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P&R briefs: Recent developments in global pricing & market access

Japan

New HTA to bte applied in April 2018 will only target existing drugs and devices

The Japanese MHLW (Ministry of Health, Labor and Welfare) recently announced that its planned Health-Technology-Assessment (HTA) process will only target products already listed for reimbursement, while new products will be exempt.

The HTA was under development by MHLW for years, with a full-scale introduction planned for April 2018. Initially the process was planned to be implemented for both new and existing products. However in the course of discussion, criticism increased regarding the application of the HTA to new drug or device pricing. Concerned voices from both manufacturers and members of MHLW itself pointed out that the targeting of new products would likely undermine timely patient access to new treatments in Japan given the likelihood of a lengthened time between regulatory approval and reimbursement listing.

The weight of this consideration was made clear during a June 28th ruling, when the health ministry panel agreed to separate the initial pricing decision for new products and the HTA. As a result, the decision regarding eligibility for reimbursement will still be made without official consideration of HTA, but a product may be subject to HTA-based re-pricing once it is listed.

Payer representatives suggest that an HTA-based repricing of existing products would target a different subset of innovative products with significant sales every three months. At the same time, the MHLW proposal from June 28th calls for excluding treatments for rare diseases, pediatric treatments, essential medicines and other treatments with high unmet need from the HTA.

Although it looks as MHLW has come to a conclusion regarding the separation of listing and HTA, many details regarding both targeted products and timing remain under discussion and are still to be decided.

China

China's National Reimbursement Drug List updated after 7 years

In February 2017, China's Ministry of Human Resources and Social Security (MoHRSS) issued the 2017 edition of the National Reimbursement Drug List (NRDL), replacing the previous version published in 2009.

The 2017 NRDL contains 2,535 drugs, including 1,297 pharmaceutical products, with the balance being traditional Chinese medicines. Among pharmaceutical products, 402 drugs are in tier-A and receive 100% reimbursement. Additionally, 895 drugs are in tier-B with reimbursement level varying from 80% to 90% depending on provincial implementation and funding ability.

Compared to the 2009 NRDL, 11% more pharmaceutical products were added to the 2017 NRDL. By therapeutic area, the number of diabetes drugs in the 2017 edition increased the most (79%), followed by pediatric drugs (60%), hypertension drugs (23%), and oncology products (13%). Select high-cost therapies, including AstraZeneca's Iressa (gefitinib) and Gilead's hepatitis B drug Viread (tenofovir, commercialized by GSK in China). Both products took place in the first round of national drug price negotiations during 2016.

Aside from product reimbursement, a key provision in the 2017 NRDL is greater specification of reimbursement scope. This edition outlines specifications of treatment standards and indications, and couples those to reimbursement eligibility. This is seen as a measure to balance the increasing expenditures expected from increased volume of reimbursed products.

On the provincial level, the local reimbursement drug lists will be established by the end of July 2017. Regions will

not be able to adjust availability of NRDL tier-A drugs. Regional adjustments will not be allowed to exceed 15% of drugs in NRDL tier-B. All provinces are required to start to use the new lists by August 2017.

In addition, MoHRSS has announced that an additional 44 medicines are under negotiation for inclusion in the list, all of which are patented or exclusively-supplied drugs with high clinical value and prices, including Avastin (Bevacizumab), Erbitux (Cetuximab), Zytiga (Abiraterone), Tykerb (Lapatinib), and Remicade (Infliximab). If negotiations lead to an agreed upon price, the drug will be included in the reimbursement list going forward. This will provide a mechanism for high cost innovative drugs to gain broad access in China.

Germany

German federal cabinet passed AMVSG (amendments to AMNOG)

In March 2017 the German federal cabinet passed AMVSG and the changes came into effect in April. Key changes to AMNOG include:

- **The price moratorium will be extended to 2022.** As of 2018, compensation for inflation will be considered.
- **The specific situation in the area of resistance of antibiotics will be included in the early benefit evaluation and reserve antibiotics can be exempted from inclusion in a fixed reference group.** To support the targeted use and clinical development of antibiotics, the reimbursement regulations for relevant diagnostic methods should be improved (no further details).
- **The specifics of pharmaceuticals used in children will be considered in evaluations.** a) An additional benefit can also be granted to subpopulations that are under-represented in clinical studies, where approval was based on transferred evidence. b) Pharmaceuticals that are eligible for reimbursement among children and adolescents only are excluded from the benefit assessment. c) Administration forms specifically created for usage in children can be exempted from inclusion in a fixed reference price group.
- **Possible consolidation of benefit evaluation and price negotiation, if launch in several indications is planned.** The manufacturer can apply for a delay in handing in the dossier, if the launch of another indication is expected within six months. The price shall, however, come into effect in month 13 after launch.
- **Shorter waiting period for re-evaluations when new evidence becomes available.** The manufacturer can already apply for re-evaluation due to new evidence after less than one year.
- **Benefit evaluation for older active substances (launched before 2011) possible if launched in a different indication:** The G-BA may initiate a benefit evaluation if the new indication is significantly different from the current indication, i.e. if the drug receives a patent.
- **Exemption from benefit evaluation due to small budget impact (<€1 million) only possible at launch.** Due to misunderstandings in the past the legislator makes clear that the regulation does only apply at launch of a drug. It does not apply if the drug launches in another indication where the expected cost to sick funds is minor.
- **Physicians will be informed on results of the benefit evaluation via the prescribing software.** These information systems shall also contain information on economic use of pharmaceuticals on the basis of price negotiations in the AMNOG process.
- **Lower reimbursement price if manufacturer hands in no/an incomplete dossier.** If the manufacturer does not hand in a dossier or if the dossier lacks specific key aspects, the reimbursement price must be lower than the price of the appropriate comparator therapy.
- **For exceptional cases, if therapies are considered as an important therapy option for patients, the reimbursement price of pharmaceuticals with no additional benefit may be higher than the price of the appropriate comparator therapy.** During a transitional period, this is also possible for pharmaceuticals where a reimbursement price has already been agreed upon or set by the arbitration board. The regulation does not apply to drugs that have been withdrawn from the market before negotiations (opt-out).
- **Negotiated reimbursement price applies to both, the office based/hospital outpatient and inpatient sector.**

UK

Changes to the evaluation and funding process for new drugs in the UK

In March 2017, the results of a consultation involving NICE and NHS England were published, detailing new rules regarding the technology appraisal (TA) process and price thresholds.

- **£20m/year budget impact test:** If the annual net budget impact of a drug is expected to exceed £20m in any of the first 3 years after launch for the indication being assessed, then commercial discussions between NHS England and the manufacturer will be triggered. These discussions will occur regardless of the drug being considered cost-effective by NICE. Discussions need to be completed by the time NICE issues its guidance, however NHS England is able to request up to 3 years for phased introduction of the new drug (vs. current 90 day mandatory funding period).
- **Fast track appraisal:** For drugs with an ICER of <£10k/QALY, the budget impact test will not apply and fast track assessment will be possible. For such drugs, the TA process can be initiated immediately after the CHMP positive opinion, and the mandatory funding period will be decreased from 90 to 30 days.
- **ICER threshold for highly specialised technologies (HST):** A sliding ICER threshold will be applied to HST based on incremental lifetime QALY gain, with automatic funding below the threshold. The threshold will vary from £100k-£300k/QALY. The budget impact test will also apply to these drugs

According to NICE, these changes aim to enable flexibility in the adoption of cost-effective high budget impact technologies, facilitate quicker access to the most cost-effective treatments and give greater clarity regarding funding of rare disease treatments.

However many have a less positive view, perceiving the budget impact test as an extra access hurdle which is likely to create long delays for innovative high cost drugs and first-to-market drugs with large target populations. NICE has been criticised for failing to provide a rationale for the £20m budget impact threshold, and for the HST ICER thresholds. The formalised HST threshold is also expected to make it more difficult for such drugs to achieve high price points.

The Association of British of the British Pharmaceutical Industry (ABPI) responded: "These new plans will prevent patients from receiving NICE approved, cost-effective medicines, undermining their basic rights under the NHS constitution. ... As we head towards Brexit we should be catching up with Europe not falling further behind."

Canada

Canada-wide increased home healthcare

The Canadian federal government has earmarked $6 billion over the next 10 years for provinces and territories to improve home care services. As of now, all but Manitoba have accepted the federal funding offer to improve access to home care, home-based palliative care, and community-based care.

On a given day, approximately 15% of hospital beds are occupied by individuals who would rather receive home or community care. Transferring site of care for these individuals will ease the burden on local hospitals, thereby enabling more patients to receive the most appropriate care with significant savings to the province. Jane Philpott, Minister of Health, believes that facilitating, "...better access to...community-based care leads to better support for patients, at a more affordable cost. With an aging population...this is one of the ways our system must adapt if it is to deliver better care".

Average Per Diem Cost in Ontario[1]	
Hospital Bed	$842/day
Long-Term Care Bed	$126/day
Care at Home	$42/day

[1] Auditor General of Ontario (2014). 2014 Annual Report of the Office of the Auditor General of Ontario.

The expansion of home care could result in increased importance of some stakeholders. Home healthcare workers may become more influential in treatment selection for home care patients, which may increase their influence in the formulary decision-making process. Hospital stays are currently fully covered, and there is no indication yet as to how or if shifting the site of care would change coverage eligibility requirements and associated cost burden for patients. If the home care program has different eligibility requirements and cost sharing implications, home care could become a financial burden for patients, particularly for long-term care (i.e., dialysis patients).

Ontario expanded drug coverage

In Canada, provinces have autonomy in designing and funding their health plans. Beginning in 2018, Ontario will fully cover 4,400 drugs as the primary payer for all 4 million residents <25 years old with no out of pocket cost to the patients. Ontario already funds a similar drug program for all residents >65 years old; this policy expansion will cost the province $465M/year. This move signals Ontario's desire for universal Pharmacare rather than filling a significant coverage gap, since the majority of young people already have comprehensive coverage through their parents' employer-based plans or through social assistance programs. This is the first program of its kind in Canada, and other provinces have not indicated that they will enact similar policies.

Expanding public drug coverage to youth underscores the continued importance of public payers in product launches as they are now responsible for an even larger share of the pharmaceutical market.

Dr. Eric Hoskins, Minister of Health and Long-Term Care, indicated that this policy, "...is a major step forward towards universal Pharmacare". If this is, in fact, the first step to true universal drug coverage in Canada, it could have significant impacts on drug budgets, formulary decisions, and contracting with manufacturers. Universal Pharmacare would put more pressure on health plan budgets and therefore on negotiations with manufacturers. 70% of provincial healthcare expenditure is already attributable to prescription drugs, and this could potentially rise if more residents rely fully on provincial health plans. Expanding universal Pharmacare could foster higher scrutiny of new products for addition to formulary and raise the provincial health plans' negotiating power with manufacturers given a larger patient population.

Stepping down value to enhance TopLine Power®

Is launching a value brand the most effective strategy for your product? A guide for making a "go-no-go" value brand launch decision by thoughtful consideration at each step of the process

By Chuck Gammal, Chris Barr, Crystal Hsu, Susan Huang

This article was originally published in "In Vivo" on June 21, 2017

The MedTech industry has traditionally grown through innovation – new products with improved features and benefits fueled revenue growth. However, innovation alone does not garner the price premium it did in the past. As customers become increasingly value-oriented, a widespread acceptance of products that are simply "good enough" threatens to further undermine the position of innovation in the value hierarchy.

As a result, going "the wrong way" down the value staircase (Figure 1) can create solutions aligned with customers' needs and willingness-to-pay. Removing select non-essential attributes creates a value brand, an offering with fewer features and benefits used to target customers with a unique set of needs.

Launching a value brand as a new product represents a wholesale shift from the traditional MedTech portfolio management strategy, wherein legacy products were positioned as the de facto low-cost and lower value option.

Yet an increasing number of leading MedTech companies are pursuing value brands - so should you be considering a value brand launch?

While launching a value brand can be an effective strategy, it is not a cure for all commercial challenges - there must be a compelling "why." Often, the companies that stand to benefit the most are premium market leaders seeking to:

- Protect existing market share against growing competitive threats
- Reignite growth by expanding market share in lower-value segments

If either of these scenarios are mentioned in your leadership meetings, then a value brand launch is likely a relevant strategic consideration. This article aims to guide established premium market leaders through the key steps that inform a "go-no-go" value brand launch decision.

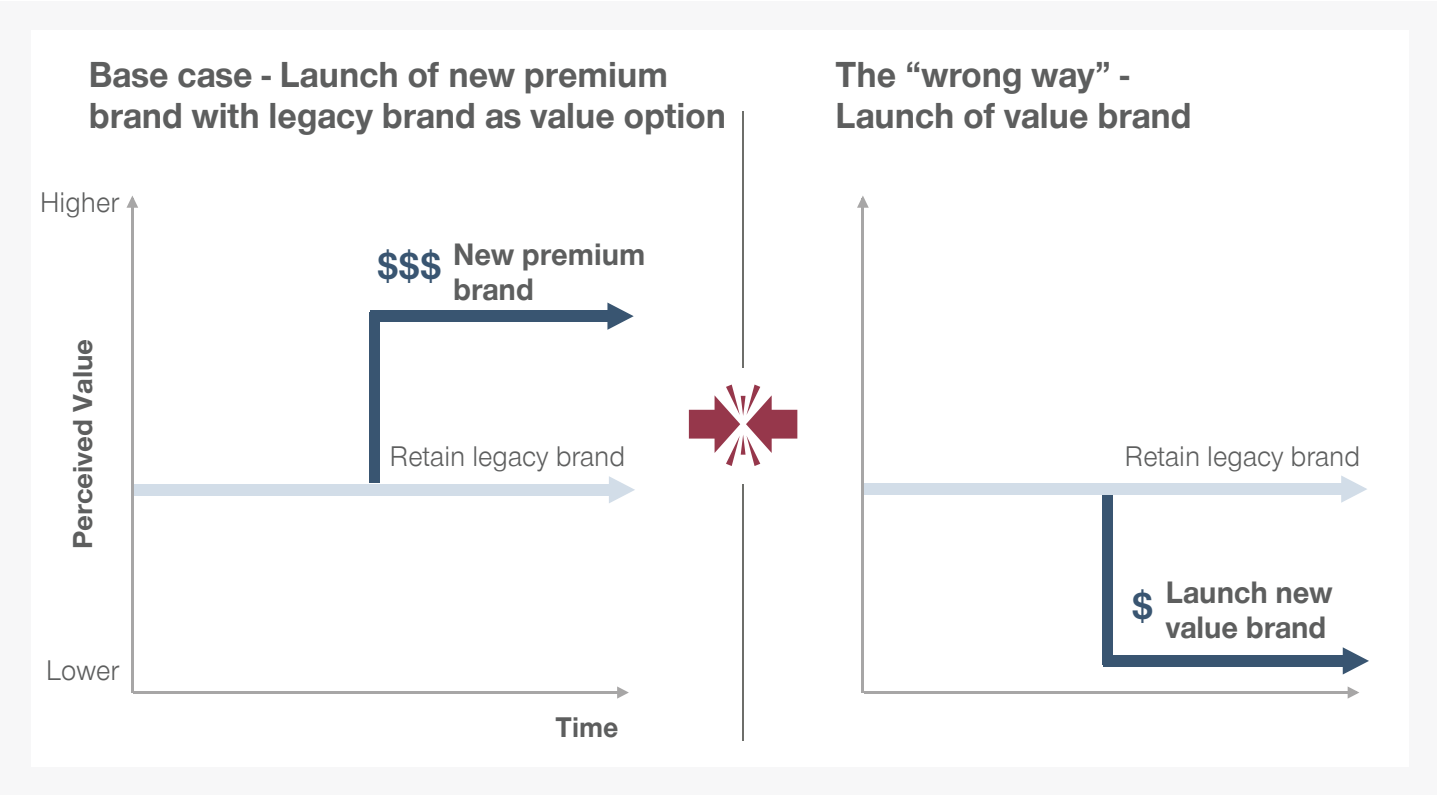


Figure 1: The established MedTech brand strategy paradigm has been to pursue innovation to create premium offerings. Launching a dedicated value brand requires a rethinking of portfolio strategy but is increasingly viable in today's MedTech market.

Figure 2: This "go/no-go" framework evaluates 5 key factors to determine whether or not a company should launch a value brand. These considerations are analyzed through a scorecard analysis to ensure that each evaluation yields a company-specific solution. Ultimately, continuous refinement of the solution will dictate long-term success.

"Go-no-go" value brand launch framework

Simon-Kucher walks clients down a five-step staircase to guide them toward the decision of whether or not to launch a value brand (Figure 2). This decision is informed by thoughtful consideration and rigorous analysis at each step of the process. Given the novel nature of dedicated value brands in MedTech, case studies (Figure 3) will highlight not only recent strategies employed in the industry, but also success stories from other industries with a more established history of value brands, such as consumer goods and industrial chemicals.

Case Summary

Medtronic
(Pacemakers)
A near term market trigger drives immediate launch of lower-priced alternatives.

J&J Ethicon
(Sutures)
Long-term headwinds trigger a value strategy to maintain market leadership.

Dow Corning
(Silicon)
Successfully driving both value and premium businesses through separation and differentiation.

P&G Basics
(Paper towels)
Category expansion by tailoring the product offering to multiple consumer segments.

Bausch & Lomb
(Contact lenses)
Multi-tier value pricing and branding backfires in the absence of functional differentiation.

Case study 1
(Urology)
Defending brand positioning across regional tender markets.

LifeScan
(BGM)
Competitive intelligence informs a market-share driven value brand strategy.

Case Study 2
(Luxury goods)
Value-brand strategy pivot informed by robust KPIs.

Figure 3: Case studies illustrate real-world learnings from companies that pursued value branding both within and outside of MedTech. While cases in MedTech demonstrate directly applicable tactics, the well-developed nature of the value segment in other markets can inform the future potential for value brands within MedTech.

Market trigger

The decision to launch a value brand should be driven by market trigger (s) – an event, either ongoing or in the future, that threatens an established market position. Determining the appropriate response to this market event ultimately guides the path forward.

The trigger magnitude is the first key consideration. The downside impact of the trigger must be substantial enough to justify investment in a value brand. Medtronic faced an imminent shift to lower-priced alternatives in a tender-controlled pacemaker market. In light of this shift, the company launched a value brand to avoid market share erosion in tenders while protecting the price position of their premium brand. Here, the downside of being priced out of the market truly justified the investment.

Next, it's important to evaluate timing of the response to the market trigger. Is this a near-term threat that must be addressed now, or a long-term headwind? Near-term threats, as seen with Medtronic, often drive commercial decision -making; however, value brands can also serve as a tool to insulate companies from long-term headwinds. For example, J&J's Ethicon suture division faced slight but persistent market share erosion in Brazil's mid-tier hospital segment. Historically, flagship private institutions (15% of market) sought the highest quality products, public hospitals (35% of market) chose products solely on price, and mid-tier hospitals (50% of market) balanced these factors. Market maturation, economic downtown, and increasingly savvy hospital administrators drove consistent, measured market share erosion from Ethicon to low-cost players in the mid-tier segment. Ethicon countered by launching Qualtrus, a "good enough" value brand, which successfully defended Ethicon's position against a persistent long-term headwind.

colourbox/Olivier Le Moal

Opportunity cost

MedTech companies have a variety of tools at their disposal to confront market triggers. Thorough vetting of available options can determine if a value brand is the right strategic option for your company.

Brand equity and brand positioning

Alignment of a value brand with the corporate brand positioning is the first consideration. Generally, launching a value brand should not jeopardize the existing brand equity unless the trigger magnitude is substantial enough to require a pivot.

However, when deviation is necessary in context of a market trigger, careful steps should be taken to insulate the company's brand equity. For example, Dow Corning, a company outside of MedTech but known for its success with value brands, is the market leader in the global B2B silicon market with a strong premium brand. When faced with market commoditization, the company introduced Xiameter, a lower-cost brand differentiated by limited services and restrictions on available products. By creating a separate brand, Dow Corning was able to protect its brand equity.

Top and bottom-line potential

High level analysis of the financial impact of a value brand launch should be an early consideration in the decision-making process.

Before Dow Corning decided to launch Xiameter, they evaluated the portfolio wide top and bottom line impact. This included cannibalization, market price erosion, and brand positioning, and multiple scenarios through the lens of a realistic go-to-market strategy. Initial models considering multiple scenarios predicted that Xiameter would improve both the top- and bottom-line, while delaying a decision would jeopardize portfolio financials.

The actual top-line success met Dow Corning's initial estimates under the final go-to-market strategy. As a result of the launch, Xiameter gained sales from cost-conscious customers, and the contrasting presence of Xiameter increased the value proposition of the Dow Corning brand, ultimately resulting in +63% portfolio revenue growth over 4 years.

While there is a common misconception that lower-value products will be less profitable, Dow Corning's financial analysis indicated the opposite. Similarly, the real-life bottom-line impact confirmed modeled expectations. Synergies with existing products as well as reduced SG&A spend facilitated profit improvement from -$28M to +$500M in the same 4 years.

Favorable ROI vs alternatives

Choosing the right strategic option is a non-trivial process, and other approaches should be considered to determine if the same or greater impact can be realized in a similar or shorter timeline.

"MedTech companies have a variety of tools at their disposal to confront market triggers. Thorough vetting of available options can determine if a value brand is the right strategic option for your company."

Remember Dow Corning? In just three months they were able to recoup their investment. While this level of Return on Investment (RoI) is easy to justify, it is highly challenging to predict. Thus, it is critical to weigh all relevant scenarios and consider contingency plans, as this will minimize downside risks. In Dow Corning's case, they also considered the RoI of creating a next generation product, acquiring existing products, or divesting assets. Dow Corning's forecasts indicated that developing a separate value brand would offer the highest RoI, but this will not be the case for every situation or company.

Distinct Segment Needs

Finding market whitespace with enough underserved need is a requisite for value brand success. This requires a customer segment with differentiated needs that will accept a product with reduced attributes at a lower price. Without a viable and discrete target customer segment with the potential to support the new brand, there is nothing to be gained from a value brand launch.

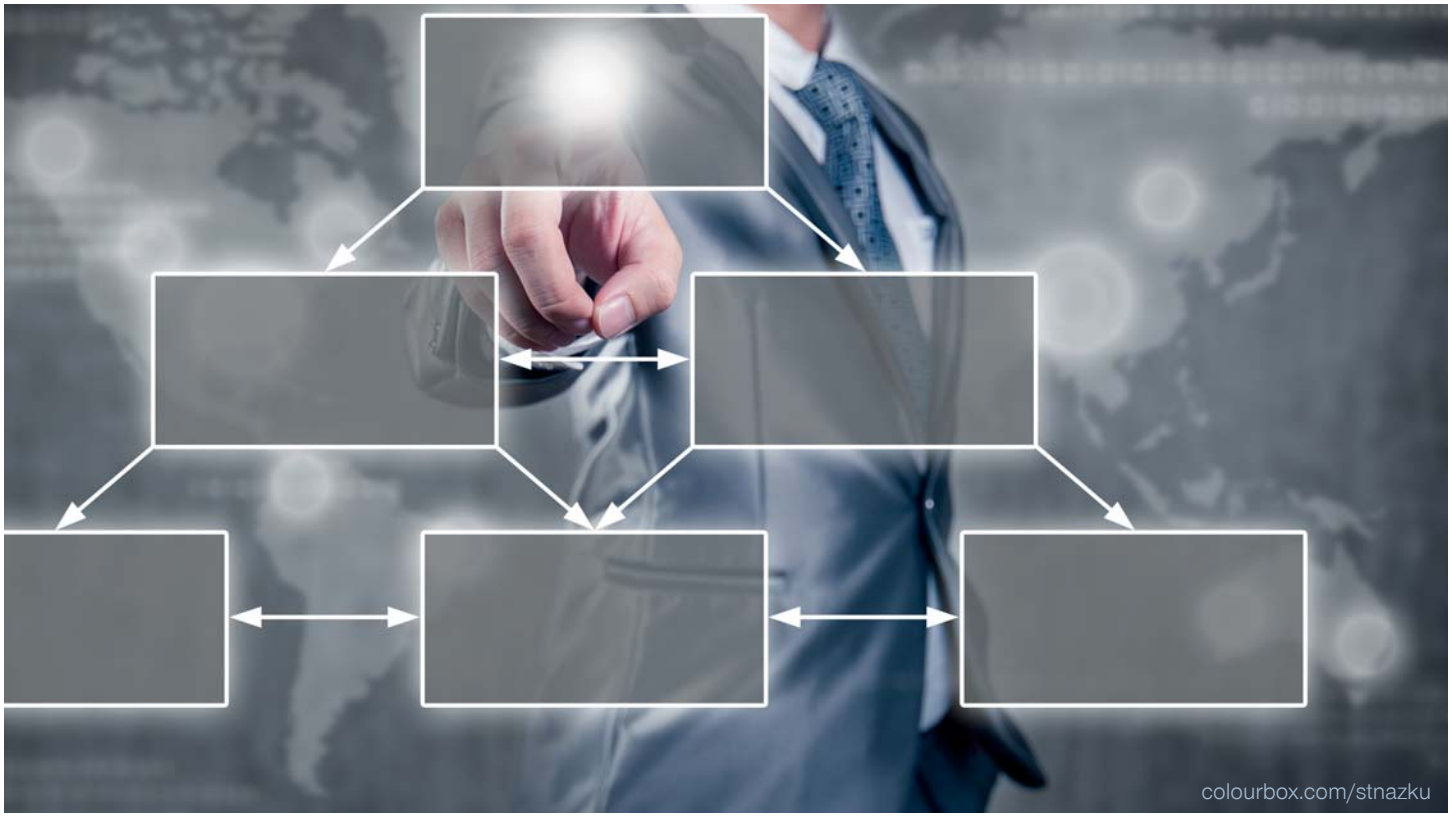
Segment separation

One consumer products company known for precision in executing on untapped market segments is P&G. The company is the household products market leader and has continually recognized opportunities for category expansion by targeting new consumer segments. P&G introduced a series of brands to serve these untapped segments, creating a "basic/better/best" paper towel product lineup. Here, P&G recognized that there were customers willing to sacrifice certain attributes, such as strength, absorbency, and softness, in exchange for lower price. This ability to segment the market strategically based on needs is key to P&G's success.

Opportunity magnitude

The market potential should be large enough to achieve the goals of the value brand. High aspirations determined in the "Opportunity cost" phase should be grounded by a deeper dive into the realizable potential of the market. P&G thoughtfully considered this – while 40% of the paper towel market preferred premium products, 60% of the 300 million consumers were willing to accept a lower value product.

Entering a lower tier market meant that P&G was competing directly with a number of established low-cost brands, which notably impacts opportunity magnitude. This is often a major barrier in niche markets that are only able to support a limited number of "me-too" brands. However, P&G capitalized on the size of the paper towel industry, leveraged existing brand equity to differentiate themselves from other low-cost products, and claimed market share as a new entrant in a crowded space.



Product fencing

Launching a lower-cost option should never come at the expense of a company's existing portfolio. A well-designed fencing strategy will guide customers to the appropriate product and minimalize cannibalization. Functional product differentiation should be apparent, targeting the wants and needs of distinct segments while steering premium customers to higher-value brands.

Necessity of functional differentiation

Multi-tier pricing and branding must be supported by functional product differentiation. A crucial consideration in MedTech is whether or not a company can actually eliminate enough valuable attributes to create a differentiated product.

Bausch & Lomb learned the importance of this the hard way when they attempted a multi-tier brand strategy by repackaging their long-wear lenses as disposables. This resulted in effectively charging a different price for the exact same lens model under different branding. While this strategy was initially successful, in ensuing litigation courts deemed the practice unfair. This type of consideration is crucial in MedTech where, by law, branding can enhance, but not create the impression of functional differentiation.

Functional differentiation strategies

Functional differentiation can be achieved through design and development that adds or subtracts product attributes in the form of features and benefits. Attributes range from low-value features (e.g., pack size) to key product benefits (e.g., quality of life improvements).

Functional product differentiation is often vital to a viable fencing strategy in MedTech. A product with limited attributes - for example, medical gauze - would be difficult to de-attribute enough to create a value brand that served a distinct segment need.

A leading medical device manufacturer known for its prior innovations in the urology and incontinence fields was highly successful in utilizing product fencing to protect against erosion of the premium brand while gaining market share with value brand offers.

Initial situation

The company had considerable stake in Russia, a diverse market with 83 regions, but increasing commoditization and cost pressure from regions threatened to erode premium positioning

Market trends:

- Local players offering low-price, "good enough" products
- Decreasing room for innovation
- Increasing commoditization
- Varying willingness - to - pay in regional tender markets (difficult to maintain premium pricing in some regions)

Value brand strategy

The company defended price differences among regions by implementing a "diffuse" brand strategy within a "basic/better/best" tier structure, using a large number of SKUs to limit price referencing between regions

Outcomes & learnings

The company was successful in protecting against price erosion while also maintaining their strong market share across regions with widely varying willingness to pay

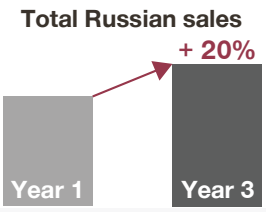


Figure 4: Case study deep dive: Urology market

But when it can be applied, successful attribute differentiation can be a powerful tool. A leading urology care provider in Russia experienced ongoing tender pricing pressure that threatened to erode the positioning of their premium brand (Figure 4). In this market composed of 83 geographic regions and hundreds of tenders, the company established several lower-cost value brands with different but substantially reduced attributes. This allowed the company to drive price sensitive tender bids through value brands, while maintaining the premium positioning of other product lines.

Once feature differentiation options had been exhausted, this company then pursued clinical differentiation to further fence products. Demonstrating a variety of quality of life improvements (e.g., pain reductions, usability), the company justified differential pricing across the value brands and premium brands. Additionally, this diffuse brand strategy limited price referencing by having a multitude of differentiated products, a tactic applicable to numerous MedTech segments.

Go-to-market considerations

The go-to-market strategy needs to be adjusted for a value brand. Companies should consider utilizing a separate brand name and correlating SG&A investment with product positioning, while also optimizing the availability of associated services. Careful alignment between positioning and operationalization will ensure that commercial costs do not prohibitively reduce the benefits of a value brand launch.

Competitive strategy

Value brand success is often a byproduct of an appropriate reaction to the changing competitive landscape. As noted earlier, there is a trend in many MedTech markets towards commoditization or high substitutability, which may indicate that a market is primed for a value brand launch, so understanding the competitive landscape is crucial.

Competitive intelligence

Understanding the positioning and expected strategies of market competitors can further reveal if a value brand is the right trigger reaction.

Historically, blood glucose monitoring (BGM) was an attractive market in developed countries with premium prices, high margins, a growing customer base, and stable reimbursement. However, a perception of product parity and deep cuts to reimbursement through numerous country-specific regulations drove rapid adoption of low-cost products from secondary competitors.

LifeScan, one of the global premium market leaders, identified this trend and created a reactionary plan based on their understanding of the tactics of low-cost secondary players. The company launched several value platforms, including OneTouch Select Plus. This product was differentiated from other low-cost products by its higher quality, but the true key to its success was the competitive strategy. LifeScan realized that their massive scale, distribution, and market access would allow them to maintain high levels of profitability, even when undercutting other value brands to secure market share in price-sensitive channels (e.g., tender bids, CCG formularies in the UK). Conversely, limited reaction to competitive intelligence by other premium competitors resulted in and steep declines in market share over the past 5 years.

Competitive reaction

Analysis of scenarios related to competitive reaction will enhance understanding of risks associated with a value brand launch. For example, launching a value brand in a basic product category with limited potential for differentiation, could substantially devalue the overall market by driving price down. A second consideration is the impact of a successful launch - success of a low-cost brand strategy may drive even more “me-too” offers to the market.

Value Brand Scorecard

When large organizations drive toward transformative decisions, the resulting decision pathway is often complex and lengthy. When it comes to a high a high investment launch decision, these challenges are magnified.

The decision process is further complicated by the variety of scenarios that must be considered and the spectrum of decisions to be made, including timing of launch, marketing strategy, and portfolio positioning, just to name a few. As a result, coming to a consensus on a “go or no-go” decision may be virtually impossible without a semi-quantitative approach to scoring the attractiveness of a value brand scenario.

Simon-Kucher addresses these challenges by leveraging the Value Brand Scorecard process, in which different scenarios are compared in a consistent manner via a series of exercises. The sum of each criteria is consolidated to provide a systematically achieved score that outlines the attractiveness of a given scenario across each of the five steps of the "go-no-go" staircase. Scores are generated by a mix of qualitative and quantitative inputs, ranging from financial impact to stakeholder perception of attractiveness. The weight of each consideration and stakeholder's response is tailored to the company's unique business situation, as firms will have varying priorities and trade-offs depending on their goals. For a recent client, Simon-Kucher prioritized the impact on market share development while effect on portfolio complexity was weighted as unimportant; however, the exact opposite may be more appropriate for a different company.

Finally, the aggregate score is used to inform a "go-no-go" decision under each scenario to provide analytical decision support for a range of options.

Targeted refinement

After a "go-no-go" launch decision, it is important to track performance and refine strategy as necessary. KPIs can be used to determine if the strategy should to stay the course or pivot in a different direction.

Key Performance Indicators

Internally, KPIs should be systematically and regularly monitored to understand both the success of the value brand and its impact on the broader portfolio. This should include both financial metrics (e.g., cannibalization, share growth of distinct market segment) as well as corporate equity metrics (e.g., quality perception, net promotor score).

Aside from quantitative measures of success, qualitative feedback from customers offer further insights on areas of improvement based on customers' desires and needs. It is important to gauge how existing and new customers are reacting to a new brand and whether there is a cross-over effect from the wrong target segment.

Externally, the impact of the value brand on the larger market and industry should also be considered. If the product has had a negative impact on the market (e.g., incites a price war), it is important to understand why and determine the path forward that will mitigate losses.

Targeted refinement in practice

KPIs were integral to refining the value brand strategy of a leading luxury consumer goods manufacturer. This company reacted to low competitor pricing by launching two new brands priced below their core premium offer, creating a "basic/better/best" portfolio structure. They continuously monitored performance of the value brand after launch in China and the US, and noticed two significantly different outcomes.

In China, the company successfully leveraged the value brands to penetrate an emerging market, while fencing their premium brands by selling them only in different stores. By monitoring cannibalization through tracking sales volumes and portfolio ASPs, the company observed significant growth in both the value and premium brands.

However, in the US, they decided to sell all brands in the same store, hoping that the prestige and equity of the premium brand would boost the value brand. Resulting price and value differentials led to significant cannibalization of the premium brand, as evidenced by declining premium brand sales volume and falling portfolio ASPs. Based on these findings, the company ultimately pivoted from their US strategy and fenced products by placing them in different stores to mitigate cannibalization.

The two strategies resulted in two substantially different outcomes – made observable by clearly defined metrics that were quantifiable and comparable. As a result, the manufacturer was able to reevaluate and revamp their US strategy to be more aligned with their intended goal for the value brand.

Adapting for the future

The MedTech industry is evolving, and the tactics that previously created paradigm-shifting innovations may no longer be the keys to success. Many customers believe that innovation in certain sub-segments has plateaued, and are instead looking for products that offer optimal value at a lower price. Launching a value brand might be the best option for you, but whether you step down or fall will depend on a rigorous decision-making process. Learning from previous experience both within and outside of the MedTech industry will help guide your decision-making. ◂

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CMED: The “Curupira” of Brazil’s pharma market

Understanding CMED price setting for innovative drugs through a retrospective study.

By Rafael Alencar, Mariana Torgal, Catarina Costa Pinheiro

Gain insight into CMED’s elusive decision-making process through a retrospective study evaluating clinical and economic criteria and list prices at launch for a selection of innovative drugs in Brazil

If you think of Câmara de Regulação do Mercado de Medicamentos (CMED), the Regulatory Chamber of the Medicine Market, as a gatekeeper for pharmaceuticals in Brazil, a resemblance to Curupira emerges.

Curupira, according to the mythology of the tribe Tupi-Guarani, is the protector of the Amazon forest, a red-haired dwarf with feet facing backward, to lose those who try to follow his trail.

Like Curupira, the CMED decisions barely leave any trail behind, despite being designed to establish rules for drug pricing in the pharmaceutical market.

The Chamber defines ceiling prices, benchmarks for wholesale and retail commercialization of drugs, and the minimum mandatory discount for purchases in the public healthcare system. Drug list prices are published, but the underlying assessment of each drug is only communicated to the manufacturer, leaving the rationale behind most decisions a well-kept secret.

Understanding CMED nuances

CMED defines pricing rules according to drug categories. Innovative drugs with a patent may achieve Category I or II. Category I is granted when a drug is able to demonstrate one of the following 3 factors: (1) superior efficacy, (2) safety improvement or (3) cost reduction over treatment comparators. If none of these criteria are met, then patented drugs are classified as Category II.

Achieving Category I is nevertheless very difficult: the only report[1] disclosed by CMED shows that less than 7% of the 209 new patented drugs, assessed from 2004 to 2011, achieved Category I.

According to CMED rules, Category I drugs are priced based on the lowest international price in a basket of 9 countries[2] plus the country of origin. For Category II drugs, international price referencing may also apply, but

[1] Efeitos da Resolução CMED nº 02/04 no processo de análise de preços de novos medicamentos.
[2] US, Canada, France, Italy, Portugal, Spain, Greece, Australia, New Zealand + origin country. Sources for international prices used by CMED are discounted by taxes and retail margins in each country (Comunicado nº 9 de 24 de outubro de 2014), and were translated into Brazilian currency for comparison with the local prices of drugs for same indication.

Table 1: Selected innovative drugs by CMED Category

	CMED category	
	I	**II**
Chronic retail	• **Brilinta** (ticagrelor) - Astra Zeneca Thromboembolism • **Champix** (Varenicline) - Pfizer Smoking cessation	• **Pradaxa** (dabigatran) - Boehringer-Ingelheim Venous thrombosis prophylaxis • **Procoralan** (ivabradina) - Servier Angina pectoris • **Valdoxan** (agomelatine) – Servier Major depressive disorder • **Forxiga*** (dapagliflozin) - BMS/AstraZeneca Type II Diabetes • **Prolia*** (denosumab) – GSK/Amgen Osteoporosis
Oncology	• **Sutent** (sunitinib) - Pfizer Gastrointestinal stromal tumor (2nd line) Advanced RCC • **Tarceva** (erlotinib) – Roche Non-small cell lung cancer EGFR+ (2nd line)	• **Velcade** (bortezomib) - Janssen-Cilag Multiple myeloma (3rd line)** • **Tasigna** (nilotinib) - Novartis Chronic myelogenous leukemia Ph+ (2nd line) • **Torisel** (temsirolimus) - Pfizer Advanced RCC

Public information on CMED category for Prolia and Forxiga is not available, but the hypothesis is Category II; **Launched 3rd line in Brazil, whereas in the US it launched in 2nd line; VTEp = Venous Thrombosis Prophylaxis; Advanced RCC = Advanced Renal Cell Cancer; PNET = Primitive neuroectodermal tumour; NSCLC = Non-Small Cell Lung Cancer; CML ph+ = Chronic Myelogenous Leukemia ph+;

*Revealing price setting for innovative drugs in Brazil" article - Graphs and figures

only if prices are lower than local treatment comparators. The average price reduction between the price requested and final approval was 18% for Category I drugs and 37% for Category II.

However, one thing is what is written on paper, another thing is what actually happens. We invite you to embark on an adventure exploring the actual decision making process based on clinical studies and historical prices at launch for 12 selected innovative drugs below.

In order to offer a view on different clinical and economic aspects[3], Simon-Kucher selected 4 Category I and 8 Category II drugs among chronic retail and oncology indications. Pre-defined criteria[4] on efficacy, safety and treatment cost provided a comparable framework to assess the performance of each drug among indications.

Then, a retrospective assessment on clinical studies, historical prices from reference countries, and local treatment comparators were used to identify the most common factors driving CMED pricing outcomes.

The green field for Category I: gain in efficacy, safety, or cost reduction?

The most common factor driving CMED Category I designation is a clinical study showing superior efficacy vs. standard of care. However, if there is no efficacious standard of care available for an indication, achieving Category I is still possible, though difficult, for placebo-controlled studies.

In any case, all drugs achieving Category I demonstrated superior efficacy based on "hard" endpoints in their respective indications, such as survival data for oncology or mortality for cardiovascular diseases. There was no clear threshold in terms of performance to achieve Category I, as it varied according to the level of unmet need per indication, comparator arm, and selected endpoints in the trials.

However, a few questions still remain. Arguably, no drug analyzed by Simon-Kucher showed significant improvement on safety. CMED most likely only sees this criterion as relevant for drugs showing a clear benefit over established treatments with frequent or severe adverse events.

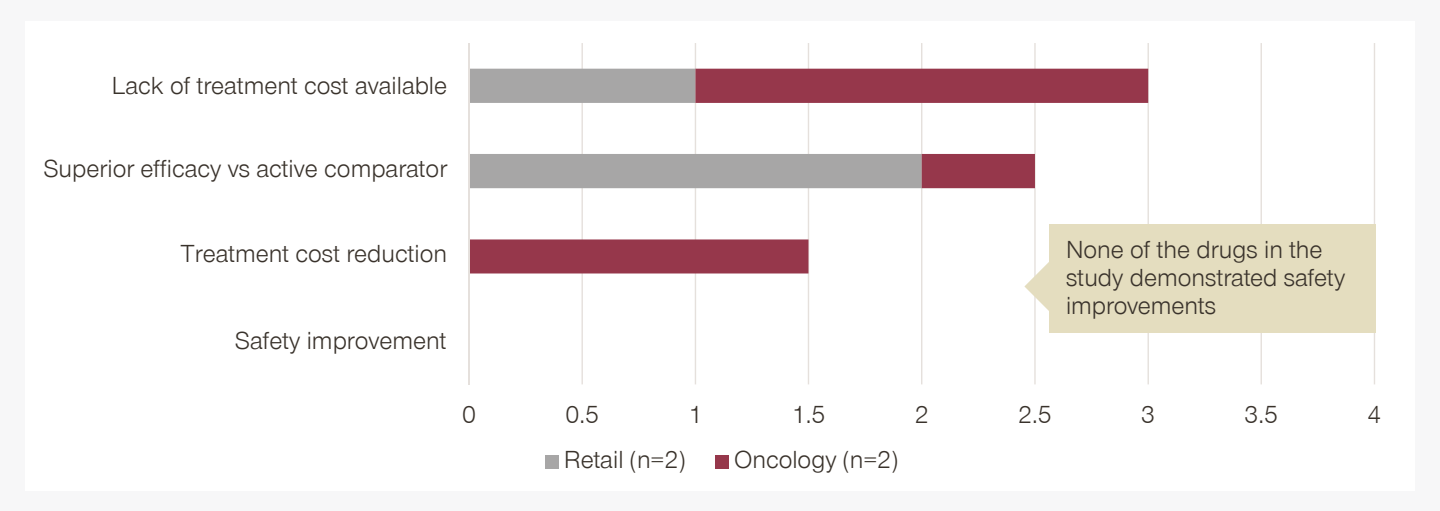

Figure 1: Clinical and economic criteria driving Category I

[3] Level of unmet need, availability of generics at launch, placebo-controlled trials, therapeutic improvement, treatment price per day.
[4] Level of unmet need, availability of generics at launch, placebo-controlled trials, therapeutic improvement, treatment price per day

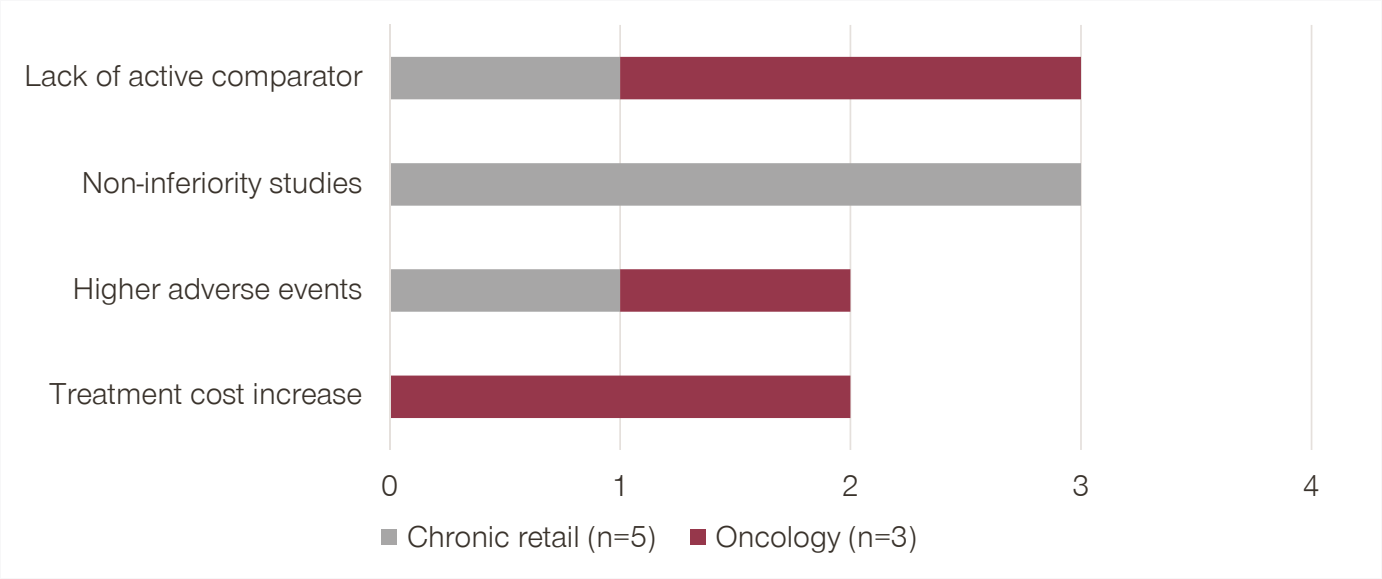

Figure 2: Clinical and economic criteria driving Category II

Local and international prices

CMED enforces the lowest international price reference for both Category I and Category II drugs. Category II drugs are also constrained by the prices for local treatments. However, in a few cases, CMED provided flexibility to accept the highest price among different comparators, e.g., the first-in-class direct thrombin inhibitor, awarded Category II, launched at a 10% higher price in Brazil than in Spain.

However, the benchmarking of local price comparators for Category II is still the most common, and has resulted in large discounts to chronic retail products in the past. The only exception was an oncology agent for multiple myeloma that obtained the lowest international reference price (from the US) because the only local comparator for its indication was a generic.

Along the same lines, there is no evidence that generics have been used as local price comparators for Category II drugs. CMED has not set the price for any innovative drug studied at the level of generic comparators. The chamber seems to consider R&D costs for new patented drugs and thus, compares these with other branded drugs.

> "Like Curupira, the CMED decisions barely leave any trail behind, despite being designed to establish rules for drug pricing in the pharmaceutical market"

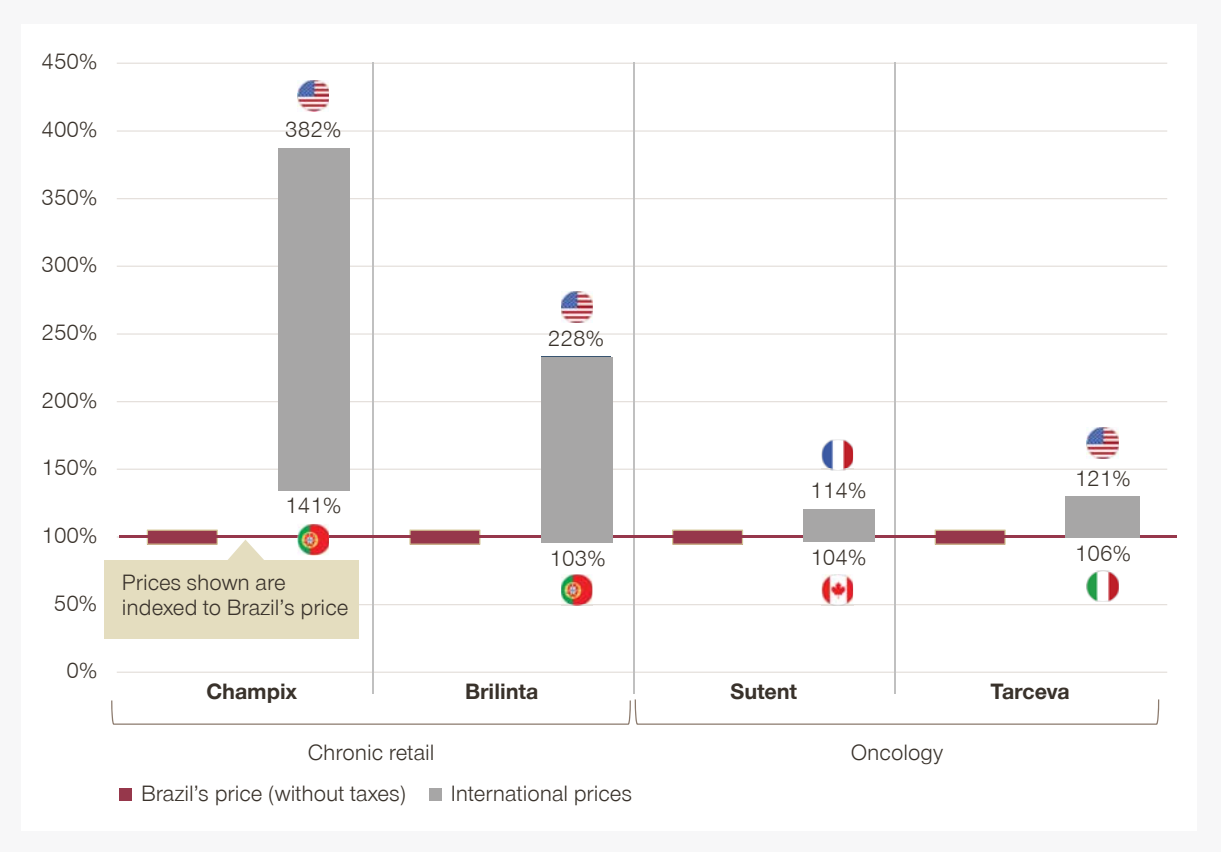

Figure 3a: Price index of innovative drugs in Brazil at launch vs. international prices (Category I)

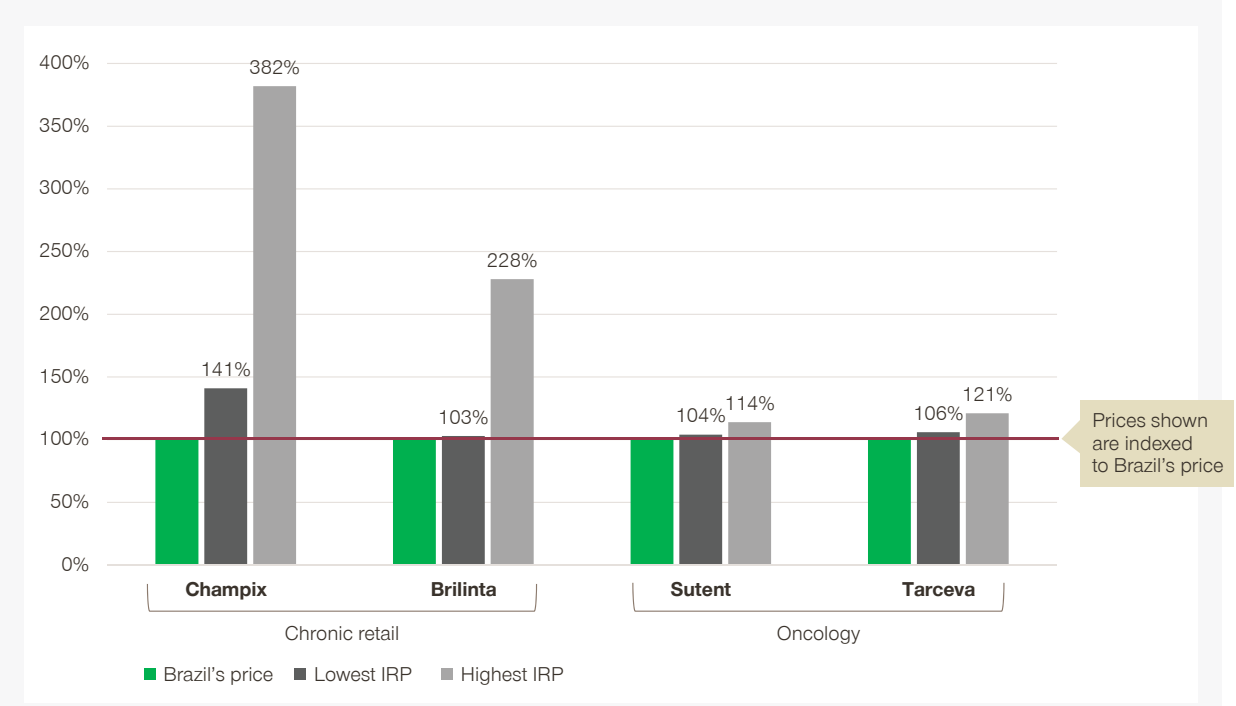

Figure 3b: Price index of innovative drugs in Brazil at launch vs. international prices and local branded comparators (Category II)

A successful price setting strategy

Just like the tribe Tupi-Guarani learned how to respect Curupira in the forest, manufacturers can benefit from some practical advice for price negotiations with CMED especially because price will have a major impact on the long-term revenues of any new drug. Therefore, we recommend to carefully examine the three items of advice below in order to increase the chances of a successful launch in Brazil.

1. **Optimize Brazil's position in the international launch sequence.** CMED accepts the price for an innovative drug once it is available in at least 3 reference countries, with no reassessment after launch. Additionally, Brazil prices are not referenced by any developed country or major emerging market. Consequently, launching early in Brazil after countries with high price potential can optimize the price negotiations with CMED and does not pose risks to any large market.
2. **Target Category I only if required evidence is available.** CMED mostly grants Category I for drugs showing superior efficacy over the standard of care. Drugs with placebo-controlled studies may achieve Category I only if no other efficacious treatment is available. Safety improvement and treatment cost reduction might only be compelling Category I criteria for drugs bringing a large benefit for the indication. Otherwise, forecasting for Category II achievement is the most reasonable strategy, despite potential upside scenario of successful application for Category I.
3. **Justify the highest price benchmark versus an acceptable comparator.** Regardless of Category I or II, innovative drugs may achieve price parity to the highest price benchmark between the lowest international reference and selected local comparator, if it demonstrates strong clinical advantage or if only old treatment alternatives are available. Manufacturers must communicate and demonstrate the unique value proposition of the drug with robust evidence to convince CMED not to enforce the lowest price benchmark.

CMED's price decisions, despite being secretive, abide by the rules. The gatekeeper for pharmaceuticals in Brazil has allowed for few exceptions. On the one hand, there is little room for high premiums, but on the other, negotiation outcomes can be anticipated. Given how relevant the list price is for the commercialization strategy of innovative drugs, manufacturers should keep this in mind and conduct a pre-launch study on the therapeutic value and international prices of their products to explore the full price potential in Brazil and around the world. ◂

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German AMNOG price negotiation black box: Which factors contribute the most to achieving a price premium over the comparator?

By Kristina Storck

There is a lot at stake when it comes to achieving the deserved price for innovative pharmaceuticals in Germany in the post-AMNOG market. Understanding the level of impact of different factors on the achievable price is crucial when developing a launch strategy in Germany

Since the introduction of the AMNOG (Pharmaceuticals Market Reorganization Act) in Germany in 2011, the pharmaceutical market access environment has been altered significantly. Germany changed from a free-pricing market to a price-controlled market overnight. While still being able to price a new drug freely at launch, all new chemical entities and indications launched after 2011 have to undergo an early benefit assessment performed by the Federal Joint Committee (G-BA). This assessment takes 6 months, and it is followed by price negotiations with the National Association of Statutory Health Insurance Funds (GKV-SV), which takes an additional 6 months. If parties don't reach an agreement on price during negotiations, an arbitration board will determine the drug's price, further prolonging the process by 3 months.

While the G-BA's methodology and results of the benefit assessment are very transparent, there is little information available on the content and agreements of subsequent price negotiations between the GKV-SV and manufacturers. The agreement according to section 130b paragraph (9) SGB V between the GKV-SV and industry associations outlines the criteria and reference prices to be considered during price negotiations. The first criterion considered is the G-BA rating on the level of additional benefit provided versus the appropriate comparator. GKV-SV and industry associations have explicitly agreed that the level of benefit should be a decisive factor during price negotiations, which is in line with the German legislators' intention. The purpose of introducing the AMNOG was to create a balance between innovation and affordability of drugs and that the added value for patients should now determine drug prices. The GKV-SV has even declared that the additional benefit for individual patient populations and subpopulations should be the central criterion considered during negotiations. Therefore, a new drug with a high additional benefit rating by the G-BA should, in theory, give the manufacturer a strong argument to justify a higher price premium over the appropriate comparator.

The second criterion considered is the EU reference price. Manufacturers have to submit the product's selling prices in 15 European countries to the GKV-SV before and during price negotiations. If manufacturers set the launch price in Germany significantly higher than in reference EU countries, the GKV-SV can demand a higher discount. On the other hand, if a manufacturer can show that the current price level is in line with other EU countries, it might become more difficult for the GKV-SV to justify a further reduction in price.

The last criterion considered during negotiations is the cost of the appropriate comparator, which is defined by the G-BA based on the standard of care. The G-BA outlines the annual therapy costs of the comparator in the benefit appraisal, making it convenient to reference during negotiations. The comparator selected is used by the GKV-SV as an important price benchmark, because it represents the costs currently incurred by sick funds for the specific indication.

Depending on the therapeutic area, the costs of the appropriate comparator and the new drug may differ significantly. Manufacturers can face very low price benchmarks if the current standard of care is available as a generic or - as for later line oncologic products - the comparator is low-cost best supportive care (BSC). Furthermore, a drug's level of additional benefit can be assessed for different patient subgroups, resulting in different appropriate comparators for each subpopulation. Most newly launched pharmaceuticals, however, enter a very competitive market with other innovative, patent-protected products that have already set a high price benchmark for the indication. Understandably, in the case that a generic is the only appropriate comparator for an innovative drug, the GKV-SV also considers other innovative therapies as price benchmarks during negotiations and the relative premium achieved can be significantly higher than when the product is benchmarked to another high-priced innovative therapy.

> "Given the implications of the negotiation outcome, it is important for manufacturers to understand the impact of the individual factors and better predict the potential of their new products."

Finally, the G-BA publishes an estimation of the new product's target population size in the appraisal and thereby indicating the potential budget impact for payers. This estimation, however, assumes 100% market share, making it an inaccurate assumption for estimating sales. Intuitively, manufacturers launching a product indicated for a broad disease area such as diabetes or hypertension face more pressure from the GKV-SV during price negotiations than manufacturers launching products in less common or even orphan disease areas.

There is a lot at stake when it comes to achieving the deserved price for innovative pharmaceuticals in Germany in the post-AMNOG world. From an industry perspective, the negotiations with the GKV-SV and the resulting reimbursement price are decisive for a product's future revenue and success. Moreover, successful negotiations in Germany ultimately can have a positive impact on other EU markets considering international price referencing. This dynamic must be a key consideration when deciding to commercialize a product in Germany or not. Therefore, it is important for pharmaceutical companies to understand which aspects have an impact on the level of discount negotiated and the resulting premium over the appropriate comparator in order to improve their negotiation strategy and, ultimately, its outcome.

Given the implications of the negotiation outcome, it is important for manufacturers to understand the impact of the individual factors and better predict the potential of their new products. To support this goal, a team at Simon-Kucher & Partners set out to build a multivariate model to quantify the relative impact of each criterion on the achievable price for a new pharmaceutical in the post-AMNOG environment. At the time of the analysis, 68 pharmaceutical products had gone through the AMNOG process and were included in the model.

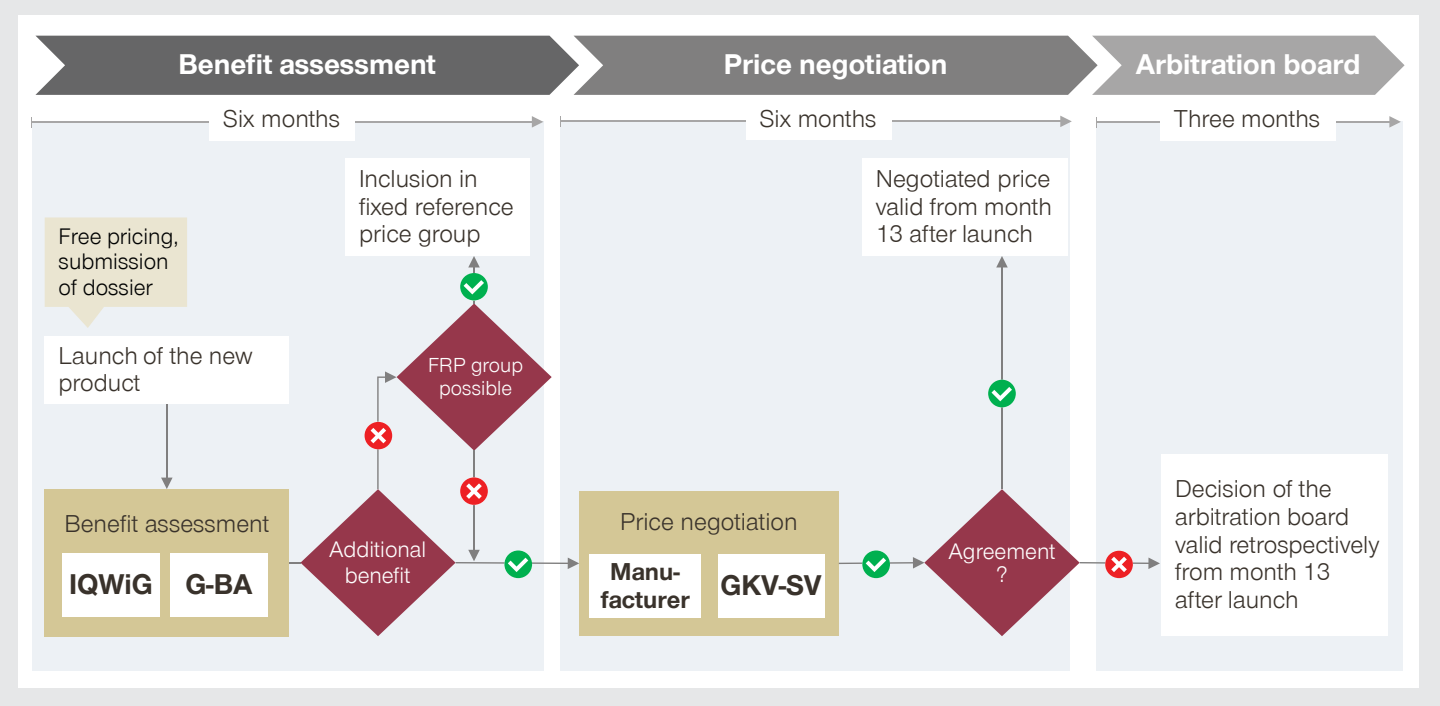
Apart from the size of the target population, all tested variables showed a statistically significant influence on the negotiated price premium. The higher the weighted benefit level achieved, the higher the achievable premium over the appropriate comparator. However, due to a large confidence interval, the absolute increase was difficult to quantify. The EU reference price had a similar impact on the achievable premium, with higher European prices compared to Germany, leading to higher achievable premiums in negotiations. Finally, the annual cost of the appropriate comparator also had a significant influence. When comparing achieved premiums, the absolute cost of the comparator was used as a control variable to account for the different situations (i.e., when a high-priced innovative treatment was compared to a generic comparator). Comparing the standardized regression coefficients showed that the EU reference price had the strongest impact on the premium achieved, while the level of additional benefit had the weakest impact. Overall, our model accounted for 60% of the variance of the negotiated price premium.

When interpreting the results, it is important to keep in mind the small sample size. The results identify initial trends and need to be further pressure-tested on their applicability for future AMNOG price negotiations. This assessment is only a snapshot of the status quo and results will need to be tracked for every new product that finishes the AMNOG process. Furthermore, other price benchmarks are often used besides the official comparator, which can play an important role when negotiating the final price.

On important conclusion from the analysis is that, contrary to the common perception of the benefit evaluation, the rating given by the G-BA is not necessarily the most impactful factor on the negotiation outcome. Achieving additional benefit only helps get your foot in the door to negotiate a premium over the comparator, because without achieving it in at least one subgroup, the achievable price is limited to the annual costs of the comparator. On the other hand, reference price in other EU countries is a very important factor for price negotiations. This implies that international price referencing, which is already frequently used by payers in other EU countries, now also plays an important role in the German price-setting process. This result emphasizes the importance of conducting comprehensive research on price potential in each major European market and to pursue an integrated and sound European pricing strategy, considering all mutual referencing procedures.

The possibility to achieve a high price despite a very low-priced comparator suggests that the GKV-SV does not benchmark a new product solely to the price of the defined appropriate comparator, but also accepts other comparator products in the respective indication. Therefore, it can be helpful for a manufacturer to identify all treatment options and propose them as alternative price anchors during negotiations. No significant influence could be found for size of the target patient population, which confirms that the GKV-SV does not apply a budget-driven approach. Sales forecasts, which are officially used by the GKV-SV as part of the negotiations, are used as a tool to terminate the negotiated agreement in case of significant higher sales than forecasted and therefore should not be underestimated.

While the GKV-SV has professional negotiation teams, many manufacturers are entering negotiations for the first time. A well-planned negotiation strategy and comprehensive preparation, including development of guidelines and objection handlers, is key to achieve the deserved



price during negotiations. Primarily, this means assessing the official price benchmarks. Most reference prices – such as comparator therapy costs and EU prices – leave some room for optimization based on assumptions regarding dosing schedules, treatment duration, country specific margins, and/or estimated discounts. Only 60% of the variance in the achieved premium for new products in our model could be accounted for by the official price references. This suggests that other, non-defined factors such as the negotiation team, individual negotiation skills, and negotiation training can greatly influence the achievable price in Germany.

Methodology assumptions:

Drugs that underwent an indication expansion were analyzed as single-indication products in order to avoid a disproportionately higher influence from any single case. Products rated as "no additional benefit" by the G-BA were excluded, as their price potential, by law, is limited to the costs of the appropriate comparator. Moreover, orphan drugs were also not considered due to the lack of an appropriate comparator.

The benefit rating was calculated as a weighted average based on the estimated target population in each subgroup to provide a more accurate representation of a product's additional value. Given that the GKV-SV uses sales to calculate a weighted EU reference price, only prices in the four biggest reference countries (France, Italy, Spain, and the UK) were used in the calculations to reduce complexity. These countries are economically comparable to Germany and have the strongest impact on negotiations. Only publically available discounts in EU markets were included in the analysis. The annual comparator cost and population size were obtained from the official G-BA appraisal.

Ex-factory price was the metric used to calculate the achieved price premium of each new pharmaceutical over the appropriate comparator, since the manufacturer and GKV-SV negotiate a rebate off of this price. A weighted average of comparator therapy costs was used since appropriate comparators may differ by subgroup. ◂

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> "... contrary to the common perception of the benefit evaluation, the rating given by the G-BA is not necessarily the most impactful factor on the negotiation outcome."

Pricing combination therapies: Does 1+1 = 2? Or 1? Or 1.5?

By Julia Ehrhardt, Mike Zhu, and Alex Kane

Experience an exclusive sneak-peek into the minds of Simon-Kucher's trusted payer network as we ask them about this issue's hot topic: pricing of combination therapies.

Innovative drugs and therapies offer an immense value to patients around the world, but that innovation often comes at a cost. To manage these costs, payers have developed various ways to control the price and access of new therapies. However, as more expensive combination therapies become increasingly common, payers face a greater challenge providing access to innovative therapies while still managing their budgets. What are their plans for these combinations? Simon-Kucher asked payers from around the world, and here is a selection of some of their comments:

> "High cost combos are a huge concern for us... but we don't have any concrete solutions yet
>
> *– US MCO Medical Director*

> This is definitely concerning, but we don't have any specific rules in place
>
> *– French CEPS expert*

> These combination therapies will increase pharmaceutical expenditure significantly, and we will do what we can to lower the prices as much as possible
>
> *– Spanish regional payer*"

Payers, it seems, are at least somewhat worried about pricing of combination products (Fig.1 of 1-7 rating scale: average 5.8). The central theme at this point, however, is that payers are trying to manage the cost of these products as best as they can, given current tools at their disposal. While letters and opinion papers such as those in France and Germany have proposed some novel solutions to managing the prices of these products, neither suggestion has been implemented or even seems very implementable. In France, a letter from the Ministry of Health proposed a "1 + 1 = 1" rule, whereby the cost of a combination product should not exceed the cost of the monotherapy equivalent. French payers, though, stressed that "this letter is not an official rule" and questioned how such a policy could be operationalized. Similarly in Germany, a position paper argued that products used in combination with each other without a formal indication should be subject to a "1 + 1 = 1.5" rule. A German hospital payer was even more negative about this proposal than his French counterpart, stating that "there is no foundation in law, policy, or anywhere that suggests where the discount should be coming from and how it would be enforced." In other words, while payers are worried about high-cost combination products, any specific policies, regulations, or frameworks for evaluating these products are experimental, or anecdotal, at best.

Payers were asked to rate their level of concern regarding the high cost of combination therapies on a scale from 1-7, with 1 being not concerned at all and 7 being highly concerned. Of all payers interviewed, the average rating was 5.8, with no payer stating that their concern was less than a 4.

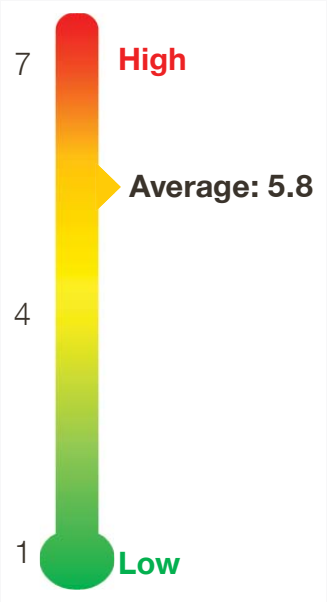

Figure 1: Payer concern with cost of combination therapies

A perfect example of an anecdotal policy shift is the launch of Tafinlar and Mekinist in Japan. According to the existing framework, MHLW should have set the price of each product against a separate comparator. However, since the products launched at the same time, MHLW referenced the combination against a monotherapy, setting each product's price at half that of Zelboraf. This is particularly interesting since Tafinlar has the same mechanism of action as Zelboraf and could have been expected to obtain a price similar to Zelboraf on its own. While MHLW did then grant a 45% 'premium for usefulness' to both products, the initial comparison was still against a single agent. Initially, this may seem like a new framework: setting the price of a combination therapy against a single therapy. However, experts in Japan explained that "this case was extremely coincidental and unlikely to be repeated." Specifically, MHLW would not have been able to assess the two products together had they not launched at the same time. Rather than being indicative of a major policy shift, the case of Tafinlar and Mekinist is simply a case of MHLW using the current pricing mechanisms for monotherapies and repurposing it for a combination therapy.

> "CEPS is likely going to try to negotiate the same way, whether the combo is from the same manufacturer or not"
>
> *– French CEPS expert*

The same is true, for instance, in the UK where the cost-effectiveness model remains key. Whether the therapy approach includes one, two, or five products, the question at the end of the day is whether NICE determines the therapy approach to be cost-effective – this alone will determine national access. In oncology, where single therapies struggle to gain access, this puts extra pressure on combination therapies. The only way that many such therapies, such as Opdivo and Yervoy, have achieved NICE approval and been deemed cost-effective is through a "Patient Access Scheme", or confidential discount.

The concept of looking at the cost of a combination brings up many potential questions, but one of the main unknowns is what happens when a combination consists of two products from different manufacturers: how will payers manage the cost of these two products? The simple answer, again, is that it looks like very little changes. Payers will still consider the entire cost of a combination, regardless of whether they are made by the same or different manufacturers. In many cases, the impetus to negotiate for access or for a particular price falls to the manufacturer of the second drug. The second manufacturer must make a compelling case to payers for why the cost of the combination therapy deserves to be significantly higher than the cost of the original agent alone. However, unless the combination is a truly paradigm-shifting therapy, it will be hard to make a case for a price too much higher than the monotherapy, and the second manufacturer may have to launch at a price much lower than they would like.

> "More and more high cost combos are coming... it will not be sustainable if we do not evolve and adapt to them"
>
> *– Germany sick fund manager*

So, what does this all mean? It is easy to read this and think that pricing conventions are going to stay the way they are. To some extent, that is partially true: payers agree that things are unlikely to change in the near future. However, that does not mean that a paradigm shift will never come. Even though payers currently have tools to curb the high cost of combination products in place, they by no means think that they are enough. It may not be as drastic as "1+1=1", but payers are actively looking for new means to manage combination pricing. This uncertainty, however, is a great opportunity for manufacturers to partner with payer organizations and come to a solution together. Payers are willing to listen to all suggestions right now and manufacturers should jump at this opportunity to have their voices heard. Alternatively, even if a manufac-

turer does not want to be a part of the process to find a solution, they should still monitor the combination pricing landscape very closely. Payers have had a long time to consider how to manage the cost of combination therapies, so while there is nothing concrete yet, that does not mean that a groundbreaking policy may not be just around the corner. In either case, it is in the manufacturers' best interest to keep a close eye on any impending policies for combination therapies and try to plan for them as soon as possible, because it may be unclear what new policies lie ahead, but it is crystal clear that how manufacturers respond to those policies will have an enormous impact on the success of their combination portfolio going forward. ◂

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About the Life Sciences Practice of Simon-Kucher & Partners

Simon-Kucher & Partners is a leading strategy and marketing consulting company with proven expertise in pricing, market access strategies, product development, and licensing due diligence. Founded in 1985, Simon-Kucher & Partners has over 205 employees dedicated solely to Life Sciences in 18 offices across North America, Europe, and Asia, including offices in all major healthcare markets. The firm's Life Sciences practice supports clients in the pharmaceutical, biotechnology, medical technology, and animal health industries. Simon-Kucher & Partners has developed strategies for 24 of the top 25 pharmaceutical companies, the top five biotechnology companies, and 30 of the top 35 medical technology companies. We combine analytical rigor with strategic insights and employ highly sophisticated methodologies that integrate quantitative and qualitative findings. Our recommendations are based on empirical data, thorough research, and extensive experience.

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Germany, **Munich**
Italy, **Milan**
Luxembourg, **Luxembourg**
Poland, **Warsaw**
Spain, **Barcelona**
Spain, **Madrid**
Sweden, **Stockholm**
Switzerland, **Geneva**
Switzerland, **Zurich**
The Netherlands, **Amsterdam**
Turkey, **Istanbul**
United Kingdom, **London**

Asia/Pacific/Middle East

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China, **Beijing**
China, **Hong Kong**
Japan, **Tokyo**
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