen anti-HCV product, Olysio (simeprevir) contingent upon a de-listing of Janssen’s existing HCV drug, INCIVO (telaprevir), to class C (not reimbursable). AIFA negotiated the agreement “to ensure sustainability” for the National Healthcare System (NHS). Further, the Italian agency directed that all unused NHS resources from a previous 24-month revenue ceiling set for INCIVO be used to reimburse treatment with Olysio. AIFA’s decision to link the reimbursement status of Janssen’s two products is just one example of a locality-specific, potentially unanticipated new policy that could impact a carefully developed global access plan.

**EMPOWER LOCAL AFFILIATES TO OWN THE VALUE STORY**

Engagement and empowerment come from participation – the earlier in the process, the better. Make sure that global pricing and access teams sit down with local affiliates to gather country-specific information and help build the product’s value narrative for that specific market from the ground floor.

Once the value story – the development rationale and the market need – is solidified, local country affiliates need to review it and provide feedback on the entire strategic communications package. They will be best positioned to judge how stakeholders may respond. A static global strategy determined from on high is not one that local groups can own or effectively work with.

For example, a new treatment for a chronic inflammatory disease was recently licensed in the EU on the basis of a clinical dossier that did not include Phase III studies using an active comparator. The German Federal Joint Committee (G-BA), tasked with grading the drug’s incremental benefit over existing therapies, denied reimbursement due to the lack of head-to-head comparison data. This same drug is still likely to win reimbursement from other European countries that will accept indirect comparisons, but the German market is important and broadly influential.

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BUILD LOCAL AGILITY INTO THE PRIMARY REIMBURSEMENT STRATEGY

Each market in Europe is different. Some countries, like Sweden and the UK, are laser-focused on cost effectiveness (CE), while others, like Italy and France, emphasize clinical efficacy. Further complicating matters, countries may change emphasis over time: France is moving to CE evaluation of innovative products with a therapeutic improvement rating (ASMR) of III or above. Thus, it is important to give affiliates the ability to adapt the global value communication plan locally in order to address reimbursement agency idiosyncrasies.

If a local market is hit by an unforeseen change in government policy or economic instability, affiliates must be able to adapt the pricing and/or value proposition as appropriate, assuming their actions are coordinated within the framework of an agile global strategy.

USE MOCK NEGOTIATIONS TO TEST-DRIVE THE VALUE STORY

MOCK NEGOTIATIONS SHOULD INCLUDE:

1. Prep sessions with role play for both payer and negotiator where story lines and counter arguments are rehearsed
2. Active negotiation sessions where country affiliates present their story and payers challenge the pricing, access and reimbursement assumptions
3. A debriefing session to analyze what did and did not work

A recent mock negotiation for a new oncology product showed how these sessions might highlight differences across markets. The interaction between country affiliates and proxy payers (retired reimbursement and regulatory experts) playing their respective parts revealed a key challenge: the new drug lacked Phase III Overall Survival (OS) data, considered by payers across Europe as the gold standard for oncology drugs, in contrast to its main market competitor which had OS data ready at launch. During the mock session, country nuances around this issue emerged into sharp focus.
A compelling value story always begins with the context: explain the rationale for development of the medicine, with the need clearly established. Present the value of the drug using exact and referenced figures whenever possible and avoid subjective “expert opinion.”

Clearly identify the target patient population and the medicine’s intended place in therapy (that is, first line, second line, and so on).

Be familiar with your competitor’s clinical data. Know which clinical endpoints are scrutinized by each country’s healthcare reimbursement system – and know how your product performs against those endpoints (or against relevant endpoint proxies). Company clinicians with extensive background on the product should be made available to payers at all times.

Be aware of potential payer objections and address those concerns proactively. For example, if a specific adverse event [AE] attracts negative attention because a high percentage of patients are experiencing it, but the company knows that this AE can be managed, and that the incidence of high severity [grades 3 and 4] AEs of this type are low, negotiators should address the data with pricing and reimbursement stakeholders before they raise the issue.

Collaborating with independent researchers in order to produce quality inputs on productivity loss will allow payers to conduct a true data-driven cost-benefit analysis.

Likewise, if a significant proportion of the societal economic burden of a disease relates to lost productivity – as is the case with major depressive disorders, for example – negotiators should include data on this specific measure in the value conversation early on. Collaborating with independent researchers in order to produce quality inputs on productivity loss will allow payers to conduct a true data-driven cost-benefit analysis. Again, don’t wait until payers raise the issue: address it head-on.
Effective communication demands preparation and creativity. Even if they are experienced speakers and communicators, Market Access personnel who make the value argument to payers need to practice until they get it right.

Recently, PAREXEL coordinated a mock negotiation for a client ready to launch its new product across Europe. The exercise included corporate global strategy team members, local market access team members and experienced proxy pricing and reimbursement stakeholders. Despite a lengthy period of research and preparation in advance of the session, our client found that its value story wasn’t as polished as it needed to be. The take-home message was that continuous repetition and refinement are crucial to successful communication.

While all communications should fall under an overarching global pricing, reimbursement and access strategy, local affiliates must be able to make a value argument that is relevant and resonant to each country’s healthcare system – and they must be ready to deliver that argument effectively, both during the initial launch, and also over the duration of a product’s lifecycle.
WHEREVER YOUR JOURNEY TAKES YOU, WE’RE CLOSE BY.

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