







A Valid Insight and Informa Pharma Intelligence roundtable at the 2019 BIO-EUROPE® congress in Hamburg brought together several pharmaceutical-industry stakeholders to discuss how they might improve engagement with payers. Payer engagement is a critical consideration, as the priorities and expectations of both industry and health care systems evolve and come under increasing pressure.

MODERATED BY:

Lucie Ellis

managing editor, In Vivo

PANELISTS:

Boris Azaïs

director public policy Europe and Canada, MSD

Axel Boehnke

director market access (EU North), PTC Therapeutics

Karen Coulton

global pricing and reimbursement director, Astra Zeneca

Frank Cousins

senior director, Valid Insight

Wenzel von der Heydte

regional controller, Roivant Sciences GmbH

James Wright

director, Valid Insight

Excellence In Payer Engagement: Strategic Outputs From A Roundtable Discussion

COLLABORATION IS KEY

Frank Cousins set the scene for the discussions: "Payer engagement is a strategic imperative for pharma companies, as market access for new medicines requires collaborative action from payers at national, regional or local levels. Partnerships between industry and payers need to be grounded in mutual interests, such as patient access to innovative therapies, aiming for improved health outcomes."

"The aspiration," Cousins added, "is unrestricted and, as far as possible, reimbursed access to new medicines for all patients who would benefit, but at a price that is sustainable for the health care system and commercially acceptable for the company. This should be our definition of optimal patient access."

Axel Boehnke highlighted just how much is involved in building a collaborative relationship. "When you say collaborative, you are thinking about the payer side and the industry partner side?" he asked. "These seem like the earth and moon from a distance. But I think you can maintain a collaborative approach when you negotiate in a transparent, clear and fair way. It has to be a pragmatic relationship, sensitive to differences."

Discussions with payers should be goal-oriented, taking a long-term strategic view, the roundtable emphasized. They must also recognize that payers have finite budgets and resources, while industry wants payers to look beyond cost to recognize value and reward innovation. However, notions of value do not always translate well.

COMMUNICATING VALUE

"In some countries it's relatively easy to create value propositions that will be fully embraced," Boris Azaïs told the roundtable. "In other countries, for cultural or budgetary reasons, the value proposition is just not going to work."

Manufacturers and payers also need to think about the significance of patient-relevant data. "Manufacturers always present clinical outcomes data to the payers, saying, 'Look how fantastic our new product is,'" Cousins commented.

"Often the human relevance, the impact the product has on day-to-day function and quality of life, is less well communicated or understood. Yet this is frequently critical in communicating the full extent of product value. Ensuring all stakeholders embrace this data, recognize its importance and, critically, include it in their evaluations, is key to ensuring optimal access."

Bringing patient advocates to the table may help to focus discussions on agreed needs, endpoints and value. "You may organize payer advisory boards in the early-development phases, to agree on something like common-goal patient benefit," Azaïs suggested. Karen Coulton pointed out that the payer constituency "is evolving to engage the patient voice. The SMC [Scottish Medicine Consortium] for years has used patient representatives and patient submissions."

However, the roundtable participants also acknowledged the significant variations between countries and health care systems in how patient-centered data and direct patient advocacy influence access decisions. It is clear that more needs to be done in terms of seeking a more consistent approach to how this data is used.

BUILDING TRUST

Preparing early for payer negotiations, drawing on crossfunctional internal resources and building trust through transparency and a willingness to share ideas are fundamental. For Boehnke, the real value lies in "having some history together ... You need to have this trust-based relationship before you can go on to effective negotiations and aligning goals."

Wenzel von der Heydte stressed the importance of face-to-face interaction. Moreover, the discussions should be as solution-oriented as possible, with all parties offering their own ideas. That way, product uptake is not driven by pharma against payer resistance. "You should be almost product-agnostic," he commented. "Get payers to work on a solution where they can say, 'This is the mechanism we are going to agree on.""

Establishing such strong and effective relationships can also provide mutual rewards. While payer negotiations often involve multiple stakeholders at national, regional and local level, it may be one person who tips the balance, noted Coulton:

"Working with the SMC, there was a single point of contact within the Patient Access Scheme Assessment Group, and she was brilliant," she told the roundtable. "Initially, the SMC rejected the company's proposal. But we had regular meetings, just with her, to discuss different ideas and brainstorm how we could solve this problem. Then she'd take these back to the clinicians and nurses on the SMC board."

CONDITIONAL ACCESS AND THERAPY-AREA MANAGEMENT

Ultimately, though, companies need to recognize that payers have finite resources. Von der Heydte mentioned that "budget limitation poses a challenge for the payer, even if there is significant support from patient advocacy groups."

Conditional-access schemes, contingent on final pricing negotiations, can help to manage payers' budgetary constraints, while ensuring that patients have early opportunities for treatment. Agreeing on a framework for conditional access can be demanding, though.



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"To ensure a final reimbursement agreement and local commercialization it is important to put a timeframe to these types of conditional access schemes," von der Heydte noted.

Therapy-area management, where the payer allocates a guaranteed budget to one company's drug portfolio or a particular therapeutic area, may be another way forward, subject to legal, administrative, regulatory or practical adjustments. Azaïs cited MSD's experience with immunology products, "where dosing is based on the weight of the patient. The payer was reluctant, because they wouldn't know exactly how much they would have

to pay at the end of the year. We said, 'Let's switch to cost per patient."

On the other hand, a "Netflix-type model" might help avoid price referencing to other markets, Coulton suggested. Von der Heydte elaborated: "A payer could say, 'I've created a budget for AstraZeneca, for a certain country. I will pay you this amount, and you make all the products available."

Azaïs warned, nonetheless, that companies migrating too much from a "pharmaceutical" to a "therapy-area" proposition might risk losing strategic focus – not to mention business. "Maybe 15 years ago, an innovative company ran this pilot in Germany," he explained.

"The company proposed: 'We can take on the full risk of your diabetes population, and you're going to pay us a certain amount of money per year.' It was very successful, so much so that the provider then decided to take it on themselves."

PERFORMANCE-BASED CONTRACTING

"Payers do appreciate efficiency gains and better health outcomes," Azaïs insisted. Payers are already talking about outcomes-based systems.

Nonetheless, trends in industry-payer partnerships, such as performance-based contracting, may be hampered by inadequate infrastructure, lack of systems integration, politically driven budget cycles or siloed pharma budgets. There are also challenges around sourcing and agreeing on suitable outcomes data.

"We are all talking about outcomes-based pricing but there is no procedure for doing it; the payer and pharma cannot agree on defined data points," von der Heydte pointed out. Boehnke continued, "In Germany, we saw risk-share contracts, such as [the statutory health-insurance fund] DAK in Germany with Novartis on Aclasta for osteoporosis.

Why didn't it work? There were differences in the reasoning to be seen as valid for sharing the risk. For example, if a patient broke a bone from a skiing accident, it was not clearly related to bone quality."

At the same time, protracted negotiations around the relevant data, endpoints and outcomes measures to be included in such contracts are in no one's interests. They can ultimately delay patient access. "Using established relationships and formal channels to discuss what is both feasible and acceptable to all stakeholders much earlier in the development timeline should be considered essential," James Wright observed.

Data privacy is another barrier. Educating patients about the relationship between data provision reimbursement or tapping into platforms where patients voluntarily share treatment experiences may help in this respect. "In the future, we may think about how health insurance can provide discounts if patients agree that anonymized data can be made available to allow performance-based compensation," von der Heydte explained.

It may be even more challenging to launch outcomesbased agreements across therapy areas such as oncology, where, "In our experience from discussions on this subject, payers often cite complexity as a major hurdle; in oncology, you have combinations with two or three other products, heavily pre-treated patients, and a lot of the outcomes are subjective," Wright noted. "The immense complexity makes it difficult for payers to feel comfortable that proposed outcomes measures and thresholds are true markers of success."

IDENTIFYING EFFICIENCIES

Established payer-engagement strategies, such as encouraging more aggressive purchasing policies for non-innovative products to clear budget space for innovation, are less suited to an increasingly integrated health care setting. There is, however, leeway for companies to sup-

port more efficient use of care pathways and associated resources, particularly at local level, to facilitate integration or to help improve outcomes measurement.

"There has been a lot of discussion about wasteful spending in health care," Azaïs noted. "In oncology, it's very clear that the sooner you are diagnosed, the better the outcome, and the less you are actually going to cost the system."

Industry would like to see a focus on total health-system costs and value over time, rather than immediate budgetary impact. That means longer-term contracts with defined outcomes and shared savings. These may be easier to achieve in settings such as hospitals, where there is clearer responsibility for profit and loss, and harder in countries where siloed pharma budgets reduce incentives to track outcomes along the patient pathway.

"You'll find more examples in the hospital setting, because many hospitals have their own P&L," Azaïs noted. "We have a product that is used after surgery. We came in with a training suite and were showing the value for the hospital in terms of bed occupancy. And that worked."

On the other hand, Azaïs continued, "It took us seven years to get [a diabetes product] recognized in Italy, because there are diabetes and coronary-health silos. They compared us with generic products that are not as good in terms of cardiovascular patient outcomes. But cardiovascular patient outcomes are another budget, so why should payers care? We had to elevate the discussion at political levels and bring in arguments on loss of eyesight and amputation."

TIMING PAYER ENGAGEMENT

Ideally, the discussions suggested, payer engagement should span the whole product life cycle. But even payers who conduct horizon-scanning to gauge future product impact may return to short-term budget planning following initial discussions with pharma.



This complex environment makes tougher demands on market-access and payer-engagement functions within companies. These must straddle datarich disciplines such as analytics and pharmacoeconomics, as well as have a solid grasp of clinical data, and how this integrates into supporting the best possible commercial value proposition.

"The truth is that once the crisis and the fear are gone, everybody goes back to business as usual," Azaïs commented. "And who's going to have the time, on both sides, to discuss what's coming in five years? ... They will continue to focus on the product that comes next."

Early interaction with payers can clarify how outcomes data from clinical trials relate to identifiable patient needs, particularly for novel drug mechanisms or in untapped therapeutic areas. "There are companies that design trials on a regulatory basis without considering payer and patient needs," Coulton said. "They may have novel tools to capture outcomes, but the payer has no idea what that actually means for the patient."

CROSS-FUNCTIONAL RESOURCES

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"They have to be so switched on, being able to understand a clinical trial, interpret the data, the massive clinical study reports, and also work with the statistician," Coulton observed. "But at the same time, you need to be very commercially savvy to communicate a value proposition in a clear, concise manner."

Market access now embraces a broader range of stakeholders, patients in particular. It must consider global strategy and country-level variations in the access landscape, while ensuring cross-functional consistency of messaging around product value. "There's far more integration and cross-functionality now, and an acceptance that every contact with an external stakeholder, whoever they are, is an element of market access," Cousins said.

EVOLUTIONARY NOT REVOLUTIONARY

Ultimately, payer engagement in European markets is an evolutionary rather than a revolutionary process, Cousins stressed. "Most of our customers have a pretty good idea of what they would like to do, based on extensive experience. It tends to be an evolution to optimize the plans, rather than designing from scratch."

Pharma companies are also operating in a highly competitive environment, where they need to maintain margins in the face of relatively blunt instruments for cost control, such as tendering. To do this, while keeping the focus on science, innovation, payer needs and patient access to medicines is the ideal win-win for both payers and industry.

"Everything is driven by science and we've seen how the regulators have picked up on that, starting with the FDA's Critical Path Report," Azaïs commented. "We haven't reached that level with payers. There's not the same level of commitment or understanding that this is a science-driven collaboration."

As Cousins emphasized though, innovation – and its cost – needs to be understood in terms of patient benefit. "How can we move payers toward a greater appreciation of, not just the price, but real value. How does a product improve the life of a patient holistically? Can it be incorporated into the value proposition of an asset, and ensure this has a positive impact on key decisions?"

The first company to answer that question "is going to be in a very strong position," he added. "But it comes through dialogue. It comes from early engagement, based upon trust. And that's not established overnight."



ABOUT VALID INSIGHT

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Valid Insight has an extensive network of payers, clinicians and other stakeholders across global markets, and several technology-enabled solutions to inform insights and recommendations.

Valid Insight was awarded the Queen's Award for Enterprise:

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www.validinsight.com

discover@validinsight.com +44 (0) 20 3750 9833



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