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Market Access Strategies: Nudging Negotiations Along

by Leela Barham

Deals in pharma to secure market access are now business as usual. More deals will be needed in future too. Yet they take time and are not easy to successfully conclude. Could nudging the negotiations help?

"Nudging" has become a common phrase in health care, with nudges being used to encourage patients to turn up to appointments through to making a game of taking exercise. According to Harvard University professor, Cass R Sunstein, "nudges are private or public initiatives that steer people in particular directions but also allow them to go their own way."

New research published in the *Journal of Behavioral and Experimental Economics* in June 2024 has taken the nudge into market access negotiations. Attentional nudges have been experimented with, inspired by the context of negotiating deals for advanced therapies in Europe.

Nudges were provided to guide some participants during hypothetical pricing and reimbursement negotiations involving more than 200 negotiators. Negotiators from both sides were given briefings on what elements of a deal would create the most value for their hypothetical organization – be that as a payer or a manufacturer – as well as six key clauses for the deal. They included: price per patient, maximum number of patients that treatment would be paid for, the location of production and R&D, division of clinical risk, time to bring the product to market and quality of data generation system.

Negotiations were done via computer and participants took part anonymously, with each receiving a real financial pay-out proportional to the value that their negotiation produced for their organization.

Some negotiators were given nudges, others were not. These nudges varied; one was to encourage negotiators to share more information about their respective negotiation goals

(transparency), the other nudge was to encourage negotiators to focus the first stage of the negotiations on topics where an agreement was easier (convergence).

Lab-Based Nudges Add Value

The lab research suggests that nudges can create value in negotiations, with payers benefiting the most. Negotiators who were nudged towards early wins could create more value, and so too were those who were nudged towards sharing more information with the other side. These can build trust, a stumbling block in many negotiations. More rounds of negotiation can create more value too.

Karine Lamiraud, Julien Patris, and Radu Vranceanu were behind the lab experiments to test out the differences nudges can make. Lamiraud and Vranceanu hail from École Supérieure des Sciences Economiques et Commerciales (ESSEC) Business School and THEMA, a research lab. Patris holds a post at *argenx N.V.*, but the research is part of his academic work as a guest lecturer at ESSEC. Patris has been working on how to do deals in a better way for some time. He is a co-author of a paper that set out a value-based negotiation framework for managed entry agreements (MEAs), published in 2022.

Patris was pleased with the results of the nudging experiment. "We've found that using nudges applying the principles of a value-based framework can help deliver higher value deals. Being more transparent – within reason – with the other side, focusing on the things that you can agree first, that's good for payers, for companies and ultimately, it's better for patients and society."

Inefficient Negotiations

There is no doubt that a better way to negotiate is needed. Adam Hutchings, managing director of rare disease market access consultancy Dolon, argued: "We have to make negotiations more efficient. There are lots of situations where there will be a need to negotiate. If every time there is a negotiation on a new treatment both sides start from first principles, it will take ages and it will cost. There's a real opportunity to approach negotiations more efficiently."

Empirical work backs up just how long negotiations can take. Researchers at the London School of Economics found that the time to reach a funding agreement for 71 re-submissions and reevaluations of cancer treatments across Australia, England, Scotland and Sweden took an average of 452 days when an MEA was part of the agreement. That contrasts with 404 days without an MEA.

The time taken can be even longer when the negotiations are more complex. The LSE work looked at bi-lateral agreements, but early experience with a multi-lateral negotiation for Orchard Therapeutics gene therapy Libmeldy (atidarsagene autotemcel), a treatment for metachromatic leukodystrophy (MLD), and the Beneluxa initiative suggests it can take years to reach agreement

on market access. The Beneluxa initiative is a voluntary collaboration including Belgium, the Netherlands, Luxembourg, Austria and Ireland. Only Belgium, Ireland and the Netherlands took forward a multi-lateral negotiation on pricing and reimbursement of Libmeldy.

The Beneluxa negotiation was supported by assessments that started in March 2021, but an agreement was only reached by January 2024. Along the way – in April 2023 – the negotiations broke down. The deal eventually reached includes pay for performance, a likely response to the uncertainty in clinical benefit.

Sometimes a deal just cannot be agreed. It is hard to know just how often that happens because there are few incentives for either side to reveal failures, but some will hit the headlines. The most recent example in England is the failure to agree on a price for Enhertu (trastuzumab deruxtecan) used to treat advanced breast cancer. According to health technology assessment agency NICE, *Daiichi Sankyo Co., Ltd.* and *AstraZeneca PLC* were not willing to offer a price that would allow NICE to recommend the product.

Contrast that to Pascal Soriot's views. The AstraZeneca CEO reportedly said on an analyst call, "It's not a question of price." He pointed instead to NICE methodology, questioning why NICE scored metastatic breast cancer as a moderately severe disease. That classification stopped NICE from applying a higher score for the benefits of treatment, resulting in the finding that Enhertu was not a cost-effective use of NHS funds.

There are insights from academic literature on why failures in negotiations happen more broadly. Lamiraud et al point to a lack of understanding of the other sides' priorities. When it comes to advanced therapies, Lamiraud et al highlight the challenges of uncertainty in the performance of therapies, the complexity of contract claims and recognize that emotions can run high.

It follows that failed negotiations, and the time and effort spent on them, are likely a big hidden cost.

AstraZeneca's Enhertu Expansion Blocked By NICE Over Price

By Andrew McConaghie

30 Jul 2024 The cost effectiveness watchdog claims AstraZeneca and Daiichi-Sankyo have not offered a fair price for use in the larger HER2low setting.

<u>Read the full article here</u>

Uncertainty Driving Negotiations

Uncertainty is at the heart of the need for negotiations on market access. "There can be inherent uncertainty on the value of new treatments," Hutchings explained. "Negotiating can allow you to reach a deal to manage that." Agreeing on a price for the uncertain value of a treatment is part

of the negotiation too. "There can be a big difference in the perception of value and what price is justified by that value between a manufacturer and payer," he added.

Managing uncertainty has not been easy to do in the past despite lots of effort. "We've seen a lot of attempts from industry and health authorities to find new ways to come to agreements on market access, managing uncertainty with things like risk sharing, annuity payments, all of those sorts of thing. There's been creativity, but really, we've not seen these being widely used," explained Patris.

Radical Empathy

Patris has identified a key takeaway for companies from the nudging research. "Don't come into a negotiation with fixed ideas. You cannot pretend you know better the interest of the other side." Instead, he urges companies to practice "radical empathy." But how to do that? "Ask the right questions of the other side," Patris said.

Chris Brown, founding partner at specialist negotiation firm Negotient, concurs with the importance of understanding the other sides' perspectives in a negotiation. "Value-creating deals cannot be done without consideration and understanding of the other side. The more complex, the more multi-dimensional the negotiation, the more you need to do this. Everyone cares about patients. Everyone cares about inequalities. Everyone cares about the financial impact. But don't assume that you know the trade-offs."

Many HTA agencies offer the opportunity for early dialogue for example, sometimes payers are there too. It's in these forums that there are opportunities to ask questions and get insights on what matters most to payers before everyone is sitting around the negotiation table. "Starting at the formal negotiations is a really inefficient approach. In reality, it is possible to have a good idea of what needs to be considered in negotiations before they formally start," said Hutchings.

Companies should do their homework too. "Look at previous decisions, understand the rules of engagement, it's not the job of the authorities to find the solution for you," pointed out Patris.

Companies should also not assume that the other side has done their homework. "People tend to spend limited time thinking about how the other side sees the world. It can help if companies help the other side to understand what is going on in the wider world. For example, don't assume that an agency like NHS England [the biggest buyer of specialized medicines in the UK] has rich information about access and uptake of innovation in other countries, or how other countries are dealing with uncertainty, or the deals that they are reaching."

Showing that the company has been able to see the other side's perspective is part of radical empathy too. "When a company gets to a negotiation, they have to articulate the value of their treatment in a way that is intelligible to the other side. They have to identify the trade-offs too

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and they have understood concerns and are willing to focus on potential solutions that mitigate these as far as they can. It's about framing the negotiation," Patris said.

However, to truly work, radical empathy needs to be a two-way relationship. Authorities should understand the broader context faced by companies.

Nudging Within The System

Negotiations happen in the wider context of the rules and legislation for pricing and reimbursement of treatments. It follows that the 'system' itself can create nudges. "To some extent, the system itself should do a lot of nudging," said Patris. "To give an example, in some countries there is a separation between the agency doing the value assessment and the negotiation. That ensures a clear difference between the assessment and the negotiation and ensures the objectivity of the assessment, and the focus of the negotiation on most important issues to resolve," he explained.

That separation shapes the negotiation's focus, for example, identifying the biggest drivers of uncertainty which could be a focus for a subsequent negotiation.

In the same vein, the system can provide opportunities for pre-negotiation dialog which can be used to get a jump start on understanding each other's perspectives. "Nudging can be thought of as part of the pricing and reimbursement process. There are opportunities in some countries for early touchpoints, there is the opportunity for companies to get early scientific advice from NICE and payers can be part of that too, for example. The NICE process includes a scoping phase too. In Germany companies can have early meetings with the G-BA," said Hutchings. The value of early dialog lies in "identifying what will be the most important elements of a later negotiation. It helps companies to really focus on what matters most," he added.

The system can also set the timer – and any clock stops – for negotiations. "There can be timelines or maximum rounds of negotiations set out for pricing and reimbursement and being too rigid, can limit the opportunity for creativity in the negotiation. Our experimental research suggests that more negotiation means better negotiation," noted Patris.

Patris thinks nudging could even be more radically implemented by policymakers. "The nudger could even be a third-party agency, like a clearing house, or there could be an IT platform, software that can be used to set sequence and structure the negotiation and share information during a negotiation," he suggested.

Could England Be The Place For A Pilot?

Piloting nudging negotiations within a value-based approach to deal-making is an exciting prospect for Patris. "I would welcome if some authorities, trade associations and companies would explore a pilot. I think it's worth the time and could build on our research. The more

actors explore the principles of value-based negotiations and nudging, the closer we could get to a solution."

Trying out nudging within a more structured approach to negotiating will need payers who want to do more about managed entry agreements. But also, those that buy into the more structured process. "I'm not sure that there are many countries that have both," said Hutchings. England could be a contender though for piloting, "England has a process through NICE and there seems to be more willingness to explore contracting," noted Hutchings.

For Brown, the new Labour government as well as the new sector deal, VPAG, agreed by the former Conservative government, but due to be in place until the end of 2028, also makes England a promising

Older Medicines Rebate Will Test UK's New Pricing & Access Scheme

By Leela Barham

20 Mar 2024

As the UK government implements a new rebate system for older medicines as part of the new pricing deal, industry trade bodies and experts suggest that exceptions will have to be made, such as higher prices or lower rebate levels for specific products.

Read the full article here

place to try out getting better at negotiating. "There are positive messages in the new VPAG as well as a new government that provides opportunities for new ways of working," he argued.

There would be ways to determine success too. "A pilot should be based on metrics to explore if nudging and conducting negotiations in a value-based framework can work. To a large extent, we have those metrics already in place. We can look at how many times there is a pricing and reimbursement submission, we can look at how long it takes for the pricing and reimbursement process to successfully conclude, we can look at how many times a contract is the result of the negotiation process," said Patris.