

Healthcare Insights

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Opportunities and risks of selling Consumer Healthcare devices online

Will future consumers be shopping online for their medical devices in the same way they already buy clothes or music?

The International Price Referencing (IPR) conundrum

What is IPR? In most markets, national P&MA decision bodies consider the product's price in other markets when determining the price of a new pharmaceutical product.

Virtual AI Nurses and the Future of Chronic Disease Management

David Lee, partner at Simon-Kucher & Partners, sits down for a fireside chat with serial entrepreneur Julia Hu to talk about virtual AI nurses and the future of chronic disease management.

and more...

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SIMON-KUCHER & PARTNERS

EXECUTIVE EDITOR

Nathan Swilling

ASSOCIATE EDITORS

Christopher Barr
Madhurima Das
Mia Marrazza
Madelane Teran
Fangting Yu

GRAPHIC DESIGN

Genevieve Solomon

ARTICLE CONTRIBUTORS

Grace Aro
Stephen Dunbar
Alison Greer
Alexandre Habib
Gabriela Honda
David Lee
Carlos Olabbari
Rainer Oppen-Rhein
Carolina Quesada-Rodriguez
Christian Rebholz
Christian Schuler
Madelane Teran
Mariana Torgal
Jeremy Winkler

P&R BRIEFS CONTRIBUTORS

Ricardo Bergau
Rebecca DeRome
Judith Flecke
Rebecca Ford
Adrien Gaussen
Gabriela Honda
Ruei-Shyuan Lee
Hugo Li
Edward Locke
Barbara Mussman
Carolina Quesada-Rodriguez
Katerina Stavri
Michelle Sukup-Jackson
Madelane Teran
Mariana Torgal
Fangting Yu

DISTRIBUTION

Perna Kakkar
Oksana Prysiashniuk
Bettina Liesenfeld
Natalie Prentiss
Goekce Muege Cil

Bonn Office

Willy-Brandt-Allee 13
53113 Bonn, Germany
+49 22 8984 30

Boston Office

One Canal Park
Cambridge, MA 02141
+1 617 231 4500

Please send inquiries to:

LSCommunications@simon-kucher.com

www.simon-kucher.com

Simon-Kucher & Partners' Life Sciences European Strategy Forum

Life Sciences European Strategy Forum 2019

Strategic Market Access – Navigating Commercial Implications

Radisson Blu Hotel Zurich Airport, October 17 and 18, 2019

Market access has a key role and fundamental relevance in commercial product development and decision making. Simon-Kucher & Partners' Life Sciences European Strategy Forum will explore this role in dynamic panel discussions, breakout sessions and with a strategy forum debutant: The P&MA "World Café". We will address the changing role of market access in the commercialization of drugs, future trends in key markets and innovative business models.

In addition to the Strategy Forum, on day 2 Simon-Kucher offers young professionals an opportunity to build and refresh their foundational understanding of P&MA. Join us on October 18 for Simon-Kucher & Partners' P&MA training for young professionals.

Alternatively, join us on day 2 at the Simon-Kucher & Partners full day session "Digital Therapeutics – Driving Factors for Market Access and Commercial Success", a platform for discussing essential industry insights and sharing examples of how to leverage growth opportunities for digital solutions in the healthcare industry.

We look forward to seeing you there.

[Learn more & Register](#)**Speakers****Joerg Kruetten**

Global Head of Healthcare
and Life Sciences
Simon-Kucher & Partners

**Dirk Kars**

Senior Partner
Simon-Kucher & Partners

**Christian Schuler**

Senior Partner
Simon-Kucher & Partners

**Dr. Matthias Liefner**

Partner
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**Jan Bordon**

Senior Director
Simon-Kucher & Partners

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



Canada

Is an overhaul of the Canadian healthcare system possible?

Several changes to the Canadian drug pricing and reimbursement (P&R) landscape have dominated the news recently. As Canada looks to lower prescription drug prices, regulators have begun to set in motion a number of initiatives including the allocation of federal funding to cover rare disease drugs, a PMPRB (Patented Medicines Prices Review Board) policy update, and the creation of a national pharmacare.

Starting in 2022, the Finance Minister has pledged \$1b over 2 years (with up to \$0.5b per year after that) to fund rare disease medications. This is a welcomed line item in the budget, but may not be enough to cover innovative and often costly rare disease medications. Furthermore, the House of Commons Standing Committee on Health in its final report on this issue recommended that the federal, provincial, and territorial governments “develop a coordinated process for the market authorization and reimbursement of drugs for rare diseases.”

There is disagreement between provinces and the federal government about who is responsible for lowering drug prices in Canada. Currently, provincial public drug plans join together to negotiate prices with manufacturers jointly through the pCPA (pan-Canadian Pharmaceutical Alliance). The pCPA is able to negotiate drug prices by leveraging their buying power as the keepers of the public drug plans, but is not able to leverage the remaining population covered by private insurance or self-pay in price negotiations.

Recently, the provinces have started to push back on their role as arbiters of price. In a briefing the pCPA submitted to the House of Commons’ Standing Committee on Barriers to Access Treatment & Drugs for Canadians Affected by Rare Diseases this past December, provinces highlighted challenges and limitations for reducing drug prices and urged the federal government to implement pricing controls through the PMPRB. Currently, the PMPRB only sets a ceiling price based on International Price Referenc-

ing (IPR) and due to the methodology used, the ceiling prices are often much higher than the prices achieved in the market. A proposed modernization of the PMPRB rules was put forward in 2018 that includes widening the basket of countries for IPR, formalizing a cost per QALY evaluation, and requiring reporting to PMPRB the best price inclusive of province-specific discounts. The implementation timeline is unclear, though some updates may yet be expected in 2019.

In parallel, the federal government has put in motion a plan to implement a universal drug plan for all Canadians. In the 2018 Budget, the Canadian government announced the creation of the Advisory Council for the Implementation of National Pharmacare. Its main goal was to provide “...independent advice to the Minister of Health and the Minister of Finance on how to best implement national pharmacare in a manner that is affordable for Canadians and their families, employers and governments.” A national pharmacare is expected to strengthen the negotiating power of the government by allowing it to leverage the full population during price negotiations with manufacturers. Therefore there is hope that this can help lower drug costs to the healthcare system overall. This June, the Council published its final report.

Moving Towards a National Pharmacare

The Advisory Council for the Implementation of National Pharmacare final report recommended the Canadian government to implement a universal, single-payer, public system of prescription drug coverage to be fully implemented within eight years.

The Council highlighted 3 foundational recommendations for the implementation of a national pharmacare: 1) Create a national drug agency, 2) Develop a comprehensive, evidence-based national formulary, 3) Invest in drug data and information technology systems. The functions of the national drug agency would include conducting HTA assessments (currently performed by CADTH/INESSS), developing and managing a national formulary, and conducting negotiations with manufacturers on drug prices and terms of listing (currently performed by pCPA), among other tasks. Already, the 2019 Budget allocated

\$35 million over four years to establish a Canadian Drug Agency Transition Office.

The Council estimated the implementation of a national pharmacare would increase the current government spending on prescription drugs by \$15.3b per year by 2027, once fully implemented. This estimate includes projected reduced drug costs achieved by harnessing the negotiating power of the entire Canadian market, as well as anticipated cost savings through condensing and reducing governmental redundancies (e.g., combining clinical evaluation, cost effectiveness evaluation, and price negotiations into one agency), but the balance sheet remains to be seen. The Council recommended the federal government to cover this expenditure via its general revenue, but did not go as far as to recommend an approach for obtaining funds.

At the CADTH symposium this past April, payers, regulatory bodies, and industry stakeholders alike shared the sentiment of uncertainty, wondering if Canada will successfully implement a single-payer national pharmacare model or fall back to old ways of filling gaps in the current system. ◀

Source: <https://www.canada.ca/en/health-canada/corporate/about-health-canada/public-engagement/external-advisory-bodies/implementation-national-pharmacare/final-report.html>



Colombia

Colombia: The hidden champion for innovative drugs in Latin America, but for how long?

Despite Colombia being a small Latam country, it has represented a great opportunity for pharma companies, as the current government objective of providing universal healthcare allows them to secure reimbursement with somewhat limited effort. So far, achieving access for innovative drugs, though evaluated on a case-by-case basis, has been fairly quick and attainable. Recently, payers have expressed growing concern about the system's sustainability and have proposed setting budgets for these case-by-case access requests for innovative drugs.

The Colombian public healthcare system covers approximately 95% of the 48mn population. The system is fund-

ed with 7.2% of total GDP (approx. 22.6bn USD¹) and is formed by three different models for coverage:

1. Contributive (Régimen Contributivo) (~ 51% patients), which includes formal and independent workers and retirees
2. Subsidized (Régimen Subsidiado) (~44% of patients), which includes people with no payment capacity, and
3. Exceptional coverage (Regímenes de excepción) (~5% of patients) which is for workers from the military, police, and oil companies.

Drugs for essential care are included in a list called PBS (Basic Health Plan), for which there is mandatory coverage by payers in all three models. These drugs are purchased by health maintenance organizations (HMOs), which are reimbursed on a capitation basis (i.e., HMOs receive a budget based on the number of covered lives for funding PBS products). The PBS includes basic drugs for indications from hypertension to oncology.

However, high cost drugs and drugs for lower prevalence diseases are funded on a case-by-case basis through ADRES (Administrator of the Resources of the General System of Social Security in Health). The funding for these drugs outside the PBS is granted by the HMOs and ADRES for 85% of requests. The remaining 15% are most often not approved due to inappropriate prescribing (e.g., prescription not in line with label). Innovative drugs are typically eligible for case-by-case funding through this pathway right after regulatory approval.

Given the lengthy and challenging listing process, most innovative therapies remain excluded from the PBS as of today. Though reimbursement is expected to be approved even on a case-by-case basis, HMOs encourage manufacturers to reach out to them in order to reach an agreement on the “best suitable” patients for PBS inclusion in order to minimize risk of not being reimbursed by ADRES. After all, inclusion in the PBS remains the most attractive pathway, as it means mandatory coverage. Moreover, in the near future, fixed budget for non-PBS drugs could be implemented. This will not come about without its challenges and controversy: What budget is appropriate/sufficient? What will be the criteria to allocate the budget for reimbursement? Which drugs will be reimbursed vs. not?

¹ Based on GDP from 2017

In the meantime, pharmaceutical companies can continue to capitalize on the available access for their products while they can. ◀



Germany

GSAV (Law for More Safety in the Supply of Pharmaceuticals)

1. Orphan drugs: Change of process for benefit evaluation

Orphan drugs will undergo a full benefit assessment if the annual costs to sick funds exceed the combined threshold of 50 million euros for the retail and hospital-inpatient settings. Until now, the threshold has been based only on the retail setting.

2. Drugs with conditional approval, approval under exceptional circumstances, and orphan drugs: Request for collection of real world evidence

Pharmaceuticals that are urgently needed may be granted conditional approval or approval under exceptional circumstances, even if complete clinical data for a full assessment is not yet available. This applies to orphan drugs in particular. In the future, the G-BA may require manufacturers to collect real world data as evidence to supplement future reassessment. The G-BA will reassess the benefit annually based on newly available evidence followed by price renegotiations. If the data presented does not meet the G-BA's specifications, price reductions will be requested.

These requests will be particularly forceful if the reassessment results in a rating of either “non-quantifiable additional benefit” for an orphan drug or “no additional benefit” for a drug with conditional approval/approval under exceptional circumstances. To ensure the quality of treatment, the G-BA will be authorized to define requirements in regard to medical processes, logistics, and personnel qualifications.

3. Biologics: Replacement originator vs. biosimilar

Physician associations and sick funds will not only be authorized to define biosimilar targets (quotas) to promote their usage (as is currently the case), but also they will be instructed to do so. The G-BA has been asked to develop guidelines on which origina-

tors can be replaced by which biosimilars and under which circumstances. For the time being, the final decision on replacements will continue to be made by physicians. However, automatic substitution for listed biologicals at the pharmacist level is expected to come into effect in three years.

4. Hemophilia: Change from direct distribution to retail via pharmacies

Today, manufacturers sell plasma products and genetically engineered coagulation factors specifically for the therapy of hemophilia directly to physicians or hospitals. In the future, these therapies will be sold via retail pharmacies. Consequently, the Drug Price Regulation (Arzneimittelpreisverordnung) will apply. Reimbursement prices for currently available drugs will be set based on current net purchasing prices. Future products will be subject to conventional price negotiations. The regulation process will include a transition period of one year. ◀



Japan

A Long Way to Go For a New Pricing Method for High Cost Cell Therapies

The long-awaited stem-cell therapy Kymriah was listed in Japan in May 2019 at a price of ~JPY 33.5 million (~\$310k USD*) per patient.

Before launch of Kymriah, the product had already received significant attention from both industry and government as high price expectations raised questions regarding viability of the Japanese pricing system for cell therapies treatments.

With the existing system, a new drug is priced by either the “Cost calculation method” (product priced based on cost) or the “Comparator pricing method” (product receives same daily price as its pricing comparator). Unlike other markets, agreements like innovative contracting, outcome-based reimbursement, or HTA-result based co-pay differentiation are not possible.

Some opinions from academia, industry and government (e.g. the Ministry of Finance) are pushing for changes to these rules in advance of novel cell therapies. One exam-

ple is the director of the National Federation of Health Insurance Societies (kenporen), who repeatedly voiced that he considers pricing based on cost data inappropriate for cell therapies as Kymriah. Despite these opinions, the health ministry MHLW has made it clear that it would take substantial time to implement such fundamental changes, and that the current pricing framework can sufficiently handle the launch of cell therapies.

Facing these kind of public announcements, Novartis decided not to approach MHLW with suggestions for an outcome-based pricing approach. As a result Kymriah was priced following the “Cost calculation method,” applying a 45% price premium for novel clinical usefulness. As Novartis disclosed limited information on the breakdown of the manufacturing cost, the premium was cut by 80%, resulting in a de-facto price premium of 9%.

Even though the pricing method was unchanged, there was one detail for the pricing of Kymriah can be considered a small innovation: the product was priced based on “cost-per-patient” basis. So far, MHLW has been using the “daily price” as the metric to determine the price of new drugs, so this can be considered as one small step of MHLW towards adjusting the pricing rules.

Additional adjustments might happen if more and more cell therapies come to the Japanese market, but so far, MHLW has not shown any signals to make a fundamental change of the pricing rules anytime in the near future. ◀

*Currency exchange rate of USD = JPY 107.75 as of July 2, 2019.



Post-Brexit Pharma – Navigating Commercial Strategy in the Face of Uncertainty

Significant Brexit milestones, delays and deadlines lie both behind and ahead of the UK. In April 2019 the EU granted the UK a six-month extension to leave the union until October 31st, and the expectation of exit treaty ratification remains in question. For the pharmaceutical industry specifically, we here consider the current and forward looking impact of Brexit on the UK’s regulatory approval, pricing, and market access landscape.

Regulatory approval

Changes to the UK and EU’s relationship have already been seen regarding regulatory approval. Most obviously as of March 2019, the European Medicines Agency’s (EMA) operations relocated from London to Amsterdam, and EMA member states took over almost all new appraisal responsibilities from the Medicines and Healthcare Products Regulatory Agency (MHRA).

Without an agreement in place between the MHRA and EMA in the future, all new products may have to be independently assessed by the MHRA to gain approval in the UK. With separate regulatory pathways for the UK vs. Europe, and no reciprocation for UK market authorisations by any other EU state, pharmaceutical companies will have to evaluate the additional resources required to support a further market authorisation application that grants access solely to the UK. From a commercial perspective, pharmaceutical companies launching new products in the UK and EU must initiate strategic planning for multiple different regulatory approval scenarios.

Pricing and market access

In contrast to likely post-Brexit changes to regulatory approval processes, significant UK pricing and market access changes are unlikely to be directly triggered by Brexit, at least in the short term. The criteria used to determine whether a NICE technology appraisal will be conducted for a new product or indication, as well as the criteria driving UK price and market access, are showing no signs of change. The NHS’s dug-in position on the £20,000 to £30,000 per quality-adjusted life year (QALY) cost-effectiveness threshold specifically has certainly frustrated the pharmaceutical industry over the years, however it has notably never accommodated even for inflationary changes. Only in some unique circumstances has NICE demonstrated some flexibility, for example in products meeting end-of-life criteria, which can access higher ICER thresholds (~£50,000 per QALY) and for Highly Specialised Technologies which are allowed even higher ICER thresholds of >£100,000 per QALY.

Furthermore, continued free list pricing in the UK was supported by the Voluntary Scheme for Branded Medicines Pricing and Access which was published in January 2019. Although arguably of little value within the UK market given embedded confidential discounts, the ability to freely

set list prices has always been a strategic cornerstone for pharmaceutical companies due to the importance of the UK as an international reference market on price. With this in mind a particular risk faced is that outside of the EU, the UK may no longer fall into the collectively defined “EU-27” or “EU-15” baskets referenced by many European countries, reducing perhaps its strategic launch importance.

Forward outlook

In the long term, setting aside possible changes to regulatory and price and market access landscapes, the UK will undoubtedly remain a dominant contributor to pharmaceutical sales in Europe. As the only certainty currently is that there will be uncharted waters for pharmaceutical manufacturers to navigate immediately post-Brexit and beyond, they need to continue to ensure that the right go-to-market strategies are in place.

For further insights surrounding post-Brexit pharma, including the impact on clinical development, supply chains, tariffs and cross-border trade, please read the full article [here](#). ◀



USA

Ambitious drug pricing proposal withdrawn by the Trump Administration

One of the claimed “most effective ways” to reduce pharmaceutical list prices was withdrawn on July 10, 2019. The abandoned rule would have eliminated rebates in Medicare Part D and Medicaid plans, removing the “safe harbor” protection from anti-kickback statutes. Together with a few other proposals, such as enhancing Medicare Part D plans’ negotiating power and increasing the price awareness of physicians and patients, the idea of lowering / eliminating manufacturer rebates is one of the key pillars of “American Patients First”, a Blueprint to Lower Drug Prices put forward by the Trump Administration on May 11, 2018. An updated version of this proposal was released in January 2019, updating the discount safe harbor to explicitly exclude reductions in price offered by drug manufacturers to PBMs, Part D, and Medicaid managed care plans from the safe harbor’s definition of a “discount”, while establishing a new safe harbor to protect upfront discounts to patients at point of sale.

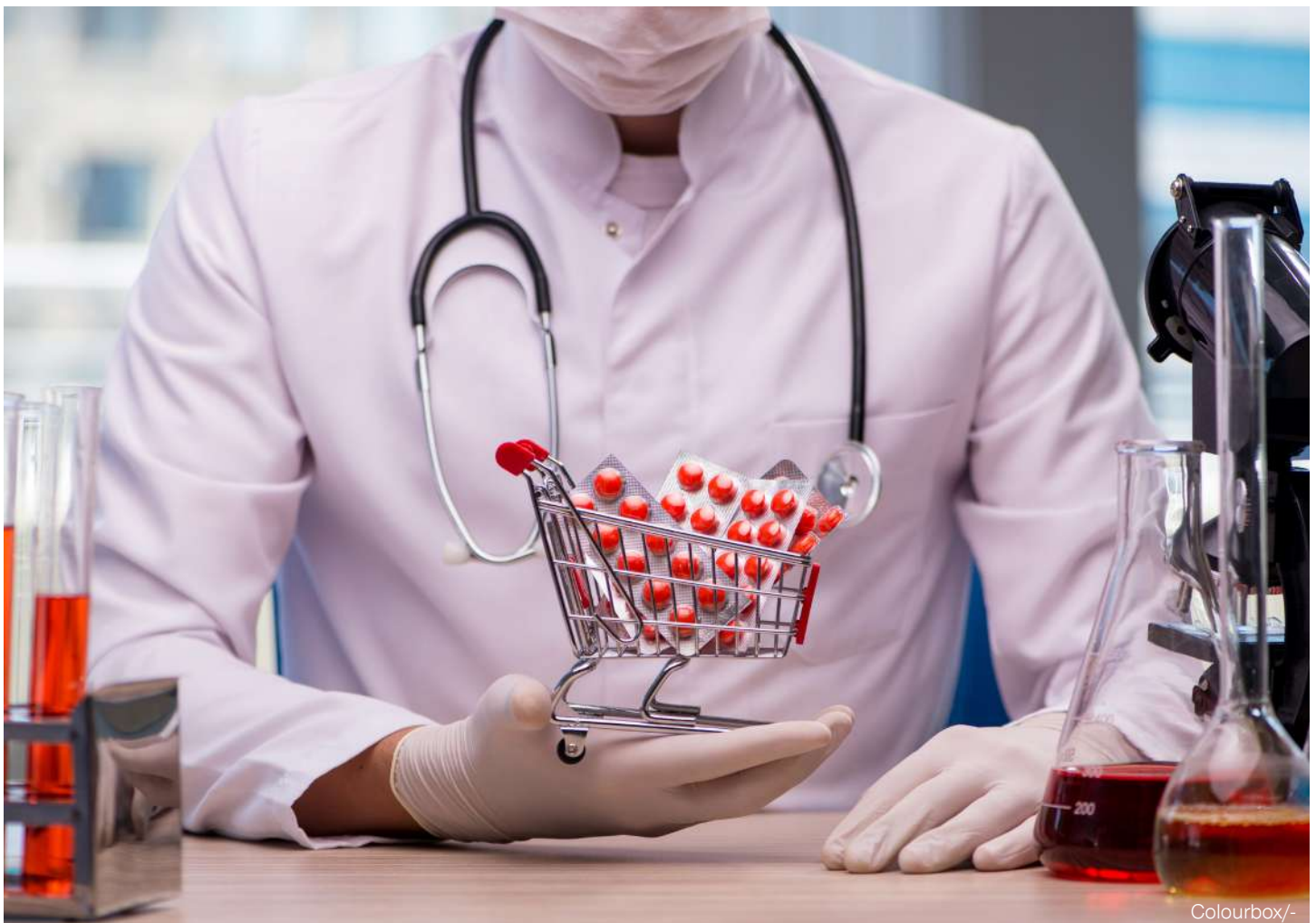
Since the time of this proposal, many pharmaceutical companies have started planning alternative scenarios to “future-proof” their market access strategy for their in-line and pipeline products. Meanwhile, the Pharmaceutical Care Management Association (PCMA) has openly opposed this proposal.

The decision to roll back this proposal was “based on careful analysis and thorough consideration”, stated by the White House. Policy experts and budget projections suggest that the rule could be costly to the federal government and may lead to higher premiums for Medicare beneficiaries. The Health and Human Services (HHS) is still working on alternative proposals to reduce pharmaceutical list prices. ◀

Opportunities and risks of selling Consumer Healthcare devices online

By Christian Rebholz, Carlos Olabbari, and Alexandre Habib

Will future consumers be shopping online for their medical devices in the same way they already buy clothes or music? In this three-part article, the authors explain how ecommerce is becoming inevitable for consumer healthcare and outline the opportunities and risks.



I. Opportunities and risks

In today's digital world, everything is available via the internet. From movies and music, to theater tickets, vehicles and groceries, even the most unexpected products and services can be found online. Now ecommerce has also become a viable sales channel for medical device companies as well. Consumers and patients are becoming ever more engaged with the online shopping experience, and previously resistant companies are starting to explore ecommerce solutions and digital platforms to enhance their sales process.

The online channel will be inevitable, with future business driven by ecommerce platforms and retailer sites such as Amazon, Ali Health, and online pharmacies. To succeed with online business and stay ahead in today's competitive markets, CHC companies must provide a shopping experience that matches up to consumer expectations.

The benefits of ecommerce are obvious for most types of online shopping. However, selling medical devices on Amazon and other sites will involve its own rewards and challenges. Depending on the maturity of the online channel, product portfolio, and company's market position, it's important to prepare for the opportunities and risks.

Ecommerce opportunities

- *Boosted sales volumes*
Ecommerce is like having a super-powered sales-force working for you around the clock
- *Access to consumers outside of the clinical segment*
It has never been easier to reach more consumers and penetrate new markets and locations
- *Less dependency on distribution partners*
You can replace the physical middlemen with your own, digital middleman
- *Detailed performance tracking and more effective marketing efforts*
Using a consumer's browsing and purchase history, you can analyze visitor behavior and continuously improve targeting

“To succeed with online business and stay ahead in today's competitive markets, CHC companies must provide a shopping experience that matches up to consumer expectations.”

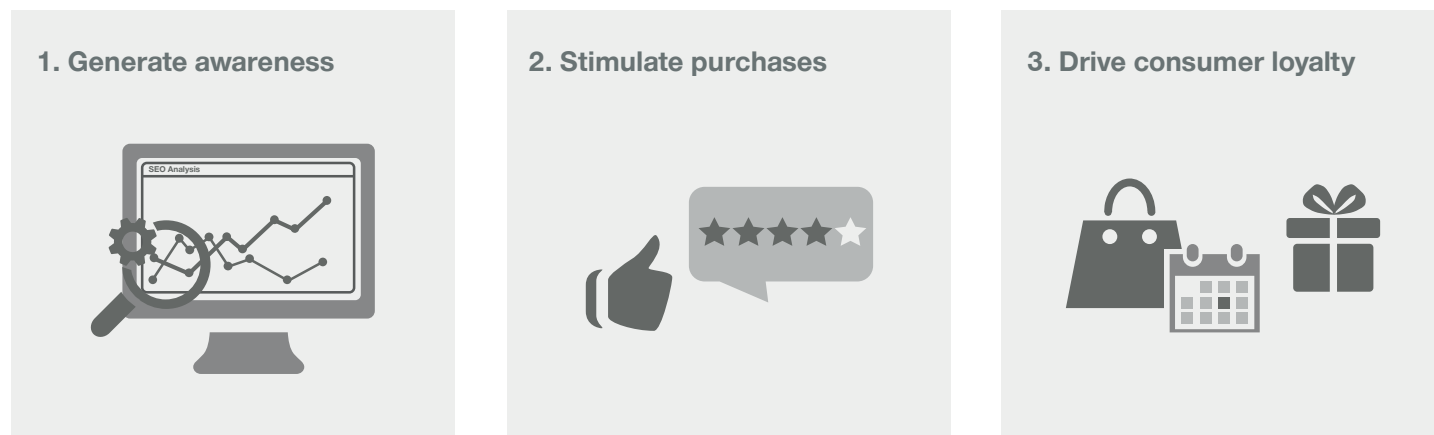
Ecommerce risks

- *Cannibalization of the offline channel and increasing channel partner consolidation*
As online sales grow, you risk losing brick-and-mortar retail sales, and you are dealing with highly concentrated ecommerce key accounts
- *Required investment in additional resources and new capabilities*
Ensuring content is up to date, paying for use of third-party platforms, and overseeing performance... an ecommerce system doesn't come for free
- *Increased price transparency and decreased price control*
Device prices become easily comparable and consumers choose the most cost-effective products

So how can the CHC device industry fully tap into the opportunities of the online channel while carefully mitigating the risks? There is a lot more to it than just allowing consumers to place orders online. Simon-Kucher's Consumer Healthcare experts have identified three key success levers for CHC device companies to become ecommerce champions.

II. Key success levers to become an e-commerce champion

Ecommerce success levers



These 3 key success levers allow companies to make the most of the opportunities of the online channel while carefully mitigating the risks. Here's what it takes to compete with the best:

1. Generate awareness: Make sure consumers find and buy from you!

Optimize for search engines (SEO)

The higher you rank in search results, the better the chances of your target consumers landing on your product and eventually making a purchase. Medical supplies are often classified by reference numbers, but this information is meaningless to the average consumer. And if you don't show up in the consumers' searches at all, then your products might as well not exist. Adapt product titles to fit with user search trends, including instantly recognizable vocabulary related to the disease or symptoms targeted by your device (e.g. blood pressure monitor). How easy it is to find the product and surrounding information will greatly impact the final purchase decision. That's why it is also worthwhile to run campaigns on relevant keywords with a good cost per click, e.g. through Google AdWords.

Enter paid social media partnerships

Another way to generate awareness and better reach consumers is to partner up with social media influencers who have an engaged following in your target niche. Companies from a wide range of industries have already adapted their advertising strategies to reflect the rise of social media. Now CHC companies are also joining this trend, with Instagram being one of the most popular networks. Investing in these partnerships can definitely pay off. By having influencers promote your products, you reach new lifestyle segments and have the opportunity to convince thousands of more potential consumers. Today's generation identify more closely with influencers than they do with traditional advertisements. If you have the right influencer shining a positive light on your device, consumers will be inspired to try it too.

2. Stimulate purchases: There’s always more room in the shopping basket

Welcome consumers to an attractive and user-friendly environment

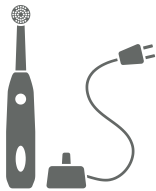
Once consumers are able to find you, make sure that they arrive on an appealing landing page. This needs to be similar in style to online pharmacies to make sure the consumer is in a familiar environment, and ultimately drive conversion. CHC companies usually make large investments in the right packaging for their devices, but often fall short when it comes to using visuals in ecommerce. However, without the opportunity for customers to physically touch or open the product, displaying devices attractively on the online channel is essential. Include detailed descriptions, 360° images, and even videos of the product in use. Always create your own page and banner, clearly displaying your brand and the associated theme (e.g. travel themes for sunscreen, fitness themes for scales etc.)

Encourage consumers to “collect” products using a product category generator

How satisfying is it to finish a jigsaw puzzle and see all the pieces fit together? People love to collect things and achieve a sense of completion. The idea with product category generators is to trigger an urge in the customer to buy more. By providing a checklist of products surrounding the main purchase, customers are encouraged to make their shopping basket “complete”. For example, toothpaste, mouthwash, and replacement brush heads go hand in hand with an electric toothbrush. The consumer might have originally only been looking for one device. But by displaying the next logical products, you simplify the decision-making process and open up new cross- and up-selling opportunities. Start by identifying the adjacent product categories to your devices, then develop the concept and engage with channel partners to explore the options their platforms have to offer. A product category generator could look something like this:

Include rankings and bestseller recommendations

One of the challenges of shopping online is information overload. Consumers can find the amount and variety of products overwhelming, and struggle to feel like they are making an informed purchase. The good news? On-line platforms allow you to incorporate recommendation mechanisms along the customer journey. Just like Netflix recommends TV shows based on its customers’ recent viewing behavior, CHC ecommerce platforms can provide active recommendations such as product rankings, most bought items from similar customers, tests, and ratings. Use data-driven analytics to understand relevant keywords and click-through rates, and establish a proactive process to manage internal SEO in your key countries. It might also make sense to partner with an external agency to provide country-specific best practices.

Shopping Cart		
Electric toothbrush		
Toothpaste		Add + 
Mouthwash		Add +
Replacement brush heads		Add +

3. Drive consumer loyalty: Grow relationships, not just transactions

Complement online subscription models with extra benefits

The digital age means new competition and increased pressure to hold on to existing customers, but it also creates several opportunities to build loyalty. CHC companies can attract and retain customers by offering additional benefits and incentives in the online store and combining them with innovative subscription programs. Just like Amazon Prime provides subscribers with faster shipping and access to music, books, and movies at no extra cost, CHC companies can use ecommerce platforms to build loyalty among their consumers by providing recurring subscription services and offering access to exclusive products, discounts, and healthcare publications.

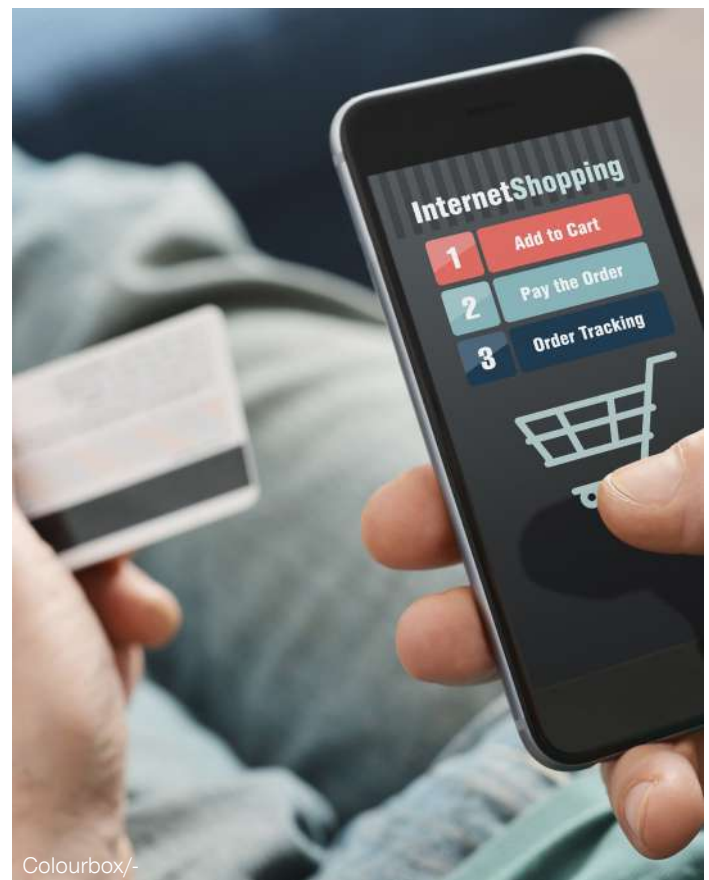
Send repurchase reminders at the right times

Don't underestimate the power of triggered emails. They are relatively straightforward to implement and can contribute up to 75% of digital business revenue. Identify consumer segments and consumer-specific buying behavior so that you can send automated repurchase reminders shortly before a customer runs out of stock. For products that are required on a regular basis (e.g. contact lenses) you can also drive loyalty by providing the consumer with their own personalized plan and order calendar.

Make re-orders automatic

Consumers need peace of mind that they will not run out of the CHC products they use most frequently. This is currently not satisfied by standard distribution approaches, and both the online and physical buying processes for medical devices can be cumbersome and unsophisticated. To lock-in customers, ecommerce platforms need to focus on convenience aspects such as rapid door-to-door delivery, 24-hour customer service, user-friendly websites, and last but not least automatic re-purchase processes. Connected CHC devices can leverage dash replenishment services such as those offered by Amazon, which will check product level on a constant basis and automatically re-order when consumers are running low. In the race to win the online health category, convenience is the best medicine!

“CHC device companies can no longer rest on their laurels. Increased competition and pressures from neighboring categories mean that the time to act is now.”



III. Best practice company: Abbott leading the way with its ecommerce strategy

This all sounds great in theory, but what does “the best” actually look like in practice? And what lessons can be learned from CHC companies that have already made this bold step?

Healthcare company Abbott enjoyed another year of outstanding performance in 2018, citing innovative product launches as a major contributing factor toward its strong growth. Among these innovations is its flash glucose monitoring device, the FreeStyle Libre 2, which now (together with the Libre 1) has over one million users worldwide.

Can the device’s ongoing success be exclusively drawn back to its mass market appeal? After all, it is profoundly changing the way people with diabetes manage their disease. It can detect trends and track patterns without the use of test strips or lancets, and enables users to monitor their glucose directly via a smartphone app.

However, we also cannot ignore Abbott’s impressive ecommerce strategy and the inroads the company has made into direct patient interaction and distribution. Not only has Abbott mitigated many risks and tapped into the opportunities of the online channel, they’ve pulled on the success levers surrounding awareness, stimulation, and loyalty. Let’s take a closer look at some of the key milestones in Abbott’s ecommerce story.

1. Abbott strategically timed the launch of its web shop

Abbott first started selling the FreeStyle Libre exclusively via its own purchase channels, and the company carefully planned the product’s launch in all key EU-5 markets to coincide with the opening of its new web shop. By launching this life-changing device and the new web shop simultaneously, Abbott maximized an early return on investment. In addition, the company circumvented the traditional middle men (typically retail pharmacies), and was able to boost margins as well as build a very promising patient database in the booming flash glucose monitoring space. However, once it obtained reimbursement for its device in most key markets, Abbott failed to maintain its preferred digital distribution channel for these specific patients in France, Italy, Spain, and

the UK. But in Germany, even for patients eligible for reimbursement, Abbott’s own platform is still going strong.

2. Abbott focused on driving consumer loyalty

Abbott secured access to the European markets for its FreeStyle Libre when obtaining the CE Mark (Conformité Européenne) in September 2016. Due to limited available clinical evidence of the device’s outcomes, Abbott did not obtain early reimbursement decisions in most markets. Consumers initially had to pay for the device out of pocket. Abbott then had to ensure they continued to engage with and remain loyal to their brand, rather than return to the reimbursed, standard blood glucose monitoring. Therefore, a constant focus on driving customer loyalty has been paramount to Abbott’s continued success. The company checks in on its consumers with regular, targeted emails. In addition, users receive around-the-clock customer service, including support through non-traditional channels such as social media.

3. Abbott ensured a premium “lifestyle” positioning.

Another way Abbott appeals to consumers is by speaking their language: “Diabetes is complex enough. Monitoring your diabetes shouldn’t be” –the FreeStyle Libre’s powerful slogan speaks directly to the patient community. Targeted messages are included in product descriptions, with the words accurate, convenient, and user-friendly prominently featured next to clear product images. Meanwhile, Abbott’s “Live Life to the Fullest” campaign is constantly sparking a conversation with the diabetic population across the globe, including online surveys, social media postings, blog content, and real-life stories, such as this piece on Thorsten Feige, Berlin marathon runner and FreeStyle Libre user. These strong communication efforts toward the target diabetic population have helped the FreeStyle Libre gain its increasing popularity and premium “lifestyle” positioning.

4. Abbott partnered up with the right social media influencers

Product reviews by diabetes patients and influencers have also been extremely instrumental in generating momentum around the FreeStyle Libre. Right from the beginning, Abbott teamed up with bloggers like Kerri Morrone Sparling and YouTubers like DiabeticDanica, providing them with free product samples and incentives in exchange for sharing their reviews with the online community. The company even hosted an exchange event for influencers, the DX2 in Sydney, so that the Abbott team could better get to know influencers in person. By having bloggers and influencers promote the device, Abbott was able to reach out to its lifestyle segments, with the chance to convince even more potential consumers.

Key takeaways for CHC device manufacturers:

- If your mid- or long-term plan includes applying for reimbursement, be sure to consider the potential forced discontinuation of your ecommerce platform upon receiving reimbursement. This should be factored in when quantifying the opportunity of setting up your own ecommerce platform
- Important success factors are targeted messaging, customer support and social media presence, and attractive content that speaks to your target consumers
- Identifying and collaborating with consumer influencers can be a very strong lever for generating awareness, especially in highly engaged groups like the diabetes patient communities

Outlook: The future of consumer healthcare and ecommerce

CHC device companies can no longer rest on their laurels. Increased competition and pressures from neighboring categories mean that the time to act is now. Although many companies are planning to propel themselves into the fast-growing emerging markets in Asia, those without the right ecommerce strategy in place will be in no position to compete.

Industry champions have already started building best practices and are leading the way with increased market penetration and expansion beyond the typical consumer base. And thanks to an increasingly widespread level of consumer comfort, more and more diverse products will start appearing on digital retail platforms. ◀

For correspondence related to this article, please contact Christian Rebholz at christian.rebholz@simon-kucher.com.

The International Price Referencing (IPR) conundrum: Strategic approaches for practical implementation

By Christian Schuler, Dr. Rainer Opgen-Rhein, Alison Greer and Grace Aro

In most markets, national P&MA decision bodies consider the product's price in other markets when determining the price of a new pharmaceutical product. This is commonly called international price referencing (IPR).



International price referencing is a powerful tool for cost containment of pharmaceuticals, allowing markets to reference external price anchors that may provide a lower base for price negotiations, or deterministically set the price of the product in the own country. Given the number of markets that have adopted international price referencing policies, today's IPR landscape is a complicated web of referencing and re-referencing relationships. (Figure 1)

The predictability of referencing also strongly varies by market. Some markets have a formal price referencing process with a clearly defined algorithm, such as the Netherlands, where the price of a pharmaceutical product is deterministically set by bi-annually referencing the average ex-wholesaler price of the product in Belgium, France, Germany (replaced by Norway in 2020), and the United Kingdom. Other markets have a less predictable price referencing process, such as Germany, where an average price (weighted by purchasing power) of up to 15 reference countries is used as one price anchor in the AM-NOG process, but this is only one of several arguments during price negotiations. This variability in formality and stringency of IPR use by a specific market is another component adding to the ever-increasing complexity of international price referencing.

This system then leaves pharmaceutical companies with two key questions: When should IPR be considered, and how can IPR considerations be integrated into the overall commercial strategy for a pharmaceutical product?

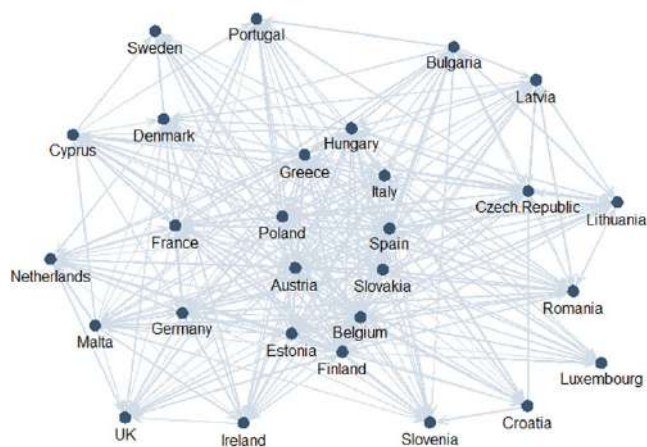


Figure 1: Referencing relationships within Europe

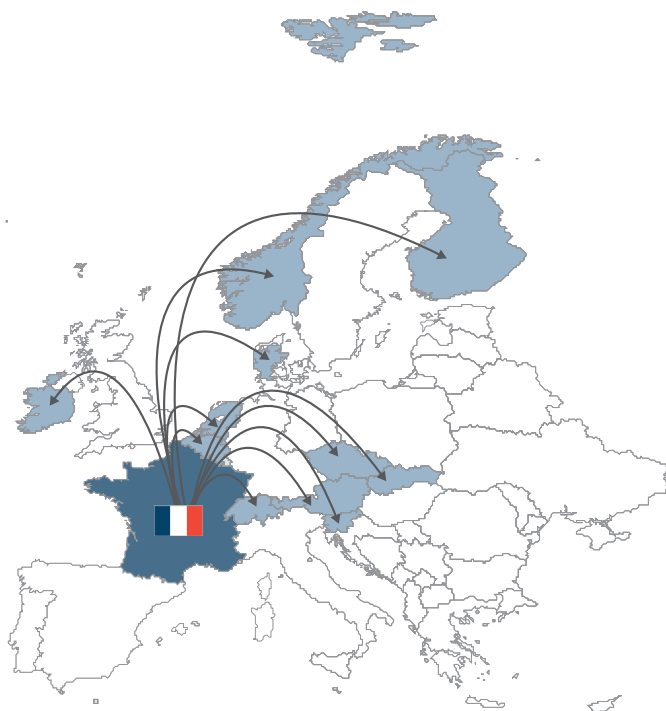
When does IPR matter, and why?

The answer to this question is quite simple: IPR matters at every point of the pharmaceutical product life cycle.

IPR at launch

At launch, IPR risks must be assessed in order to set a global list and net price corridor for a new pharmaceutical product, optimize its international launch sequence, assess the time-to-market per country, and develop and execute a global launch strategy. After target prices are assessed for each market individually, an IPR impact and risk analysis will need to be conducted in order to confirm if these country-specific optimal prices are actually achievable given prices in international markets, or if cross-country adaptations and sacrifices need to be made. Without such an extensive IPR risk analysis, it is unlikely that a global pricing strategy for a new pharmaceutical can be executed and ultimately be successfully implemented.

Example: The French affiliate of a mid-sized biotech company is hoping to improve the market access position of a drug within France by launching 20% below the target price. In the business case submitted to Global Headquarters, the French affiliate has determined that, within France, the price-volume trade-off favors the 20% lower price and will result in an additional €15.8m upside in NPV within 5 years within France. However, when the affiliate submits the request and the global P&MA analyst team conducts a sophisticated IPR risk analysis, it is determined the 20% lower price in France would result in a global loss of €11.7m in NPV in the same time frame, due to international price referencing implications that would reduce NPV outside France by €27.5m (Figure 2). If the manufacturer did not have a global launch price strategy with comprehensive cross-country analysis, the French affiliate's suggestion based on an isolated market would have cost the company millions.



IPR impact of a price reduction in France

Cumulative NPV (5 years, in mio. €)

	Austria	-1.7 €
	Belgium	-4.6 €
	Czech Rep.	-0.1 €
	Denmark	-1.3 €
	Finland	-2.0 €
	France	15.8 €
	Ireland	-2.0 €
	Netherlands	-9.9 €
	Norway	-1.8 €
	Slovakia	-0.1 €
	Slovenia	-0.4 €
	Switzerland	-3.0 €

Figure 2: Spill-over of pricing decisions to other countries

IPR throughout the product lifecycle

Although price referencing at launch is important to achieve a drug's target pricing and ultimately its initial commercial goals, vigilant monitoring of IPR during a product's entire lifecycle is of critical importance for its long-term commercial success. Prices of pharmaceuticals are referenced and re-referenced in regular or irregular time intervals by pricing authorities all around the globe. This means IPR risks need to be constantly monitored and need to be considered both for strategic price changes in individual markets, where manufacturers typically face price-volume tradeoffs, as well as in day-to-day price management, to avoid unwanted and unnecessary price erosion over time.

Example: The decision by a top-10 multi-national pharma company to remove an anti-epilepsy drug from the German market serves as a good example demonstrating the analysis required for strategic decisions within the product life cycle. The product was approved by EMA, and soon after entered the AMNOG process in Germany, which resulted in a verdict of a "no additional benefit" rating for the drug. After this decision, the manufacturer faced a choice between 2 scenarios:

Scenario A: Keep the product on the German market, with an expected negotiated, visible ex-manufacturer list price equal to only 10% of the freely set pre-AMNOG price (i.e. a 90% price drop in the German market). Subsequent international price re-referencing across Europe would drop the international pricing corridor significantly (Fig 3a)

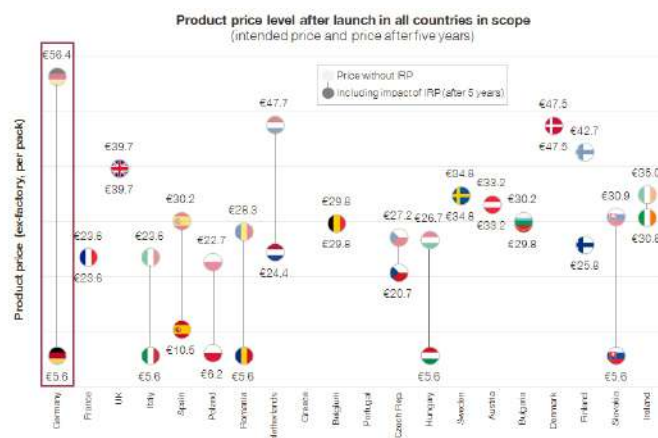


Figure 3a: Accepting IPR impact from Germany after the AMNOG process (Scenario A)

Scenario B: Remove the product from the German market and give up all sales in Germany, but protect the achieved price levels of the product in other EU markets. Some price re-referencing occurs in other markets even without a low price in Germany, but the international price corridor remains relatively constant (Fig 3b)

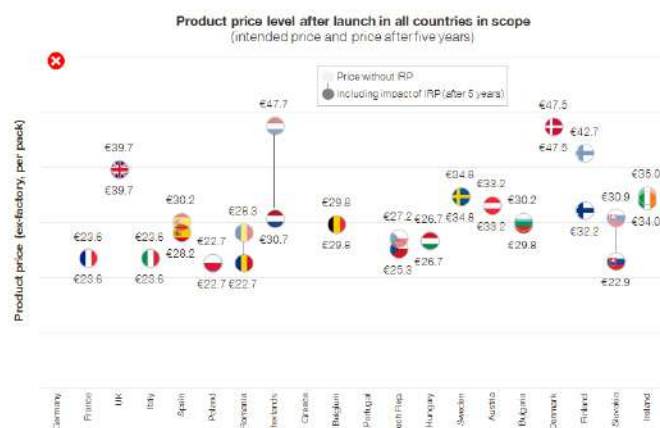


Figure 3b: "Opt-out" IPR impact from Germany after the AMNOG process (Scenario B)

Simulating this case using Simon-Kucher's proprietary International Price Referencing Analytics Model, we can determine that the volume loss in Germany would not have outweighed the IPR implications and risks, as the 5-year Net Present Value (NPV) is 19.8% higher for Scenario B than for Scenario A. The manufacturer actually withdrew the product from the German market and used the "opt-out" option in the AMNOG price negotiations.

Without a sophisticated IPR analysis, it is impossible to accurately weigh the pros and cons of strategic options and any decision would have been at best an educated guess by senior management.

How should IPR impact and risk assessment be integrated into a company's strategic processes?

Awareness and consideration of the implications of IPR is just the first step. IPR assessment and monitoring must be formally operationalized and appropriately integrated in a company's global price governance process in order to avoid unwanted negative cross-market repercussions.

IPR assessment should not end once a product is launched. Constant post-launch price management needs to be a key consideration in the day-to-day work of every P&MA department. Existing global pricing databases or international price management systems can be integrated with sophisticated IPR analysis tools in order to carry a product or portfolio successfully through its lifecycle. Having a structure to ensure IPR is considered at each strategic decision point in the lifecycle of a pharmaceutical product (e.g. new indication launch or administrative price cuts in certain markets) is equally as important as having a system to analyze IPR implications. Establishing a global hierarchy and escalation process for price change request approval through global price governance is essential in avoiding unnecessary price erosions as a result of IPR (Figure 4).

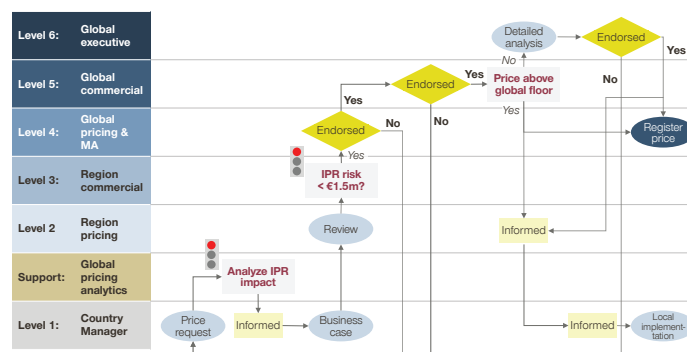


Figure 4: Price governance that systematically considers IPR impact assessment

What is needed to use IPR strategically?

In order to cover and integrate IPR management appropriately and ultimately strategically into a P&MA departments day-to-day business requires the following ingredients for success:

- 1. An up-to-date, state-of-the-art IPP library:** Knowing the specifics and complexities of a different country's IPR rules lies at the heart of best-in-class IPR management. A state-of-the art information set is ideally constantly updated (at least twice per year) and includes information that goes far beyond a "who-references-who" IPR matrix. Information such as exact referencing method and method of calculation,

referencing process (formal vs. informal), referencing metric (e.g. list ex manufacturer vs. public price), timing of referencing, products that referencing applies to (reimbursed vs. non-reimbursed, retail vs. hospital vs. OTC products, patented vs. generics vs. biosimilars etc.) all ideally needs to be included in a sophisticated IPR library (Figure 5). Simon-Kucher constantly tracks IPR details in nearly 100 countries of the world.

2. **A detailed pricing lexicon:** Often P&MA stakeholders from headquarters struggle to identify the right pricing metric for IPR in their communication with their affiliates. A company-wide pricing lexicon needs to be developed and adhered to in order to have a common understanding on the multitude of different pricing metrics along a country's price waterfall and know to which pricing metric in a specific country the IPR rules apply (Figure 6).
3. **Detailed knowledge of product characteristics:** IPR rules don't apply in the same way to all pharmaceuticals. In order to apply the existing IPR rules across markets consistently, a P&MA manager needs to know which rules apply and how they apply to a certain pharmaceutical product. Is the product in question a retail or a hospital product? Is it reimbursed vs. non-reimbursed or partially reimbursed in a certain market? What is the perceived benefit? Does it have a special status within the P&R system as it is (e.g., blood-derived products for diseases like hemophilia)? These and many more – often country-specific – questions need to be known in order to use the correct IPR rules in certain markets.

4. **IPR Matrix:** An international price referencing matrix (at launch and after launch incl. re-referencing) is the ultimate aggregation of IPR complexities for a specific pharmaceutical product. It can be used as a quick look-up for likely price reactions when a price in a specific market is set or decreased (Figure 7).

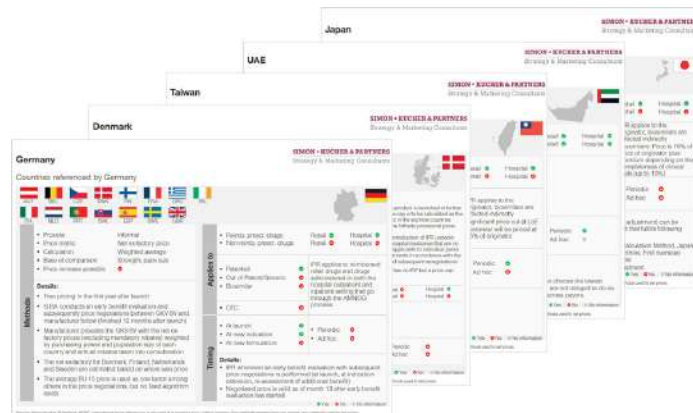


Figure 5: Price referencing library

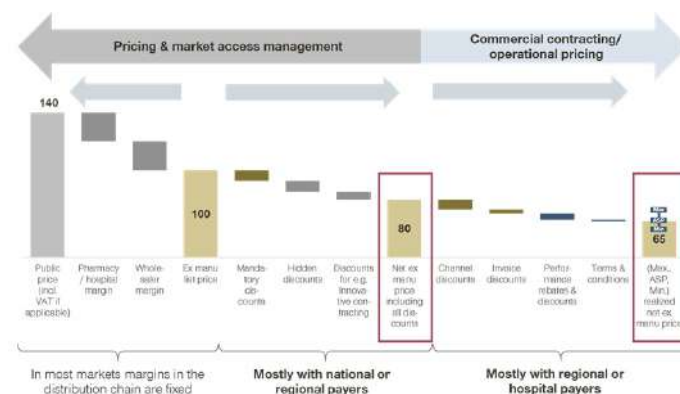


Figure 6: Price waterfall as a part of a pricing lexicon

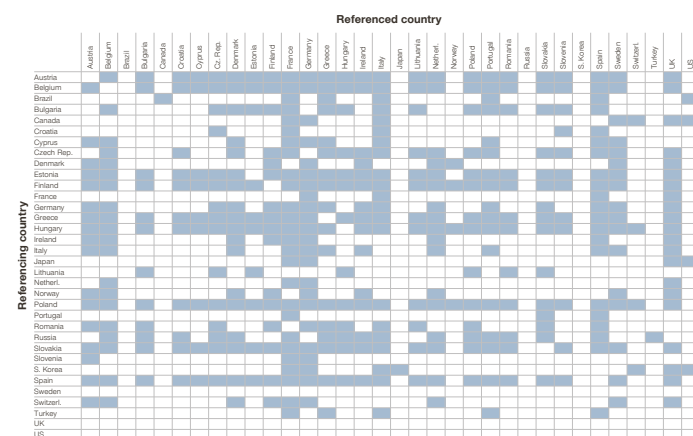


Figure 7: IPR matrix for selected countries

5. Sophisticated, state-of-the-art IPR analytics model:

Developing a robust, yet still manageable, IPR tool that is intuitive and user friendly is challenging. According to our knowledge, a lot of companies have tried to do so but only very few have succeeded. Most of the off-the-shelf solutions have limitations and don't capture the full complexities of IPR as outlined above. In addition, to correctly consider the trade-off between price and volume effects, information on price elasticities and volume assumptions also need to be known and included for a specific product.

According to our market expertise, a state-of-the-art IPR analytics model should cover the following key items (among others):

- Correct and comprehensive price referencing rules including multi-period considerations (re-referencing) and informal (non-deterministic) price referencing
- Different price metrics (e.g., list ex-manufacturer price, net ex-manufacturer price, ex-wholesaler price, public price) to be able to calculate international price referencing on the same price metric as the national authorities
- P&MA negotiation timelines (which may also depend on the aspired product price level)
- Volume and price elasticity assumptions, including assumptions on uptake, to allow for NPV calculations
- External events (i.e., all events that impact price and volume in certain markets, but that don't originate in the IPR mechanism)
- Algorithms to improve/optimize the launch sequence and price corridor

Without those detailed considerations, an assessment of the impact of IPR is often not only less precise, but simply wrong.

Simon-Kucher uses its comprehensive experience in pricing and the health care industry to develop a state-of-the-art IPR tool to analyze and mitigate the impact of international price referencing. The Simon-Kucher IPR Analytics Model is specifically developed to cope with the real-life complexities of IPR. The model factors in all key consider-

ations for IPR using multi-dimensional data, including idiosyncratic price referencing rules, re-referencing, informal (non-deterministic) price referencing, product-specific price elasticities, estimations on P&MA negotiation times, COGS, product characteristics, and external events. In doing so, it can support in optimization of launch sequencing, definition of international price corridors, revenue/profit/NPV forecasting, assessment of IPR risk, parallel trade, cannibalization, and more (Figure 8).

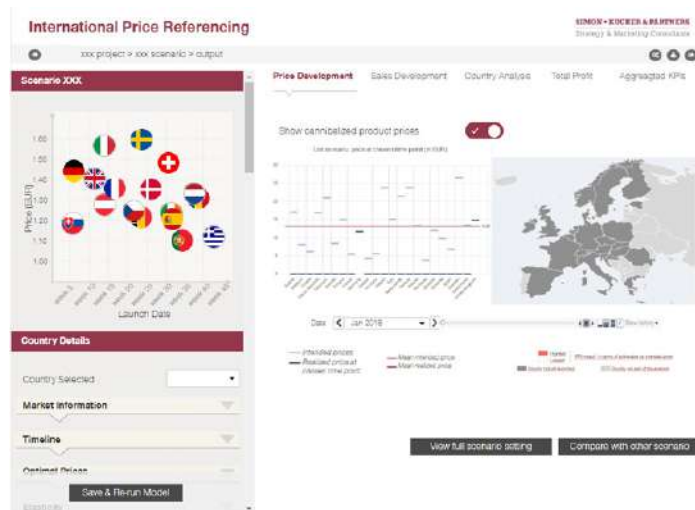


Figure 8: Simon-Kucher's IPR assessment tool

Looking forward: How might IPR change?

With healthcare costs put on center stage in recent months, resulting in scrutiny of drug prices and development of new policy, close consideration of developments around IPR on a global scale will become even more important.

In the US

On October 25, 2018, Centers for Medicare & Medicaid Services (CMS), issued an Advanced Notice of Proposed Rulemaking (ANPRM), soliciting public comment on a new rule titled the International Pricing Index (IPI) model. The IPI model would propose benchmarking of CMS reimbursement for Medicare Part B to international prices.

This proposal comes in response to increasing Medicare Part B drug expenditures and a recent study comparing the US drug acquisition costs for 27 Medicare Part B physician-administered drugs to that in 16 other coun-

tries: Austria, Belgium, Canada, Czech Republic, Finland, France, Germany, Greece, Ireland, Italy, Japan, Portugal, Slovakia, Spain, Sweden, and the United Kingdom. The study found that, on average, acquisition costs in the US were 1.8x higher than in comparator countries, with a range from parity pricing up to 7 times higher for some US drugs.

The IPI Model would begin in spring 2020 and be in effect until the spring of 2025 for a selection of providers and products, including single source drugs, biologicals, biosimilars, and multiple source drugs with a single manufacturer. For each Part B drug, the new Medicare payment would be set at a Target Price derived from an IPI factor based on pricing data from 14 countries considered to either have economies comparable to the US or that are included in Germany's market reference basket: Austria, Belgium, Canada, Czech Republic, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Japan, Netherlands and the United Kingdom.¹

Given the importance of US sales for the pharmaceutical industry, the IPI model may have significant implications for global markets, resulting in reactionary strategies in which products are not launched or are delayed to launch in ex-US markets.

Global price transparency

Similarly, on May 28, 2019, The World Health Organization (WHO) approved a draft resolution to support international price transparency at The World Health Assembly in hopes of universally lowering drug prices. The resolution "urges Member States in accordance with their national and regional legal frameworks and contexts to take appropriate measures to publicly share information on the net prices of health products," where "net price or effective price or net transaction price or manufacturer selling price is the amount received by manufacturers after subtraction of all rebates, discounts, and other incentives."²

Not unlike implications of the US IPI Model, the resolution

On July 5th, 2019, President Trump announced his administration was working on an executive order that would lower drug prices for the US government. Under the proposed order, called the "favored-nations clause", payment for drugs included would be capped at the lowest international benchmark among developed nations. Further details on scope of the order and timing for implementation have not been specified. There are a number of questions as to which programs this would apply to, as the federal government is a direct purchaser of drugs through the VA and DoD programs, but typically only an indirect purchaser through programs such as Medicare. The administration is still working on a plan in parallel to set government reimbursement for physician-administered drugs based on an index of international drug prices.

¹ Centers for Medicare & Medicaid Services: Advance Notice of Proposed Rulemaking, International Pricing Index Model for Medicare Part B Drugs, October 25, 2018

² World Health Organization: Draft resolution of the Seventy-Second World Health Assembly, Improving the transparency of markets for medicines, vaccines, and other health products, May 28, 2019.

toward "Improving the transparency of markets for medicines, vaccines, and other health products" may result in limitation of differential price arrangements for low and middle-income countries in order to protect price levels in higher-income markets.³

Beyond these two specific proposed policies, IPR is becoming increasingly relevant as it begins to take on a more prominent role across the globe. IPR is being used as a mechanism for price control in more markets, and IPR rules are becoming stricter in markets where IPR is already in place. Additionally, it is increasingly common for markets to reference global prices informally, without any specific market reference basket, or referencing rules, or calculations, making it more difficult to predict and plan for cross-market interdependencies. As such, a sophisticated and comprehensive IPR analysis is all the more essential to inform a list and net price strategy of a pharmaceutical product, both at launch and throughout the product life-cycle. (Figure 9)

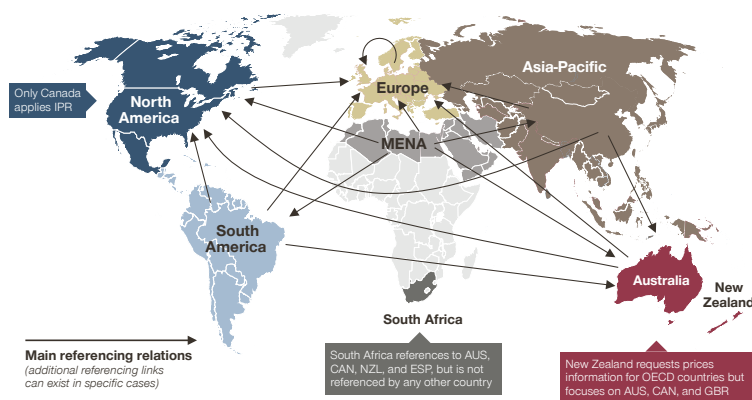


Figure 9: Global cross-regional price referencing relations

Quick tips: Dos and Don'ts of IPR

Though every product and market situation is unique when it comes to IPR implications and must be assessed as such, a few takeaways hold true for IPR across contexts.

Dos

- i. Incorporate IPR into a product's strategy from launch and continue to monitor IPR implications throughout the product lifecycle
- ii. Always evaluate strategic decisions for IPR implications to ensure that affiliates understand the risks and do not approve price changes without considering other markets
- iii. Consider the specific IPR rules of each country, not only the basket of markets which it references, to avoid oversimplification and subsequently inaccurate conclusions

Don'ts

- i. Don't rely on rudimentary analysis to quantify IPR impact. A robust and sophisticated IPR analysis is essential in capturing country-specific nuances and intricacies
- ii. Don't only account for formal price referencing, as informal price referencing may have just as much impact
- iii. Don't rely fully on technology to carry out IPR analysis and deliver the optimal strategy. Expert opinion is necessary to transform analysis into an actionable and realistic strategy
- iv. Don't focus solely on main markets. Smaller countries can compound, especially if referenced by larger markets.

³ The Economist: The global battle over high drug prices, May 21, 2019.

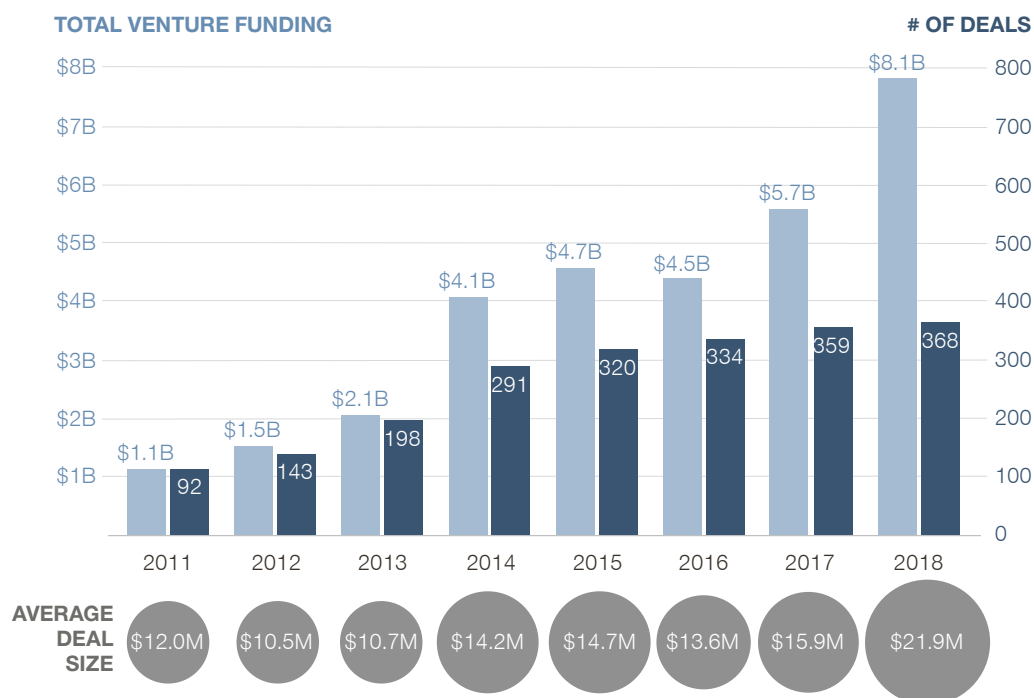
For correspondence related to this article, please contact Christian Schuler at christian.schuler@simon-kucher.com.

Preparing pricing and market access teams for the digital future

By Stephen Dunbar, Madelane Teran, and Jeremy Winkler

The digital healthcare space is becoming more prominent than ever before with \$8.1b USD invested worldwide in 2018 (Figure 1). It has gained the attention of healthcare providers, insurers, and governments alike, with Express Scripts and CVS in the US recently announcing the start of a stand-alone digital health formulary and many countries starting to reimburse certain digital health products.





Source: Rock Health 2018

Figure 1: Digital Health Funding (2011-2018 U.S. dollars)

For companies looking to market a digital health product, understanding the unique market access opportunities and challenges compared to a traditional pharmaceutical will be crucial. Manufacturers will need to adapt their current market access activities and functions to meet the needs of this new category of healthcare products.

Monetization of a traditional pharmaceutical can be relatively straightforward: You seek reimbursement/market access using defined pathways. On the other hand, there are multiple different ways companies can monetize a digital product, some involving reimbursement and some not (Figure 2). In some cases, payers might be willing to reimburse the digital health product itself as a fee-for-service, as was achieved by Sleepio and Pear Therapeutics. Additionally, manufacturers can pair a digital product with a traditional therapeutic in their portfolio to achieve a higher realized value of the portfolio product, either by increased volume or by achieving a higher reimbursed price thanks to a higher value perception (data collection, improved outcomes, etc.). If a decision is made to seek reimbursement for the digital health product, manufacturers will need to adapt the what, the how, and the who of traditional P&MA processes for digital healthcare. Small organizational changes can ensure the responsible teams have all the tools needed for a successful launch (Figure 2).

Activities: “What you do”

Once the decision is made to pursue market access for the digital health product, determining potential pathways will be one of the key initial tasks. Market access for traditional pharmaceuticals typically follows a well-established pathway, and the teams working towards achieving this goal are very familiar with the requirements and timeline. Reimbursement and funding pathways for digital health products are currently poorly defined and vary significantly by market. Therefore, pursuing reimbursement will be a continuously evolving process requiring in-depth country-specific knowledge and flexibility to explore creative ideas for funding, and will need to be routinely monitored and re-assessed.

Furthermore, using established market archetypes or extrapolations between markets, which is common for traditional pharmaceuticals, becomes ineffective for digital products given the level of variability. For example, France and Germany are typically considered to have similar evaluation processes for traditional pharmaceuticals, however, this is not the case when it comes to their evaluation of digital products. In France, there is an established national pilot program for tele-monitoring products but in Germany, no such program exists and reimbursement is often

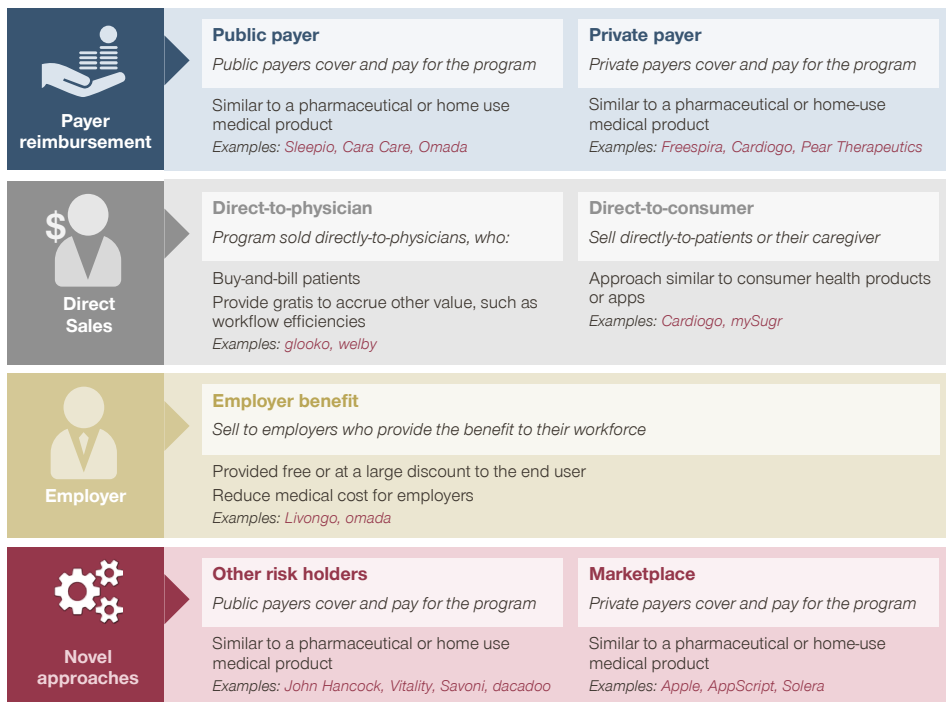


Figure 2: P&MA process flow for digital products or traditional reimbursement pathway for digital therapeutics

driven by negotiations with individual sick funds. Despite differences in the evaluation process, both markets offer unique opportunities in the digital healthcare space. The teams involved in securing reimbursement for the digital product must first understand any existing regulations and policies but also harness the skills and knowledge to create / propose / materialize new market access pathways if none are available.

Processes: The “How”

Strategy development: Digital health requires a much more flexible and road-mapped approach when developing a launch strategy. With a traditional pharmaceutical, a great deal of time and effort is typically put into developing the product strategy leading up to launch. For a digital health product on the other hand, there might need to be an initial strategy for launch, for example, selling direct to consumer, before moving forward to a traditional reimbursement pathway after a certain time has passed.

Evidence generation: Most evidence generation is front-loaded prior to launch for traditional pharmaceuticals. As a result, companies typically have well-established processes for generating evidence to support market

access. This includes draft trial protocols, an established set of stakeholders to engage, a clear timeline of when input is needed, and so forth. However, as seeking reimbursement at launch might not be the primary goal for a digital product, existing evidence generation processes may not apply.

In France, to qualify for national reimbursement via the tele-monitoring pilot program (ETAPES), all that is required is to demonstrate that the digital health product offers tele-monitoring and has a protocol for a real world study. In this case the market access pathway requires minimum evidence generation upfront but requires significant evidence generation post-launch. Manufacturers might need to have an evidence generation strategy at launch and then develop a new strategy for X number of years post-launch, depending on the ultimate market access goals. In other cases, manufacturers might have already gathered significant amounts of evidence at launch and still face MA limitations due to an inherent data skepticism in the digital health space. To avoid this, having a clear understanding of the evidence requirements imposed by the appropriate stakeholders is paramount.

Stakeholder engagement: Stakeholders involved in evaluating products, negotiating prices, and deciding on reimbursement of traditional pharmaceuticals might not be the same stakeholders involved throughout the launch and commercialization of a digital health product. For example, in Germany, the requirement to achieve funding for a digital therapeutic product may not rely on the G-BA but instead, individual sick funds. While the G-BA is very clinically-focused, sick funds are much more interested in reducing their annual spend. In some organizations and government bodies, even an entirely new team of individuals might be responsible for evaluating digital health products (e.g., innovation teams at ESI). This means that payer strategies will need to be tailored to the value drivers of these new set of stakeholders.

The talent: The “Who”

As market access might not be the ultimate goal for the launch of a digital product, the organization will need to internally align on what success means both at launch and post-launch, in order to establish clear expectations for the P&MA team. Lastly, success will require planned talent management to be able to attract market expertise in an evolving field where many gaps currently exist. A good understanding of how new digital health products are entering the commercial arena and a strong foundation of the payer requirements will be needed for anyone leading a digital health product P&MA team. Given the evolving nature of the digital healthcare space and the variability between markets, manufacturers might prefer to harness these skills at the global level instead of the affiliates, which might not have the bandwidth to take on additional tasks.

Future challenges and opportunities

The P&MA function will likely need to evolve with the coming of age for new digital health products. Understanding the different approach in the “who,” the “what,” and the “how” will support a successful market access pathway for a non-traditional product that may be driven by a different set of principles. Preparing for this new wave of digital health products will require organizational set-up, operational effectiveness, and customized talent manage-

ment. Having the right operational plan in place will allow the P&MA function to quickly adapt to new payer mind-sets as different lines of thinking develop around how these products demonstrate clinical value and how this value is realized. ◀

For correspondence related to this article, please contact Stephen Dunbar at stephen.dunbar@simon-kucher.com.

Virtual AI Nurses and the Future of Chronic Disease Management

By David Lee

David Lee, partner at Simon-Kucher & Partners, sits down for a fireside chat with serial entrepreneur Julia Hu to talk about virtual AI nurses and the future of chronic disease management. Hu founded Lark Health in 2011 with the goal of scaling personalized, digitally driven health care to anyone in the world.



JULIA HU

Julia Hu, founder of **Lark Technologies**, has become something of an expert on the digital health environment and the role of prevention in the US health system, having worked with large tech players such as **Apple, Amazon, Google** and **Samsung**. She shares her insights into future trends and opportunities in this space

Lark's *AI nurse* is the first non-human technology to fully replace a live health care professional and be fully reimbursable with a CPT code. It is managing the equivalent caseload of 20,833 full time health care professionals. Lark works with health plans and providers to provide infinitely scalable health care.

Having managed her own chronic disease throughout her life, Hu felt the benefits of 24/7 compassionate care. Together with health experts and coaches from Stanford, Harvard and artificial intelligence technologists, she developed Lark – a 24/7 personal AI nurse that texts with people to help them manage and prevent chronic disease. Prior to founding Lark, Hu ran global incubator Clean Tech Open, a green buildings startup, and was an entrepreneur in residence at Stanford's StartX. Hu has also advised former US president Barack Obama, is a faculty member at Singularity University, and is on the board of the Council of Diabetes Prevention.

David Lee: When did you know that you wanted to be a health entrepreneur?

Julia Hu: I loved entrepreneurship ever since I discovered it when I was at Stanford. After starting two companies in cleantech, I jumped right into health care because of my own health issues. I've had a chronic disease all my life. It wasn't diagnosed until I was in my 20s. My chronic condition was a pervasive part of my life as a kid. My dad looked for professionals and after 30 failed attempts with specialists, we ended up finding nutritionists. There were weekly meetings for over 12 years, which got rid of 95% of my attacks. I completely changed my diet and how I managed my medication and exercise. It was a transformative experience. I was lucky to have this 24/7 personal health team helping me manage my chronic condition, but unfortunately most people don't have access to this type of health care. I really wanted to see if we could scale this personalized compassionate health care to anyone in the world, especially those at high risk of or suffering from chronic conditions. So, that's what started Lark, and we

have been working at it for almost seven years. Today we work with major health plans and have close to two million members on our platform.

Lark has a clear focus in diabetes and hypertension. Could you speak about the focus around chronic disease and some of the market related choices you've made?

Our health care system is very good at addressing infectious diseases but structurally unable to fully support long term chronic conditions. That's why we're seeing that 86% of all health care costs are in chronic conditions. Our goal is to reduce that burden and cost, and that is why we focus on the most burdensome diseases of our generation – diabetes, prediabetes, hypertension, etc. We also work very closely with a lot of Harvard and Stanford behavior change experts and therapists to help people manage depression, and the emotional baggage that is a common comorbidity of these chronic conditions, with cognitive behavioral therapy. We focus on chronic conditions because it's all about long term engagement and self-efficacy. There are a lot of behavioral and lifestyle changes that impact how you feel every day.

You mention the emphasis on making a meaningful impact for patients and we have read a lot about how you have worked to make your AI "compassionate". What role do you think that has played in the success Lark has had, and what are your thoughts on how that can be brought more broadly into digital health, because there are so many solutions out there that leave people feeling cold?

It's a huge part of our philosophy. When I was a kid I felt very alone. I couldn't play on sports teams like my friends could. It felt unfair that I would have random attacks at night. I sometimes felt frustrated and a bit scared, but I felt like so much of the love and support given to me made it feel fine to live with a chronic condition. We really think that the key to chronic conditions – even more than medical advice, which you might get from a doctor, such as "Lose some weight, exercise more, take your pills" – is truly a behavioral health and behavior change problem. So, if you can get to the heart of the problem, you can easily transform the situation.

In my mind, it is a bit ironic, but I think that the AI nurse is the only way to send the love and care of a nurse or doctor to everyone in the world in a manner that is unlimited and 24/7. I think that only an AI would be able to not provide judgment when you're telling them about how hard it is to. It's about using the benefits and strengths of technology to show that we are seeing your efforts and that we are coaching you and training you to be better. We try to make sure that all the coaching is personalized. We would never tell a marathon runner to go and try to do 10,000 steps today nor would we ask a very obese diabetic to go run 2 miles if they never run. Really, it has to be personalized based on the continuous data that we are getting from all sorts of sources – from your phone, from the 75 health monitors that we link up with and directly get data from, from the blood pressure monitor to genetics data that we are pulling in. We are trying to create a behavioral model of each person, and then seeing their efforts and then coaching them to become better.

A virtual AI nurse is a bit of a radical concept. How do you work with the existing health care system and clinicians? What are some of the obstacles you've encountered and how have you overcome them?

Obviously, no one is going to disrupt the health care system in the ways that maybe less regulated and less complex industries have been disrupted. So, we really try to stay within the workflows of the health care system. For example, our diabetes prevention program is CDC recognized. It is fully medically reimbursed as a program that anyone can use if they have the correct insurance companies. We went through the steps for CDC Full Recognition, of getting our own NPI number to be a provider, and to be medically reimbursable. We worked with a team of about 16 Harvard and Stanford faculty members who helped us translate the latest gold standard of care. As an example, we translated the American Diabetes Association guidelines into the coaching protocols for type 2 diabetes management and hypertension management. And we worked with the chief medical officer of the Joslin Diabetes Center, which is the largest diabetes center in the world run by Harvard, to make sure our AI Diabetes Care services focused on the key issues. We really try to make sure that the program both conforms to the latest gold standard of care but also is delivered in a way that is in conjunction with the health plans that we work with. For example, a

nurse at a call center can in one minute onboard a patient with our AI nurse.

One of the things that came up fairly early for your company development was the decision to migrate from a device and software company to being a software-only company. Could you share a bit of your thinking around that and how this decision has shaped your approach going forward?

It was a difficult decision because we had achieved a couple million dollars in revenue, and the hardware and software business was really growing at that time as an industry. So, this was a personal decision. We felt like we wanted to be an AI coach, an AI nurse, on top of all devices – not just our own. We wanted to share that signal very strongly with the market to make sure that other hardware companies did not feel that we were competitive in any way. Because we wanted to be the layer on top of all this data. We made the difficult decision to step back from hardware, and undergo about another three years of R&D to try to link up to multiple devices. That's why today we sit on top of 95% of the smart phones and sensors, we sit on top of 75% of health monitors, we sit on top of genetic data, and so forth.

To me, startups can't do multiple things at once. We chose the AI coaching piece to focus on. We changed early in our company's existence, within the first year. So, most of our life we've been in the world of software-only, but I think we also have a good sense of hardware and how to connect with sensors to pull data from them in an effective and efficient way so that we get real time behavioral models on every one of our 1.5 million patients.

You mention that decision to be the application layer on top of the data. When we talk about digital health, we inevitably come back to tech companies like Apple, Google, Amazon and Samsung and their ambitions in health care. Would you share some of your thoughts on partnering with large players? What are your key lessons learned?

We've had some exciting opportunities to work with many of those players closely. Health care is so complex and fragmented from a regulatory standpoint. The companies that can figure out how to localize and aggregate all of the health care and consumer health data into

one unified data repository will unlock a lot of potential in health care. Claims data is great, and we should absolutely integrate that into one place, but a person's life generates so much more consumer health data – where they go for meals, what pills they're taking from their local pharmacy, how much exercise they do, what their daily glucose level is – all of that information. If someone has the ability to aggregate it into one place then I think there will be a lot of value. Apple's Health Kit and consumer centric data approach is interesting. You're also seeing that successful consumer-centric approach with Amazon and their recent acquisition of PillPack – which is a delightful consumer-centric pharmacy experience.

I am excited about some of the consolidations that are happening in the tech and health tech space. Certainly, we believe that understanding a person's context enables more personalized health care services. If you can gain the trust and engagement of a patient, they will share more information about themselves. That is a positive feedback loop and it is the basis of Lark's AI engine. Our AI nurse has improved by close to 40% just within one year of launching our fully medically reimbursed DPP (diabetes prevention program). Now, within a year we are the second largest DPP program in the country. All of that data is really helping the AI nurse get smarter.

The CMS Innovation Center has named DPPs as one of two pilot programs to reduce cost, improve quality and outcomes. What do you think is primarily responsible for that? What about the program design or protocol makes it so effective?

It's great that our health care system is looking at prevention so seriously now. DPP is the first fully medically reimbursed program that focuses on prevention and not chronic disease management, and we're excited to be one of the fastest growing and second largest CDC-recognized diabetes prevention provider in the country. Prevention can be done so much more cheaply than management of a chronic condition. If you can prevent someone from being a type 2 diabetic that is \$8,000 to \$20,000 of cost per year for the rest of their life that is averted. The program is relatively inexpensive to distribute and serve. In my mind, if we can continue to focus on the root of the problem, which is helping people before they are suffering from chronic conditions, everyone wins.

“My idealistic dream is to provide anyone in the world suffering from or at risk for a chronic condition personal compassionate health care. It doesn't matter if they are 500 miles away from a hospital or a good clinic, or can't afford care.”

– Julia Hu

The FDA just published a new strategic framework about the use of real-world data and real-world evidence in drug and biologics development. What role do you see for Lark as a partner to pharma and biotech companies as a source of patient recorded outcome tool, and real-world evidence generation?

There is a lot of benefit to society from this. Pharma and biotech companies can create much more impactful products by using data from larger populations than was previously available through clinical trials. You're seeing 23andMe doing a lot of great work in sharing their huge databases to move science forward.

Currently, we are focused on helping major health insurance providers and self-insured employers manage their chronic patient population or wellness population. However, our mission is to offer free 24/7 chronic condition care services to all members everywhere, so who knows where that will lead.

You recently announced a collaboration with 23andMe for the integration of genetic insights into new weight loss and diabetes prevention programs. Can you share some of your thoughts on the partnership and the role of genetics in Lark's development going forward?

23andMe and Lark created a new genetics based chronic disease management platform together and we think it's a breakthrough for personalized medicine. By taking 23andMe's incredible insights about genetic variants and the impacts of genetics on certain lifestyle interventions, Lark is able to provide even more personalized real-time interventions for chronic patients or those at high risk of chronic conditions. We're so happy 23andMe chose Lark among all the larger potential partners in its efforts to create actionable meaning from genetics.

Let's now pivot to some of the challenges of running a high growth company. You mentioned earlier it's hard for startups to do more than one thing well. How do you balance doing that one thing well and keeping focused on the mission, but also leaving room for experimentation for new concepts that you are inevitably presented with?

Doing one thing well, in our case providing infinitely scalable compassionate chronic care for all, actually necessitates a lot of experimentation. We act more like a consumer product company in that respect. We do a lot of user testing and experimentation on which features are best, which recruitment philosophies are best. On the other hand, where we try to be very disciplined is to not chase after shiny projects that are not our core competency. We've been lucky enough to be regarded as one of the creators of the AI chatbot modality and get a lot of interest from chief information officers in other industries working on chatbots. We just see that as very flattering but something that we cannot proceed with at this moment. It's more looking at your mission and your goals and seeing if you are the best person for the job and if it's aligned. It's always hard but we try to stay focused in chronic disease, in areas where there is self-efficacy involved, in areas where there is passive data involved. We are focused on a pipeline of new chronic diseases, where we think our technology is good for solving those problems.

When you think about the marketplace, what are the biggest threats to your business? Is it more about changing the consumer mindset or fending off larger companies who are trying to co-opt some of your capabilities?

Neither of those really keep me up at night. Text messaging is mass market – we don't need to train the consumer here. My 85-year-old aunt is better at texting in WeChat than I am. Alexa and Siri have proven that people feel comfortable with having conversations with AI. The problem for startups like us is competing against much more well-funded and larger companies who market similarly. We are spending time building a clinical portfolio with rigor that conservative health plans and other health care players are comfortable with. We're lucky because scaling to their millions of members is not an issue – it's more the brand awareness and long sales cycle that keep me up at night.

Based on what you see in the marketplace today, what parts of consumer health engagement do you think are most ready for further disruption? What do you see as key white spaces and opportunities?

I still feel like chronic disease management is a huge play for technology, especially building on top of Internet of Things and the vast data that society is generating. The recent Propeller Health exit is a great example of an IoT connected device plus app service.

Other key white spaces I'm excited by are genomics and mental health. The next step of genomics is to field action rather than just be a cool study about yourself, while mental health startups are focusing on real-time need. I'm very excited that digital health has continued to be a hot early-stage venture bet even though you're not seeing as much of the immediate unicorn deals. Health care in general has a much longer life cycle, but huge value is created in those areas.

As an entrepreneur, is there anything that you would be looking for from the government in terms of standards or interoperability that you think would accelerate the achievement of your mission?

I'm not a policy expert by any means, and I was not very involved in policy until I realized that changes in policy have huge ramifications. So, I joined a couple of boards to advocate for policies and leadership – Council for Diabetes Prevention and the Silicon Valley Leadership Group. The reimbursement of the CDC recognized diabetes prevention program was a huge step in the right direction. I think it would be incredible to have CPT codes that start addressing diabetes and hypertension and other chronic conditions. There are some great advances in telemedicine codes. I think that if these codes can be extended to AI and digital counseling, that would drive real scale.

Looking at international expansion and other markets, have you given much thought to potentially extending Lark's reach to other markets?

My idealistic dream is to provide anyone in the world suffering from or at risk for a chronic condition personal compassionate health care. It doesn't matter if they are 500 miles away from a hospital or a good clinic, or can't afford care. We have architected our systems so that we can internationalize. We've been approached by a lot of partners and have been having great conversations with large health plan partners that are able to help us navigate the complex regulatory environment and business environment.

“Our health care system is very good at addressing infectious diseases but structurally unable to fully support long term chronic conditions. That's why we're seeing that 86% of all health care costs are in chronic conditions. Our goal is to reduce that burden and cost, and that is why we focus on the most burdensome diseases of our generation - diabetes, prediabetes, hypertension, etc.”

About the Author

David Lee leads the global sales practice within Simon-Kucher's life sciences activities. His focus is on helping medical technology and pharmaceutical clients drive organic growth by advising on monetization strategy, sales force optimization, key account negotiation, and commercial excellence programs. He is also a member of Simon-Kucher's global medical technology practice, advising health care IT, digital health, diagnostics and medical device and equipment clients on sales, marketing and pricing initiatives.

For correspondence related to this article, please contact David Lee at david.lee@simon-kucher.com.

Early access routes in Latin America that can improve KOL/physician support prior to formal reimbursement

By Gabriela Honda, Carolina Quesada-Rodriguez, and Mariana Torgal

It is common for pharmaceutical companies to explore early access programs, such as ATU in France or Law 648 in Italy. Given the typical delay in regulatory and reimbursement decisions in Latin America, early access programs are a great opportunity to improve KOL & payers' product value perception in these markets as well.



However, there is not a lot of transparency on which drugs are approved through early access programs and why. Here we highlight a few available programs in selected Latam markets:

Brazil

There are 2 available programs, and both are for severe and life-threatening diseases for which there is no other satisfactory therapeutic alternative registered. The “sponsor”, typically a private or public healthcare facility, submits the request to ANVISA, the Brazilian regulatory agency, and must provide a guarantee of coverage of full treatment free of charge for the patient (i.e., patient cannot incur in any out of pocket expenses for the treatment).

1. The **compassionate use program** is for individual patients and is applicable for drugs without ANVISA registry in any phase of clinical development and with scientific evidence demonstrating efficacy
2. The **expanded access program** is for patient groups, for drugs without ANVISA registry, and with phase III trial under development or concluded

These programs are different from legal injunctions, by which the patient gets access granted in court given the universal constitutional right to healthcare and in which the manufacturer cannot be involved.

Mexico

The **importation of special treatments** is available for low incidence diseases with social repercussions that represent a risk to vulnerable groups. This applies for drugs without local regulatory approval. Requests can be made by any person, manufacturer, or health service providers (public or private) and the authorization is valid for 180 days. However, there is limited information available regarding the funding and other criteria that may apply.

Argentina

There are 2 programs very similar to the ones available in Brazil. Both are for severe and life-threatening diseases for which there is no other satisfactory therapeutic alternative approved by ANMAT, the Argentinian regulatory agency.

1. The **exceptional access program** must be requested by the physician and is only applicable for drugs commercialized or in clinical trial in countries with regulatory similarities. The maximum treatment

authorization is for 60 days, or 180 days for chronic treatments (new requests can be made thereafter)

2. The **expanded access program** must be requested by the manufacturer, but this program requires the manufacturer to commit to market authorization submission within the next 12 months (if not already submitted). The maximum treatment duration is 12 months and it must be provided for free for the patient and the healthcare system (*prepagas*, private payer, or social security).

By law, there is no explicit statement regarding who funds the treatment for the exceptional and expanded access program.

Colombia

Vitales no Disponibles is a national program for products treating life-threatening or debilitating medical conditions that are not available in the market, either because they are not approved or are approved but not commercialized. *Vitales no Disponibles* is applicable for individual patients or groups. Funding is granted through ADRES, the health resources administrator, following a request by any “natural or juridical person, public or private”. Authorization is valid for the duration prescribed by the physician. If additional treatment is needed, a new request must be made. There is a public list available, which makes Colombia more transparent than the other markets previously mentioned.

Overall, these programs, despite lack of transparency and/or wide reach, could represent an opportunity to enhance reimbursement prospects by:

- Increasing KOL/physician support early in these markets (which is of high importance for reimbursement decisions)
- Enabling the collection of real world evidence locally, which is often helpful in gaining access in these markets

Manufacturers should target a few reference centers in the market, usually led by university hospitals, to rollout these programs. This will secure physician uptake, awareness and much needed local advocacy and support when local public funding negotiations come to play.

For correspondence related to this article, please contact Mariana Torgal at mariana.torgal@simon-kucher.com.

Introducing our new partners



Jan Bordon

Jan Bordon leads Simon-Kucher's Digital Health and health IT activities outside of the US. He furthermore focuses on advising medical device companies on commercial excellence related questions. Jan has worked out of the Simon-Kucher offices in Bonn and Munich (Germany) for more than 9 years. In his work at Simon-Kucher, Jan focuses on pricing and packaging, market access and commercialization strategies for (digital) innovations and solutions as well as supporting healthcare companies in pricing excellence by optimizing internal pricing processes and capabilities on a global and local level. Jan has consulted for leading pharmaceutical and medical device companies across a wide variety of therapeutic areas in the US, Europe, and Japan.

Jan received his degree (diploma) in Business Management with a focus on Marketing and Production Management from the University of Mainz (Germany). In addition, he received his Master in Business Management (MBA) from the Colorado State University.



Diane Cosset

Diane is a member of Simon-Kucher's Life Science practice in Paris. Since joining the team in 2011, Diane's consulting activities have focused on the development and implementation of pricing and market access strategies for pharmaceutical and biotechnology companies in all major healthcare markets. She is also supporting clients to develop market access dossiers and to prepare for price negotiations with payers, especially in France. She is an expert of the French pharmaceutical market and has worked on numerous products across a wide range of therapeutic areas, with special emphasis on oncology, dermatology and orphan/ultra-orphan indications.

She holds a MBA from ESSEC Business School, majoring in finance and accountability and was a member of the Chair of Therapeutic Innovation and the Chair of Health Systems. Prior to joining Simon-Kucher, Diane worked in financial audit and gained experience in a variety of industries, including healthcare industries.



Lisa Sun

Lisa Sun is a partner-elect in the Life Sciences division of Simon-Kucher & Partners in New York. She helps develop and drive commercialization strategies to capture the full value of high-value, innovative products for global pharmaceutical and biotech companies. Her consulting engagements have focused on product launch planning, pricing and market access, and marketing strategies across a range of specialty and primary care therapeutic areas, including extensive experience in oncology and orphan diseases. She has also specialized in affordability solutions, innovative financing, and social impact, applying her prior experience with the Clinton HIV Access Initiative. Lisa assists her clients with both American and international business issues, drawing from her on-the-ground experience in the USA and Germany as well as consulting engagements in more than 30 global markets across Europe, North America, Latin America, Asia, and Africa.

Lisa graduated from Wellesley College with a BA in Economics and speaks English, Japanese, and Mandarin Chinese fluently.

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, commercial strategy and sales. Founded in 1985, Simon-Kucher & Partners has over 205 employees dedicated solely to Life Sciences in 20 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, 30 of the top 35 medical technology companies, and 7 of the top Consumer Healthcare 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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