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SIMON-KUCHER & PARTNERS' LIFE SCIENCES EUROPEAN STRATEGY FORUM AND PRICING & MARKET ACCESS ACADEMY 2018 IN ZURICH

MONETIZING MEDICINES IN A NEW ERA – INNOVATIONS MEET REGULATION

Venue: Radisson Blu Hotel - Zurich Airport

Day 1 Forum: from 10:30 a.m. to 05:00 p.m. (with subsequent network reception) on Thursday, October 11, 2018.

Download a detailed program **here.**

Day 2 Academy: from 09:00 a.m. to 04:15 p.m. on Friday, October 12, 2018.

Download a detailed program **here.**

Staying ahead of peers means investing in new products, capabilities, and innovative business models. Experts from Simon-Kucher & Partners, along with speakers from the industry and payer landscape, will present perspectives and discuss practical solutions about successfully monetizing innovative and new paradigm-shifting therapies in the light of stricter evidence demonstration requirements by HTA bodies.

Our forum, which will be held in English, will give you the opportunity to network, discuss, and share views with experts from across Europe.

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

Germany

German Federal Joint Committee (G-BA) withdraws exception rule for inpatient drugs

On March 16, 2018, the German Federal Joint Committee (G-BA) concluded to change its procedural order to mandate an early benefit assessment and national price negotiations with the National Association of Statutory Health Insurance Funds (GKV-SV) for drugs that are solely used in the inpatient setting. The change will come into effect once the Ministry of Health confirms the ruling.

Prior to this adjustment, pharmaceutical manufacturers were able to apply for an exemption from the early benefit assessment for new drugs used primarily in the inpatient setting and expected to achieve outpatient sales of <€1 million per year (incl. 19% VAT). This enabled the manufacturers to set the drug's list price freely and directly negotiate net prices with hospitals.

Under the new ruling, any drug achieving sales >€1 million per year, regardless of the predominant treatment setting, will be subject to the AMNOG process (early benefit evaluation by G-BA followed by national price negotiations with GKV-SV). The negotiated price will then serve as a ceiling for any subsequent negotiations on a hospital level.

If it is not possible to determine drug expenditures via available pharmacy sales prices, manufacturers are required to provide other data sources (e.g., ex-manufacturer prices or federal extra tariffs (Zusatzentgelte)) to prove that the overall expenditures for the statutory health insurances are below the €1 million threshold.

This decision was driven by a recent trend of statutory health insurances facing a significant number of extra payments to hospitals for inpatient drugs exempted from national price negotiations as DRG payments did not cover inpatient drug expenses.

Once the adjustment to the G-BA procedural has been confirmed by the Ministry of Health, the statutory health insurances hope to gain better control over inpatient drug costs. ◂

Spain

The Spanish Ministry of Health's concern regarding sustainability of public funding resulted in the General Directorate of Pharmacy and Health Products (DGFPS) announcing intentions to change the overall approach for P&R negotiations.

Specific goals outlined by the DGFPS include category-level P&MA decisions and shorter overall decision timelines. The effect of focusing on these goals is clear at two levels: shorter average length of negotiations and an increased number of "non-funding" decisions.

Negotiation length: The average time in negotiations went from 16 months in 2013 to 9 months in 2016. Prior to 2016 many products (e.g. Arzerra for CLL) entered 2-4 negotiations. In comparison, the longest approval since 2016 had a maximum of 23 months of negotiation (Kanuma).

Non funding decisions: From 2013 to 2015 none of the 55 therapeutic positioning reports (IPTs) issued reflect a non-funding decision by the Ministry of Health. However, over the past 3 years, an average of 17% of the drugs evaluated received a negative funding resolution (13% in 2016, 20% in 2017 and 22% in 2018). These decisions were especially prevalent among innovative therapies seeking very high prices, such as Imlygic for melanoma, with a list price of ~90,000€ per year in other European markets.

Future trends

The DGFPS is also seeking innovative funding approaches for high budget impact therapies. Biogen's Spinraza is the first drug evaluated under a proposed new funding approach, where the Ministry of Health moves from a price-centered negotiation to a holistic review. As a result, the funding decision for Spinraza included the following parameters:

- A treatment cost of 400,000€ for the first year of treatment with Spinraza, followed by 200,000€ the subsequent years

- A usage protocol developed by the Ministry of Health in collaboration with the Autonomous Health Governments, in order to ensure homogeneous access
- Cost of treatment for patients under clinical trial covered by Biogen
- A patient registry has been set up to monitor real world evidence on treatment outcomes and determine the success and potential continuation of the program in the future

It is clear that payers are starting to realize the importance of rewarding innovation while ensuring sustainability, and they are certainly moving in the right direction with these new funding initiatives. However, this approach is yet to be leveraged systematically, and it is still too soon to evaluate the real-world impact of this model, and say whether these actions will really lead to a paradigm shift in Spain P&R.

UK

Cancer Drugs Fund update

The new Cancer Drug Fund (CDF) began operating in July 2016, replacing an earlier iteration criticized for budgetary overspend and poorly defined exit criteria. To date, 58 drugs (97 indications) reaching 19,700 patients have received funding via the CDF following NICE approval.

The core purpose of the new CDF is to fund Managed Access Agreements (MAA). MAA provide access to innovative treatments which show promising, but uncertain, cost effectiveness, while further clinical evidence is collected.

For manufacturers, an additional benefit of the CDF is that 'interim funding' can be received prior to NICE final guidance publication. They can opt for this as soon as a NICE positive recommendation is granted in the appraisal consultation/final appraisal document, reimbursing 100% of the agreed price. Furthermore, if the first consultation document is published prior to EMA approval, funding can be initiated immediately following market authorisation.

Financially, the CDF appears to be performing better than the previous iteration, operating well within its yearly fixed budget (£340 million), spending only £141 million in the first three quarters of 2017/18. Breaking this spending down, interim funding and MAA, only account for 18% and 16%, respectively, with legacy indications that are currently being reappraised, accounting for the Lion's share (62% at time of writing). Extrapolating expenditure, an overall spend of approximately £200 million is estimated (60% vs. total fixed budget).

While the CDF represents a successful process change, one shortcoming is the ability for indications to receive a final NICE guidance recommendation, leave the CDF and stop receiving funding. After 2 years in operation only one indication (Adcetris (brentuximab)) has been removed from the CDF. Given that MAA durations are regularly exceeding 2-years, close monitoring and analysis are required to determine the extent to which the new CDF offers a sustainable, effective and time sensitive funding option for innovative oncology products vs. alternative contracting options. Therefore it is crucial for pharmaceutical manufacturers to fully understand the process, timelines and implications of CDF funding prior to launch.

UK

The Accelerated Access Pathway: An impactful opportunity for the most innovative products?

In 2014, the UK government commissioned the Accelerated Access Review (AAR) to investigate steps to speed up access to innovative technologies. In 2016, the AAR presented 18 recommendations, of which a key component was the creation of an "Accelerated Access Pathway" (AAP) for the most innovative and transformative products. The government responded positively, and in November 2017 announced that they would be going ahead with the creation of an AAP.

The AAP aims to utilize existing pathways, but streamline regulatory and market access decisions by up to 4 years for "highly beneficial and affordable innovations". Products set to benefit from the AAP include medicines, medical technologies, diagnostics and digital products. Products will be selected by the "Accelerated Access Collaborative" (AAC), which is made up of representatives from a range of organisations including NICE, NHSE, MHRA and governmental departments, as well as industry representatives. On entering the pathway, clinical and cost effectiveness assessments will be conducted, followed by streamlined commercial discussions with key national bodies. Each innovation selected will receive bespoke case management.

While the AAP introduces an exciting opportunity to truncate the review process, there are important caveats that limit the near-term impact

1. **Competition for pathway access:** Only ~5 products per year are expected to be selected for the AAP, with drugs, medical technologies, diagnostics, and digital products all competing for limited positions.
2. **Cost and therapeutic improvement:** The annual group of products selected will need to meet the requirement of being cost neutral to the NHS; any product considered cost additive must be offset by other products in the basket delivering cost savings. This is likely to pose a particularly large barrier to the pharmaceutical industry: innovative technologies such as CAR-T therapy are likely to be too expensive, while cost neutral 2nd generation drugs and biosimilars are unlikely to qualify as transformative medicines.
3. **Need for leadership:** The entire project has temporarily been put on hold due to the AAC chair, ex-GSK Chief Executive Sir Andrew Witty, standing down from his newly appointed role earlier this year; it doesn't seem that any products will be benefiting from accelerated access any time soon. ◂

Japan

Pricing rules overhaul effective on April 2018

The Ministry of Health, Labor and Welfare (MHLW) introduced an extensive healthcare system reform package in April 2018. This policy overhaul has broad implications for launch pricing and re-pricing of existing drugs. Below is a high-level summary of the most significant changes that were just implemented.

1. **Price cuts can be applied soon after indication expansion:** Until April 2018, price cuts could only be made at the biennial National Health Insurance (NHI) price revision period in April. Even if the sales of a drug increased significantly above the projected level at launch, MHLW was required to delay a price cut for up to 2 years. A prominent example of this policy's shortcoming is Opdivo, which initially earned an orphan indication and then expanded its use to include lung cancer, a disease carried by a much larger population. These sorts of delays have led to calls for change from both the Ministry of Finance (MOF) as well as the MHLW. Starting in April 2018, re-pricing of such products with an annual NHI sales exceeding JPY35b will be conducted up to four times a year.
2. **New Drug Development Premium becomes more difficult to achieve:** The New Drug Development Premium was introduced in 2010 as an incentive for manufacturers to launch innovative drugs in Japan. This premium has acted as a "protection" from regular NHI price cuts for innovative drugs, so that the NHI price level can be maintained while a drug is still patent-protected. However, since its introduction in 2010, almost all new drugs were granted the premium regardless of whether they were innovative. Starting in April 2018, MHLW has introduced stricter drug requirements to qualify for the premium. Now, the scope of eligible products are narrowed down to (a) orphan drugs, (b) drugs developed at government requests, (c) drugs that were granted pricing premiums because of their clinical efficacy, and (d) drugs with new mechanisms of action. As a result, the number of products eligible for the New Drug Development Premium decreased from 823 to 560 products.
3. **Overseas Price Adjustment (OPA) can be applied once after launch:** Previously, OPA could only be applied at the time of initial NHI listing. This limitation was especially problematic in cases where a new drug was priced by the so-called "Cost-calculation method," which essentially sums manufacturing costs and is highly dependent on overseas prices. For example, Opdivo was launched in Japan, ahead of all other countries, and overseas prices were not available at that time. Starting in April 2018, a new rule has been introduced that makes it possible to conduct OPA once after launch if no OPA was possible at the initial launch. It should be pointed out that the post-launch OPA only allows downwards price adjustments.
4. **Pilot cost effective assessment (CEA) has been introduced:** MHLW is aiming to introduce a CEA system for re-pricing of drugs after launch based on their cost effectiveness. Under this system, the cost effectiveness of selected drugs and medical devices with large markets, especially those priced by the cost-calculation method, are re-evaluated according to the new CEA policies. The NHI prices of these selected products are revised based on the results. So far, the adjusted price range can only be within

the price premium that was granted at launch, so the overall drug prices remain relatively stable. To introduce the new system, a pilot CEA program was implemented: in 2018, 3 products were re-priced based on their cost effectiveness. At the same time, the MHLW has been conducting discussions on the details of the CEA system implementation, aiming to reach final conclusions about scope and evaluation method details by April 2019.

MHLW is striving to find the balance between maintaining a sustainable healthcare system and giving sufficient incentives for the development of innovative treatments. The new pricing rules from April 2018 have led to strong criticism from manufacturer side. For example, PhRMA Chairman Robert A. Bradway sounded an alarm over the outlook of Japan's pharma market, claiming the reform has eroded its reputation for predictability and added a "big question mark" about its attitude towards biopharmaceutical innovation. In contrast, the MOF is pushing for even stronger measures to further cut healthcare expenditures. Both sides of the debate will be monitoring the situation closely as the impact from these changes becomes clearer over time. ◂

Canada

Proposed changes to drug pricing in Canada

The Canadian Department of Health proposed new amendments to the Patented Medicines Regulations for the Patented Medicines Prices Review Board (PMPRB) in December 2017. The Department of Health prefaced these amendments with the claim that the PMPRB is not fulfilling its mandate to protect Canadian citizens from excessively high prices given that Canada has among the highest drug prices globally.

PMPRB proposal

The proposed amendments to the PMPRB includes a more robust risk-based framework of drug price evaluation built along 5 pillars:

1. **Interim international price reference test:** The PMPRB will test the list price of a new drug against the list prices in 12 countries. Prices exceeding the median list price will be considered potentially excessive
2. **Categorization:** The PMPRB will identify drugs as high, medium, or low priority based on the anticipated impact on Canadian patients. Considerations include therapeutic improvement, therapeutic alternatives, and cost relative to a GDP threshold
3. **High priority drug review:** The PMPRB will test high priority drugs for "excessivity" by examining cost effectiveness data, including the marginal cost of a QALY and the total cost impact to payers over 3-5 years. If the drug fails these tests, the patentee must try to prove that their price is not excessive. If the price is found to be excessive, the public ceiling price will be set by international price referencing
4. **Medium and low priority drug review:** The PMPRB will test the prices of medium priority drugs against the median public list prices in the PMPRB12. Each successive entrant will be required to reduce their price relative to the price of the drug that came before it. Low priority drugs will not be tested
5. **Re-benching:** There will be periodic "re-benching" to ensure that previous price determinations remain relevant

Key impacts

Under the new amendment, the PMPRB will redesign the list of countries used as price references in Canada. The PMPRB will expand their list from 7 countries to 12 by replacing the US and Switzerland with 7 new markets. The PMPRB12 will be composed of Australia, Belgium, France, Germany, Italy, Japan, the Netherlands, Norway, South Korea, Spain, Sweden, and the United Kingdom. The net impact will be overall lower price references.

The second major impact is that the PMPRB will assess the value of new drugs by reviewing cost-effectiveness analyses like those submitted by the Canadian Agency for Drugs and Technologies Health (CADTH) and also consider payer-level cost impacts.

Heath Canada estimates that these key changes will deliver a net benefit of CAD$12.6B (NPV) to Canadians over 10 years, driven primarily by lower expenditure on patented drugs. This net benefit takes into account a total benefit to the healthcare system and lower drug expenditure of $21.3B and an industry cost around CAD$8.6B (NPV). There has been no action from the PMPRB yet, but they are expected to officially consult on a revised set of proposed guidelines in the spring of 2018, with an implementation goal of 2019. ◂

China

In 2018 China has continued to drive forward its healthcare reform program, with key developments including a restructuring plan for government agencies and the removal of cancer drug tariffs.

Agency restructuring

In March, China's State Council released a massive cabinet reshuffle plan, with select changes likely to impact market access and reimbursement of foreign drugs and medical devices. Key changes include:

- **China Food and Drug Administration (CFDA), along with two other administrations, will be merged into the National Market Supervision Administration (NMSA),** which will be responsible for the administration of market-access measures in China, anti-monopoly enforcement, and certification of product quality. The CFDA, becoming China Drug Administration (CDA) under NMSA, will specifically address the regulation of pharmaceuticals, medical devices, in vitro diagnostics, and cosmetics across the lifecycle of products. The integration of agencies will strengthen government supervision of pharmaceutical and medical device markets, streamline the registration and approval process, and lead to more timely and standardized inspection and post-market surveillance.
- **National Health and Family Planning Commission (NHFPC),** the group that was responsible for drafting laws, regulations, plans and policies related to public health is abolished. Instead, a new body, National Health Commission will be responsible for formulating national health policies, coordinating and advancing medical and healthcare reform, establishing a basic national medicine system, supervising and administering public health, medical care and health emergencies, as well as organizing family planning services. The restructure aims to promote the Healthy China initiative and ensure the delivery of comprehensive lifecycle health services to the Chinese people.
- **State Medical Insurance Administration** will be established and responsible for formulating and ensuring the implementation of policies, plans and standards for medical insurance, maternity insurance and medical assistance. The administration will also supervise and administer related medical care funds, improve the platform for trans-regional medical services and expense settlement, and organize related parties to fix and adjust prices for drugs and medical services, amongst others.

Cancer drug tariffs

Starting from May 1st, 2018, the Chinese government will remove import tariffs on 28 drugs, including those essential to the treatment of cancer

- **Up to a 20% price drop is expected for imported cancer drugs** resulting from the removal of the 4-6% tariff combined with the inclusion of these innovative drugs on the national medical insurance list
- **China is also seeking to stimulate sales of domestic drugs in the long term** by driving local development of treatments. Domestic drug development will be fueled by an accelerated approval process, a plan to lower taxes on cancer drug production, and enhanced intellectual property rights.

Monetizing digital therapeutics

Unique ways that healthcare manufacturers are monetizing digital therapeutics

By David Lee, Steven Chase, and Ian MacPherson

Digital therapeutics have arrived on the healthcare scene, and are being integrated into clinical practice across a wide range of diseases, from substance use disorder to chronic disease management. All of these companies have confronted a key commercial question: What is the best way to monetize digital therapeutics?

colourbox/-

What are digital therapeutics?

Digital therapeutics are a new class of healthcare products that use digital technology to treat medical conditions. They are often confused with "digital health solutions," but not all digital health solutions are digital therapeutics (Figure 1). We view digital therapeutics as a subset of digital health solutions, distinguished by their focus on driving clinical outcomes for patients. This focus on clinical outcomes also distinguishes digital therapeutics from popular consumer health-oriented technologies such as step-counters and calorie-counters (e.g., FitBit and MyFitnessPal, respectively).

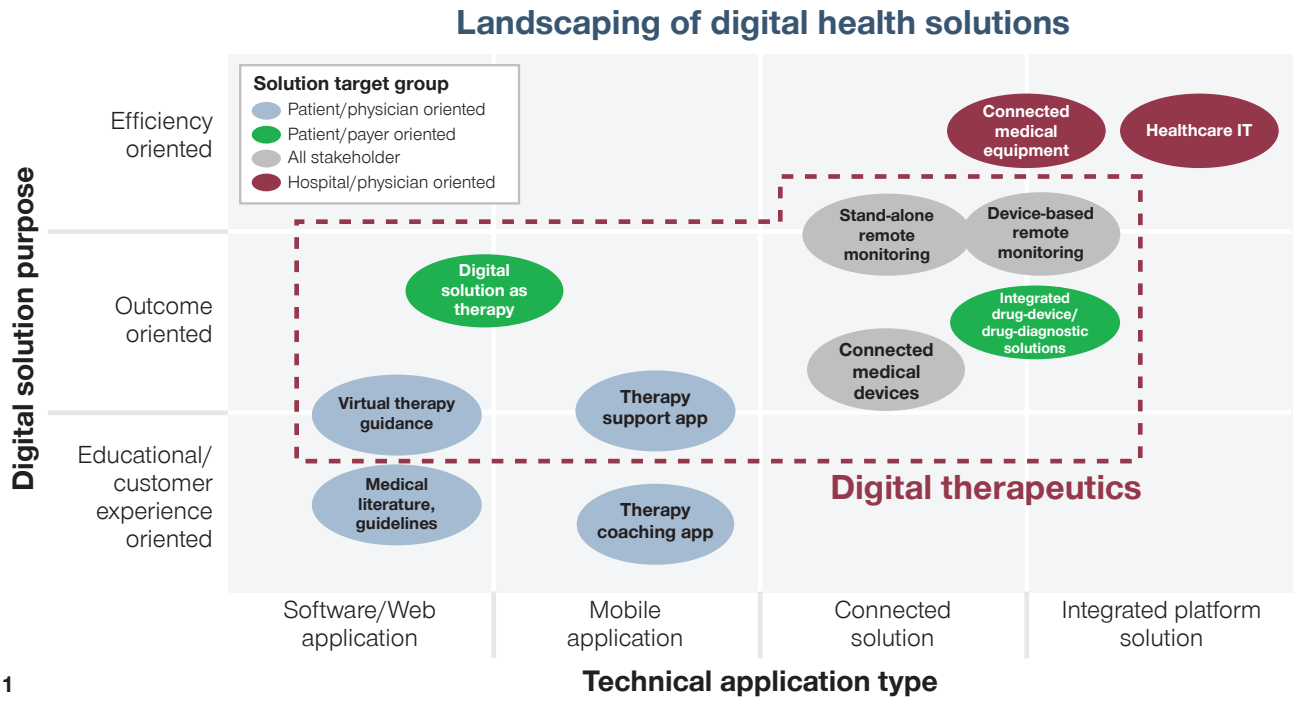


Figure 1

Digital therapeutics encompass a wide range of product types, including mobile apps, wearable devices, and telemedicine platforms. All of these types of therapeutics can help drive clinical outcomes, but they differ in the strength of their claims (Figure 2).

	Digital services	Adjunctive digital therapies	Drug-replacement
Description	▪ **Support or improve** patient habits and behavior ▪ **Independent** of traditional pharmaceuticals ▪ **May have peer-reviewed evidence** of clinical benefit ▪ **Not regulated** by the FDA	▪ **Adds value to existing** pharmaceuticals ▪ **Improves clinical benefit** of the associated drug by, for example, tracking adherence ▪ **Requires FDA approval /** clearance for claims clinical benefit and safety	▪ **Direct, clinical benefit** from the digital product ▪ **Can be standalone therapy** or used in conjunction with a traditional drug ▪ **Approved and regulated** by the FDA similarly to traditional drug therapies
Examples	**Omada Health** **Omada program**: a program focused on changing habits to reduce the incidence of chronic disease **Roche** **mySugr**: a diabetes management platform including logging, analysis, and coaching to improve disease management, but has not received FDA approval for dosing recommendations	**Proteus Digital Health** **ABILIFY MYCITE**: a drug-device combination to manage adherence to orally-taken Abilify **Propeller Health** **Propeller**: an add-on device for tracking adherence to inhaler-based medications	**Pear Therapeutics** **THRIVE**: a prescription therapy for schizophrenia used in conjunction with a traditional therapeutic **Pear Therapeutics** **reSET**: a stand-alone prescription therapy for substance abuse disorder **Akili Interactive** **AKL-T01**: a video game based prescription therapy for attention-deficit / hyperactivity disorder

Figure 2: Spectrum of digital therapeutics

We observe three tiers of digital therapeutics, in order of increasing strength of clinical claims:

- *Digital services*. Digital services typically aim to modify patient behavior in some way. These digital therapeutics will often publish studies that show that their therapeutic can help drive a clinical outcome but will not claim a specific therapeutic benefit. A well-known digital therapeutic that falls under this tier is Omada Health's digital behavior coaching platform that aims to help patients reduce their risk of diabetes and other chronic diseases. The digital therapeutic is a 16-week online program that seeks to promote weight loss by guiding participants through nutrition and daily activity changes. While Omada reports that their average participant loses weight during the course of the program, the company stops short from making the claim that the platform reduces the participant's 5-year risk for Type 2 diabetes, stroke, and heart disease.
- *Adjunctive digital therapeutics*. The next tier of digital therapeutics support the use of traditional therapeutics. These therapeutics can assist in improving clinical outcomes, but they do so indirectly by enhancing the effectiveness of the traditional therapeutic and typically stop short of claiming a therapeutic benefit. An example of this tier is Proteus Digital Health's Discover medication adherence platform. The system consists of a tiny ingestible sensor that is incorporated into a traditional pharmaceutical, a small wearable sensor patch that the patient places on their body, a mobile patient application, and a provider online portal. Proteus has recently partnered with Otsuka to manufacture Abilify MyCite, which uses the Discover technology. While Proteus is very likely to contribute to improved adherence and thus improved efficacy of Abilify (aripiprazole, an atypical antipsychotic), they do not claim therapeutic benefit from using their platform itself and instead make their claim through the Abilify MyCite FDA label.
- *Digital drug replacements*. These therapeutics seek to provide a clinical benefit through the digital technology itself, and not through any other source. Because of this, digital drug replacements require significant scrutiny by way of clinical trial results and FDA-review. The first-to-market (and only) digital therapeutic that falls in the digital drug replacement category is Pear Therapeutics' *reSET* application for treating substance use disorder (SUD). The company calls *reSET* a prescription digital therapeutic because the app was proven to promote a higher rate of abstinence in a clinical trial than the standard of care in SUD (outpatient face-to-face counseling) and the results were submitted and approved by the FDA. Prescription digital therapeutics operate very similarly to traditional therapeutics, as they are prescribed by physicians and follow many of the same distribution and payer coverage pathways.

> "A growing number of major pharmaceutical and healthcare companies including Roche, GSK, and Novartis / Sandoz have recently invested in or partnered with digital therapeutic companies."

What value do healthcare leaders see in digital therapeutics?

While digital therapeutics is a relatively new field that is largely dominated by small players, large healthcare, pharmaceutical, and insurance companies have begun to take interest in this space. Recently, Cigna began offering Omada Health's product to their plan subscribers to control costs through chronic disease prevention, and cemented this relationship by leading a Series C round of investment worth $50 million. This and similar investments signal that there is significant interest in a wide spectrum of digital therapeutic products and the associated positive patient and financial outcomes.

A growing number of major pharmaceutical and healthcare companies including Roche, GSK, and Novartis / Sandoz have recently invested in or partnered with digital therapeutic companies.

- *mySugr offers Roche new monetization options for their diabetes management portfolio*. The mySugr

platform offers automated logging, analysis, and reporting for diabetes management complementing Roche's line of Accu-Check monitors. This move brings Roche into the growing mobile diabetes management market by acquiring one of the current market leaders. While Roche currently plans to keep the platform open to competitor's blood glucose monitors, they gain several options to monetize their unique position of owning both the digital and physical product. First, they have begun to offer packages of their monitors, test strips, and virtual coaching through the app and are able to do this more economically by vertically integrating. Second, the platform offers access to a large, targeted population to whom Roche can sell monitors. Third, Roche can engage mySugr users with new services, such as insulin dosing recommendations, as they rollout via the app. While there is the risk of new diabetes management platforms being created, mySugr's significant market share and perceived best-in-class offering mitigate this downside for Roche.

- *Propeller Health improves outcomes in asthma and COPD, offering novel contracting opportunities to GSK*. The Propeller platform (which is compatible with inhalers other than those produced by GSK) tracks medication use to monitor adherence, provides insight into symptom causing factors, and connects patients and physicians by sharing relevant data. Use of the platform increases adherence and improves patient outcomes. GSK will utilize this partnership to increase sales and revenue through innovative adherence-based contracting with payers and evidence generation to drive prescribing by physicians across their inhaler-based portfolio. The primary risk is that payers and physicians may not engage with adherence management solutions, but Abilify and Proteus suggest strong interest for these systems in the market. Additionally, GSK can license this technology to other inhaler-based medication manufacturers, balancing platform growth with competitive concerns. GSK and Propeller health have been partnered since 2015 for the development of a clip-on sensor to track adherence for the ELLIPTA Inhaler and extended this collaboration in August 2017. Further, GSK and Propeller are continuing research and development on the platform to show how improved adherence can improve patient outcomes.
- *Pear Therapeutics' reSET and THRIVE makes Novartis the leader in prescription digital therapeutics*.

Earlier this year, Novartis, and subsidiary Sandoz, partnered with Pear Therapeutics to develop and commercialize digital therapeutics for the treatment of psychiatric disorders. With this partnership, Novartis / Sandoz adds value, credibility, and market access to *reSET* when it enters the market as the first drug-replacement digital therapeutic, while adding significant value to Novartis' brand by demonstrating their leadership in this new market. These digital prescription products may have additional upside compared to traditional pharmaceutical acquisitions through data generation, innovative contracting, and some of the other monetization schemes described below. The products associated with this partnership, including reSET, reSET-O, THRIVE, and a therapy for multiple sclerosis, offer multiple potential future platforms with significant upside for Novartis, and lower downside risk compared to traditional pharmaceuticals as the investment required to reach the market is likely lower. Sandoz specifically will work with Pear for the commercialization of their *reSET* app for the treatment of SUD, while Novartis will help Pear develop THRIVE for the treatment of schizophrenia. Novartis has long been involved with Pear including involvement in Series A and B funding in February 2016 and January 2018, respectively. Their investment in Pear is part of Novartis's larger mission of developing technologies to monitor patients in real time, increase adherence, and improve outcomes.

> "The primary risk is that payers and physicians may not engage with adherence management solutions, but Abilify and Proteus suggest strong interest for these systems in the market."

As digital therapeutics demonstrate their upside as supportive services, adjunctive therapies, or drug-replacements, the influx of money and partnerships from major players in the healthcare industry are likely to continue.

How can companies monetize digital therapeutics?

But how should companies select from the broad range of monetization opportunities that are available to digital therapeutics?

We see two core types of monetization that any product can leverage: *explicit monetization* and *implicit monetization*. Explicit monetization of a product is characterized by the direct increase in revenue from the product itself. Implicit monetization of a product is often characterized by non-revenue benefits including higher adoption rates, greater customer engagement, or more robust data capture.

> “While reimbursement as a prescription drug will not be available to all digital therapeutics, it will be open to drug-replacement therapies like Pear Therapeutics’ reSET. Additionally, traditional reimbursement may be possible for some adjunctive therapies where the therapy is not linked to a specific drug.”

Explicit monetization: Monetizing the digital therapeutic itself

Here are a few of the top explicit monetization opportunities:

- *Traditional pharmaceutical or medical technology reimbursement*. Some digital therapeutics will have the opportunity to be reimbursed through insurance plans in the same way as drugs or medical technologies. While reimbursement as a prescription drug will not be available to all digital therapeutics, it will be open to drug-replacement therapies like Pear Therapeutics’ *reSET*. Additionally, traditional reimbursement may be possible for some adjunctive therapies where the therapy is not linked to a specific drug. WellDoc’s BlueStar, which provides real-time coaching to individuals living with type 2 diabetes, is reimbursed by several insurance companies as a medical benefit. Additionally, this monetization pathway is compatible with several of the other explicit and implicit schemes described below.
- *Offer multiple versions or a customized offering of the digital therapeutic*. While it is often a goal of digital therapeutics to seek and obtain payer coverage as seen above, digital therapeutics bring the unique opportunity to develop and bring to market varying tiers of their therapeutic. For example, companies that develop prescription digital therapeutics can create “lite” versions of their therapeutic that are available for cash pay, in order to capture patients who do not have insurance coverage. While companies will need to ensure they are not eroding the value of the prescription version of the therapeutic, there is the opportunity to monetize their therapeutic differently for consumer vs. prescription patient segments.
- *License the digital platform to other manufacturers*. Digital therapeutic manufacturers with a proven platform may be years ahead of manufacturers who have not begun developing their own platforms. The original therapeutic could monetize their digital platform by collecting licensing fees from the interested manufacturer. While the digital platform owner would not want to license the technology to a company producing a therapy in the same therapeutic area, strategic out-licensing would enable monetization in a new market.
- *Sell data to other manufacturers*. Because digital therapeutics provide a stream of patient engagement and clinical data, there may be an opportunity to sell

access to anonymized and aggregated results to other manufacturers. Apps like Roche's mySugr app collect large quantities of patient efficacy and utilization data regarding patients' diabetes care management. This data would be incredibly valuable to any manufacturer in the diabetes field, as they can learn from the data and incorporate the insights into their own therapeutics. Digital therapeutic manufacturers in this case hold the "key" to this data, and there may be a business case for selling this data as an additional stream of revenue from the digital therapeutic.

Implicit monetization: Indirectly monetizing the digital therapeutic

Here are a few of the top implicit monetization opportunities:

- *Creating a strategic competitive advantage from artificial intelligence (AI)*. AI is rapidly being integrated into businesses' strategies and everyday operations. One of the major requirements for having a competitive advantage with AI is to have a proprietary data source that cannot be easily replicated. Digital therapeutics create the opportunity to collect this proprietary data through the therapeutic and use it as training, input, and feedback to data to deploy AI effectively. For example, WellDoc's BlueStar diabetes management platform can collect massive amounts of data on glucose levels and insulin dosing, and then use this proprietary data to improve insulin dosing through artificial intelligence as more and more data becomes available.
- *Innovative contracting*. One of the key barriers for traditional therapeutics in executing innovative contracts is capturing the data that will be used to track performance. For example, contracts based on medication adherence can be very hard to create and enforce because adherence data is often difficult or impossible to collect. The data from digital therapeutics significantly improves the ability to execute innovative contracts because the data is captured just through use of the digital therapeutic itself. This data can then more easily be relayed to payers to support the metrics chosen for an innovative contract.
- *Improved value story and P&MA negotiation*. Improved data availability also creates interesting opportunities to present clinical efficacy data to payers to help prove the value of the product to payers. Demonstrating real-world efficacy of therapeutics once the treatment is used outside of a hyper-controlled clinical trial setting along with long term product use is key to supporting the core value story. The data capture from digital therapeutics allow payers to run efficient and valuable pilot-runs of digital therapeutics before fully covering it on their plan. Manufacturers can take advantage of this by participating in the pilot and proving the value of their therapeutics to payers in a real-world setting.
- *Increased product engagement through updates and upgrades*. Digital therapeutics allow manufacturers to rapidly update their products over the lifecycle of the product, unlike traditional pharmaceuticals which must undergo long periods of product development to make product changes. Digital products require a simple software or application update that can be included in the next "version" update of the app, which can happen as often as the manufacturer would like. The ability to update digital therapeutics over the course of the product lifecycle gives the sales teams improved sales pitches to bring to providers on sales calls. With updated products, they have new features and capabilities that they can bring to providers in order to convince them of the value of the therapeutic. Digital therapeutics have the ability to improve over time as the manufacturer learns what patients and providers desire, and sales teams can leverage this improvement during their sales pitches.

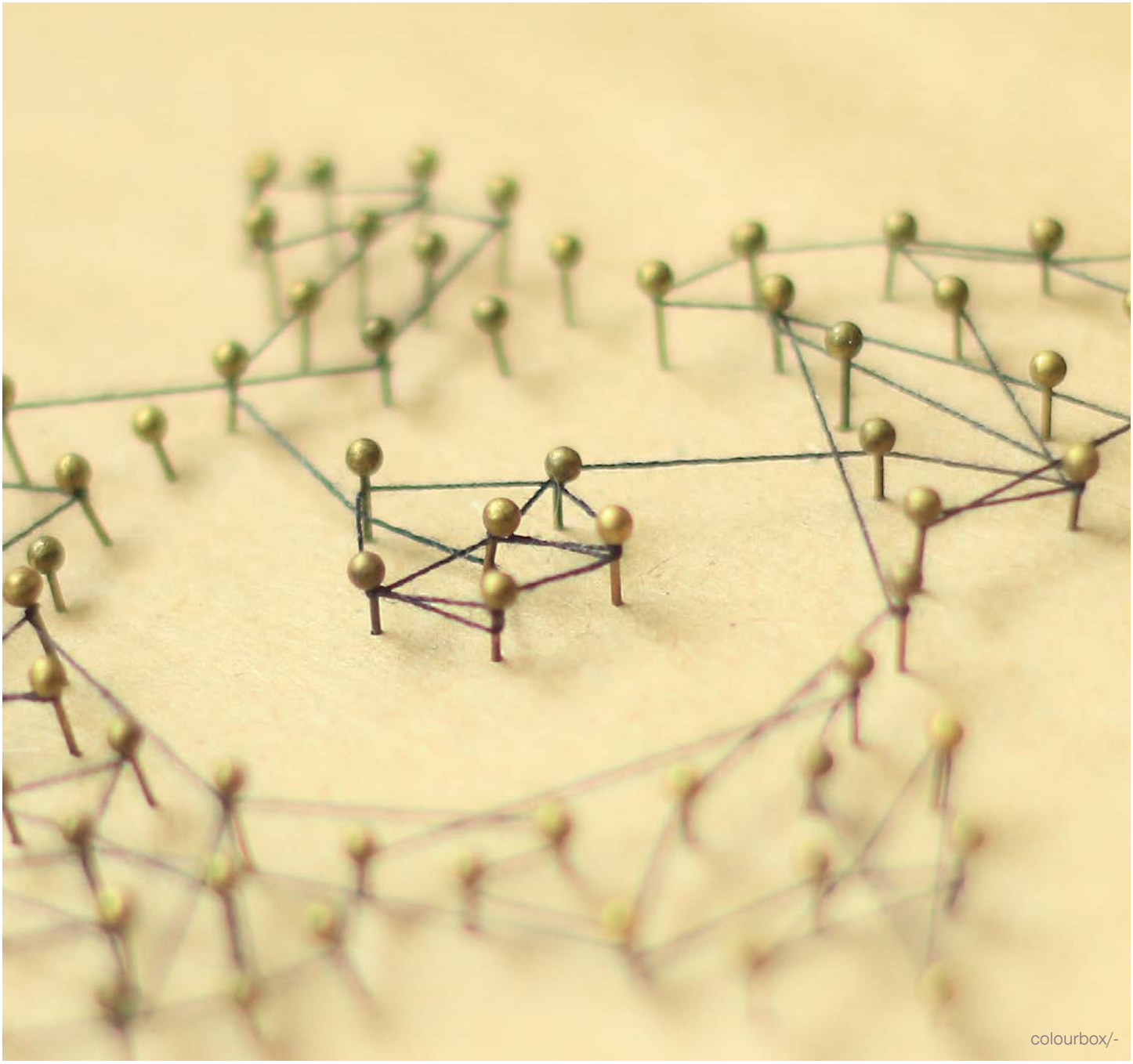
Summary

The adoption of digital therapeutics continues to grow, and we believe that pharmaceutical companies, medical technology companies, and payers will continue to invest in this new class of treatments. The unique features of digital therapeutics offer manufacturers a diverse array of both explicit and implicit monetization opportunities, providing novel revenue streams. Carefully selecting the right monetization pathway is critical to unlocking the full potential of digital therapeutics. ◂

Organization of the Pricing and Market Access Function

Success factors for organizational set-up, operational effectiveness, and talent management, including specifics for German affiliates

By Stephan Schurz and Maximilian Rödder



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Introduction

The Pricing and Market Access (P&MA) function plays a critical role throughout a drug's lifecycle. During clinical development, P&MA input is crucial for prioritizing drugs which deliver the highest value and for shaping clinical trials based on payer requirements. From early development to beyond loss of exclusivity, the P&MA function supports optimal pricing and market access which lay the foundation for patient access and commercial success.

With pharmaceutical executives and managers looking to optimize the organization and operations of the P&MA function, fundamental questions emerge. Is the P&MA function set up in the right way? Do P&MA professionals focus on all relevant activities at the right time? Are the required P&MA competencies covered and what is needed for a sustainable talent management in P&MA? These topics are outlined in this article building on the experience and expertise Simon-Kucher & Partners has developed through numerous projects in this area.

Throughout the article, the authors highlight organizational success factors which are applicable on the global, regional and local level. Since the introduction of the "Pharmaceuticals Market Reorganization Act" in Germany (Arzneimittelmarktneuordnungsgesetz – AMNOG), P&MA has become an increasingly challenging and complex endeavor further raising the importance of organizational excellence in German affiliates. Consequently, specific best practices for P&MA teams in Germany are highlighted.

Pricing and Market Access Excellence

P&MA Excellence rests on three pillars: organizational set-up, operational effectiveness, and talent management (fig. 1).

Organizational set-up:

The organizational set-up of a P&MA function provides the foundation for P&MA activities on the global, regional, and affiliate level. It is defined along the organizational dimensions structure, reporting, and sizing.

Structure and reporting on the global and regional level

The P&MA organization structures in top 20 pharmaceutical companies frequently combine elements of functional and matrix design. Each structure is unique as its characteristics have evolved over time driven by the company's strategy, portfolio, corporate culture, and history of mergers and acquisitions (fig. 2).

A variety of parameters can be used to assess the organizational set-up of the P&MA function on the global and regional level.

Visibility and impact: The proximity of the P&MA function to the CEO supports the elevation of P&MA topics onto the executive agenda. In many companies, the highest P&MA representative is at least three steps below the CEO as depicted for "Company A" and "Company B". Establishing an Executive Vice President (EVP) who is re-

Figure 1

sponsible for P&MA and is only two steps below the CEO, as shown for "Company C", allows for increased visibility of P&MA-related business questions.

P&MA capability development: In many successful companies all P&MA activities are overseen by one senior executive. This approach allows for effective P&MA capability building and minimizes redundancies in executed tasks. This set-up also enables companies to leverage P&MA opportunities arising in the context of a broader product portfolio more easily.

Alignment of P&MA and evidence strategy: Best-in-class companies guarantee that P&MA and Health Economics and Outcomes Research (HEOR) work hand-in-hand to enable payer-rationalized trial design which ultimately maximizes the P&MA potential of a drug. Consequently, companies such as "Company C" establish a single Senior Executive who oversees global P&MA as well as global HEOR. In cases in which HEOR has a different reporting line, e. g., for "Company A", it is particularly important to institutionalize cross-functional collaboration between P&MA and HEOR to guarantee that separate reporting lines do not lead to misalignment between evidence strategies and P&MA requirements.

Cooperation with company-internal business partners: A business unit driven set-up of P&MA teams, as shown for "Company B", naturally links P&MA to the respective commercial teams. In case of a less institutionalized link between P&MA and commercial teams, it is crucial to establish regular touch points between both sides to avoid "silo mentalities" and the perception of P&MA being distant from the business.

Cooperation between P&MA teams on the global and regional level: An optimal organizational set-up between P&MA teams on the global and regional level enables alignment on key objectives, a systematic exchange of information as well as sustainable talent management across both levels, including job rotations and succession management. Consequently, as shown for "Company C", many successful P&MA organizations establish a dotted reporting line between regional and global P&MA.

While there is not one ideal organizational structure for a P&MA function, optimal solutions exist on a company-individual level. Any solution should consider the status quo of the organization as well as the company's strategy, portfolio, and corporate culture.

"An optimal organizational set-up between P&MA teams on the global and regional level enables alignment on key objectives, a systematic exchange of information as well as sustainable talent management across both levels, including job rotations and succession management."

Organizational structure and sizing for P&MA teams in Germany

In German affiliates, five P&MA functional areas can frequently be identified:

- Market access and dossier development for The Institute for Quality and Efficiency in Health Care (IQWiG) and The Federal Joint Committee (G-BA)
- Strategic pricing and price negotiations with The Head Organization of the Association of Statutory Health Insurances (GKV-SV)
- Operational pricing (including price management for established products)
- Regional payer management (including individual sick fund contracting, physician associations)
- Hospital payer key account management and contracting (including terms and conditions)

To ensure a consistent P&MA strategy and a seamless execution, most best-in-class companies locate all of these functional areas within one organizational unit. Thus, the

German P&MA leadership can manage all P&MA activities holistically – from list price to net price, from early development to beyond loss of exclusivity.

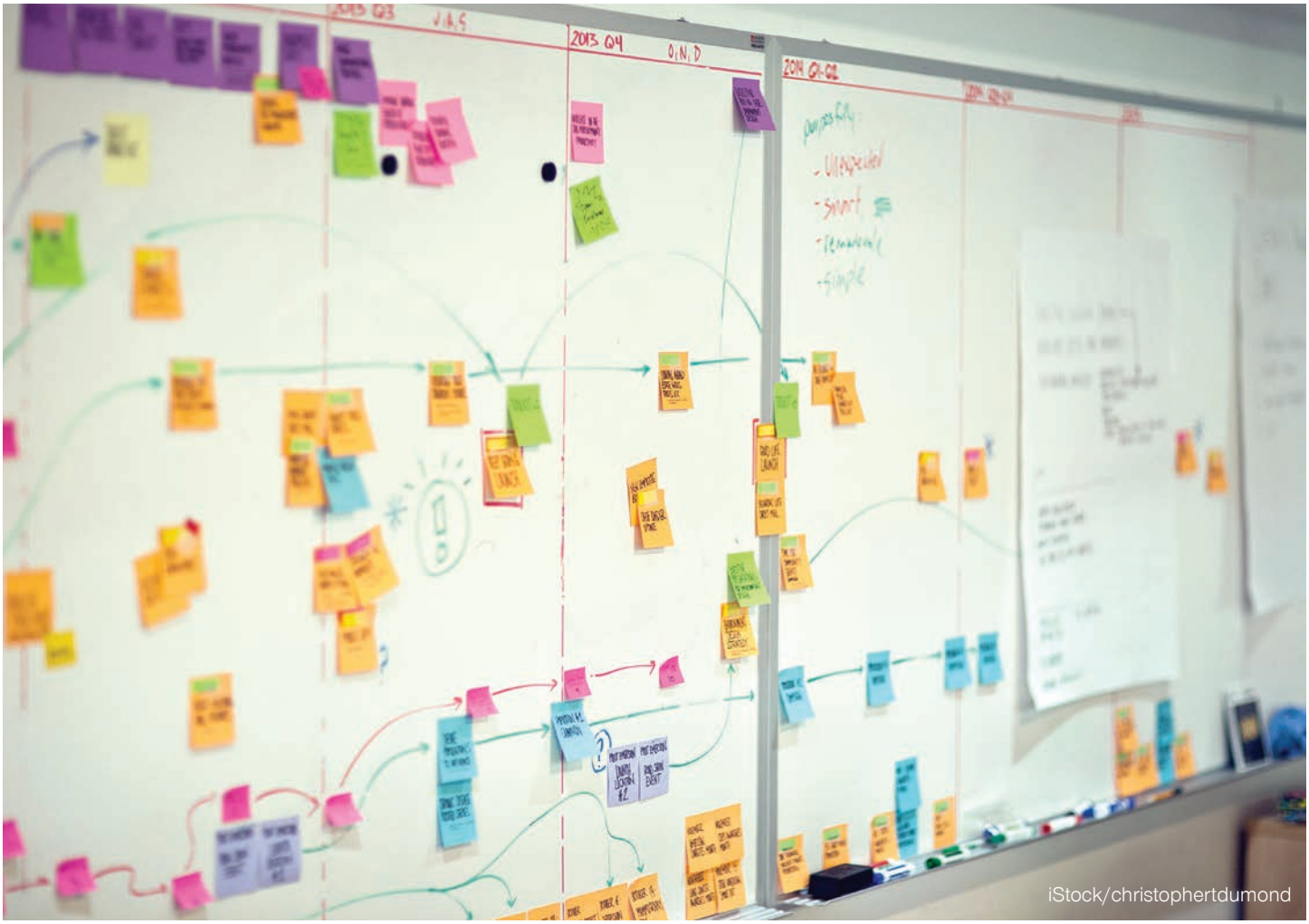
Some rules of thumb for the appropriate size as well as the degree of specialization of affiliate P&MA teams can be deducted from business practice. As a general guide, a company should employ about 5–6 P&MA full time equivalents (FTEs) per 100 million Euro yearly revenue in Germany. This includes all P&MA related jobs which range from market access to strategic and operational pricing, contract management, and payer field force/payer key account managers. For a company with yearly revenue of 500 million Euros, this would lead to a P&MA team of 25–30 professionals who would be capable of handling all five functional areas. Such a specialized set-up is favorable for companies which have several products in their portfolio and a number of product candidates in their pipeline. For smaller companies and (biotech) companies launching their first product in Germany, a less specialized set-up would be appropriate. In such a case, a variety of these tasks is typically outsourced to external service providers with the necessary expertise and specialization in the respective P&MA field. Nonetheless, best-in-class companies with a smaller P&MA presence in Germany still make sure to understand all payer requirements as early as possible and have a dedicated team with the appropriate overview to steer the relevant P&MA activities and therefore lay the foundation for successful price negotiations and commercialization.

Operational effectiveness

The key questions needing to be clarified to improve operational effectiveness focus on the "What?" "When?" "How?" and "Who?" of P&MA activities. Best-in-class companies clarify these questions for all areas of P&MA activities and throughout the entire lifecycle of a drug – "from cradle to grave".

Activities

"What?" relates to the scope of P&MA activities that are necessary for successfully developing an asset from a



iStock/christophertdumond

P&MA perspective. It is crucial to make sure that resulting deliverables are aligned with expectations from internal business partners. In fact, Simon-Kucher observed that best-in-class companies regularly assess whether all P&MA deliverables optimally contribute to commercial success and if any gaps in terms of activities and deliverables exist.

Processes

"When?" and "How?" deal with approaches and processes that support efficient task execution. Consistent approaches to all activities warrant reliable, high-quality P&MA input throughout a drug's lifecycle while specific how-to-guides and templates ensure that materials are no longer highly variable. A systematic use of customized tools can also be helpful in this endeavor.

Roles and responsibilities

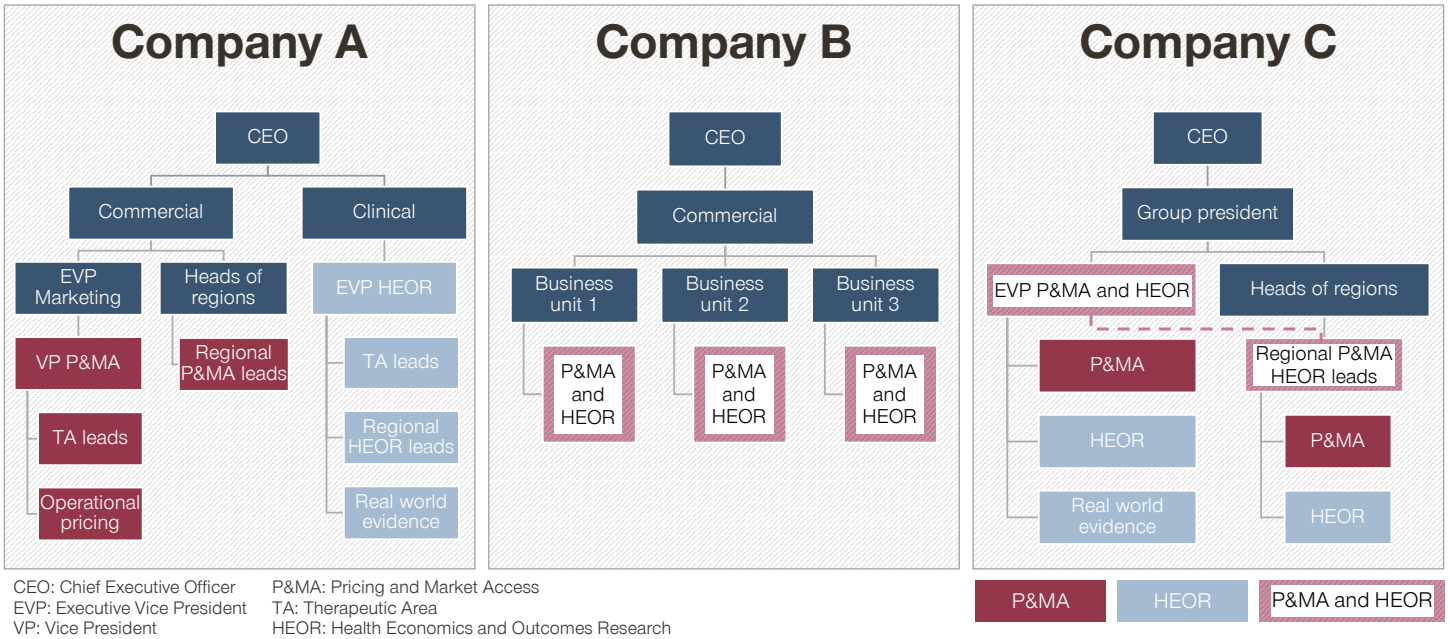
"Who?" relates to a transparent assignment of roles and responsibilities to support effective task execution and decision-making. It should be determined which parties are responsible, accountable, consulted, and informed (RACI) for each activity. Furthermore, the clear definition of the P&MA function's role in key committees is advisable in order to create cross-functional touch points and support function visibility, e. g., by ensuring that P&MA has a seat in all key clinical development and brand strategy committees.

Since Germany is an example for a country with a relatively wide range of P&MA topics, it is crucial that the representative of the German P&MA team in the brand strategy committee is able to speak to all P&MA topics which might be relevant for a given product at a given point in its lifecycle. In theory, this can be achieved by appointing different P&MA professionals depending on the stage in the lifecycle, assuming that the P&MA focus tends to shift from dossier development towards price negotiations with GKV-SV and hospital/regional payer contracting. In practice, a variety of P&MA topics can be relevant at any point in time. Therefore, best-in-class companies nominate P&MA professionals who have the required breadth of experience and business sense for this role. These companies also articulate the requirements for this important role in a job description.

All in all, summarizing the scope of P&MA activities, processes, as well as roles and responsibilities in a tailor-made P&MA framework is widely regarded as a success factor for P&MA. Such a framework sets specific expectations, establishes accountability for key activities, and fosters internal alignment. It encourages cross-functional collaboration to guarantee that the P&MA perspective is considered throughout a drug's lifecycle, starting in early clinical development. To facilitate smooth onboarding and consistency in task execution, key P&MA activities can also be described in a detailed P&MA handbook.

Pricing governance

When it comes to operational effectiveness, one topic of particular importance is pricing governance. Pricing governance is about systematically managing prices and es-



CEO: Chief Executive Officer
EVP: Executive Vice President
VP: Vice President
P&MA: Pricing and Market Access
TA: Therapeutic Area
HEOR: Health Economics and Outcomes Research

Figure 2

tablishing a framework to enable this price management – particularly to steer, implement, monitor, and report on pricing. Smart pricing governance allows for effective and efficient price control as it balances flexibility for business optimization with safeguarding target and floor prices. It aims at capturing a drug's full price potential without stifling business opportunities or overwhelming the organization with internal price approvals. Consequently, escalation processes for price decisions are clearly defined.

Three types of price approval workflows can be differentiated: pricing strategies, launch price requests, and price change requests. It is important that list and net prices are both subject to pricing governance, since list prices impact international price referencing and net prices impact profit. Another success factor is the increase of governance scrutiny with the commercial importance of each brand. The tiering of products, e. g., based on lifecycle stage and/or annual revenue, can be key in this context. This approach follows the principle of optimal pricing governance which is to decentralize where possible and require only senior management approvals when needed to maintain optimal prices.

Depending on the product portfolio, additional aspects need to be considered for developing optimal pricing governance. For example, biosimilars require a more proactive approach and frequent reviews as well as adjustments of price targets and floors as this business is characterized by shorter negotiation cycles and the risk of a low-priced commodity market.

> "A good business sense and strong communication skills are required for establishing successful relationships with payer customers and with stakeholders across the organization."

Talent management

The third pillar of P&MA Excellence is talent management. Successful P&MA professionals possess a combination of P&MA expertise, a good business sense and strong communication skills.

On the one hand, specific P&MA expertise is a prerequisite for developing optimal P&MA strategies. In German affiliates, profound knowledge of IQWiG and G-BA requirements as well as processes (e. g., GBA early advice, G-BA hearing procedure, etc.) is essential for successful dossier development. Moreover, in-depth expertise regarding the AMNOG process is of paramount importance for P&MA teams to understand the possible levers for a specific product. Best-in-class companies also ensure that P&MA professionals negotiating with the GKVSV possess strong negotiation skills and are aware of the specifics of these negotiations compared to other types of negotiations (e. g., the negotiation partner is in a "monopolistic situation" and acting within a formal framework of regulations specifically set up for drug price negotiations in Germany).

On the other hand, a good business sense and strong communication skills are required for establishing successful relationships with payer customers and with stakeholders across the organization (e. g., with Commercial/Marketing, Clinical/Medical, Governmental Affairs, Finance). These working relationships provide the basis for productive cross-functional collaboration.

Competencies

Most successful P&MA functions detail necessary competencies by role and level (e. g., entry, mid-management, and leadership) to establish clear expectations for all P&MA professionals. The creation of role profiles can help to define core responsibilities, skills, and expertise. In this context, it is important to regularly assess required skills and competencies because they might evolve as the company and the market environment change.

Progression

Second, it is advisable to design career progression paths so that professionals regard P&MA as an attractive function for career development. Career progression paths illustrate options of what prototypical careers could look like in terms of sequential positions, roles, and stages. Such a path illustrates career opportunities within the P&MA function as well as opportunities to switch across functions including temporary job rotations. Since pricing and market access are critical drivers of future success,

C-level executives need to be familiar with these topics. Ideally, this is reflected in respective career paths which are developed in cooperation with the Human Resources department. As a result, P&MA becomes a stepping stone to upper management positions as it has been the case with other functions in the past.

At the same time, companies need to rely on a certain level of continuity and a backbone of expertise for which a retention program can be supportive. Furthermore, a succession management plan ensures the maintenance of the function's performance in case important P&MA professionals leave.

Development

Finally, it is recommended to invest in proper training and skill development to achieve continuous skill growth in the P&MA function and to ensure that all P&MA professionals possess the required skills for their current role. This can be implemented in a comprehensive "Pricing and Market Access Academy" which is regularly updated to prepare P&MA professionals for future challenges and opportunities.

Conclusion

The P&MA function plays a critical role throughout a drug's lifecycle as it lays the foundation for patient access and commercial success. Consequently, optimizing the organization and operations of the P&MA function is a priority for any company looking to succeed in a challenging payer environment. To achieve continued P&MA Excellence, successful companies ensure that P&MA is a central and integrated part of the organization which is reflected in its organizational set-up, operations, and talent management. ◂

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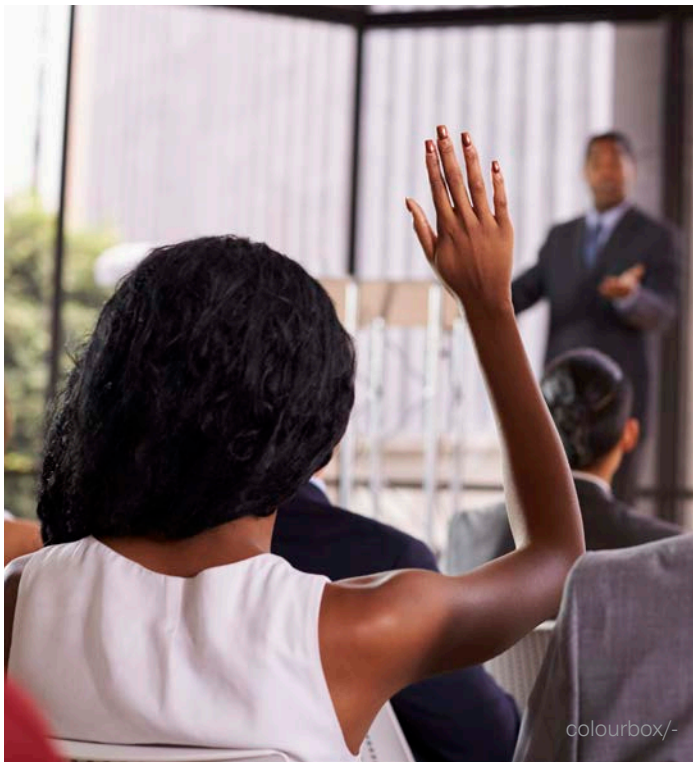
ask a PAYER

The Biosimilar Dilemma:

Long Term Cost Savings vs. the Valley of Lost Rebates

By Julia Ehrhardt, Mike Zhu, Alec Moretti, and Scott Heim

In 2017, the top 10 biologic pharmaceutical products accounted for ~$45 billion in US revenue combined. Biologics also represent 5 of the top ten highest selling pharmaceutical products based on US revenue (figure 1), and managing their costs is a top priority for all US payers.



Enter biosimilars: a new wave of biologics that are almost clinically identical to currently available, soon to be off-patent, original biologic products. While biosimilar entry will undoubtedly reduce future healthcare costs, they likely won't do so at the same level, on a percentage basis, as we have seen with generics in the past. With barriers such as high manufacturing costs and complex regulatory approval processes, the expectation is that biosimilars will offer a lower level discount compared to what we have seen historically with generic, small molecule products.

Furthermore, many manufacturers of originator biologics have contracted heavily with US payers to achieve preferred access on health plan formularies. If payers choose to add biosimilars to their formulary, they risk voiding these contracts and forfeiting millions of dollars in lost rebates.

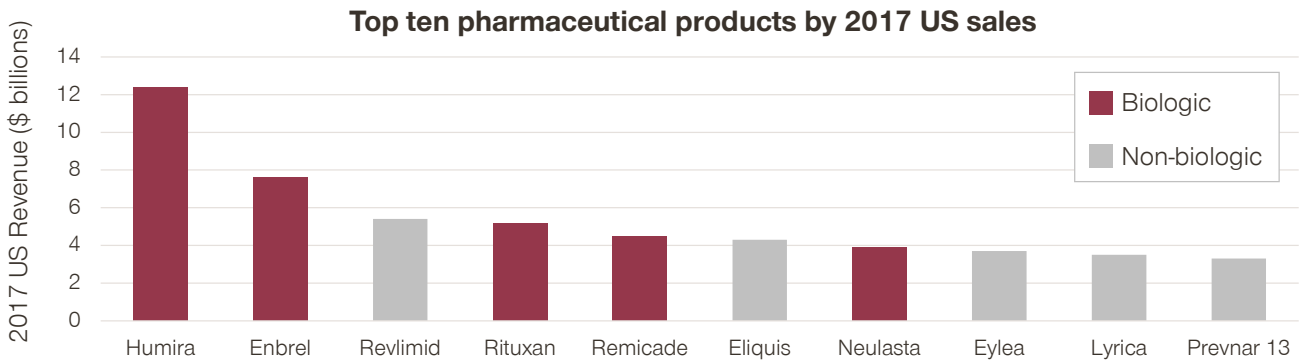
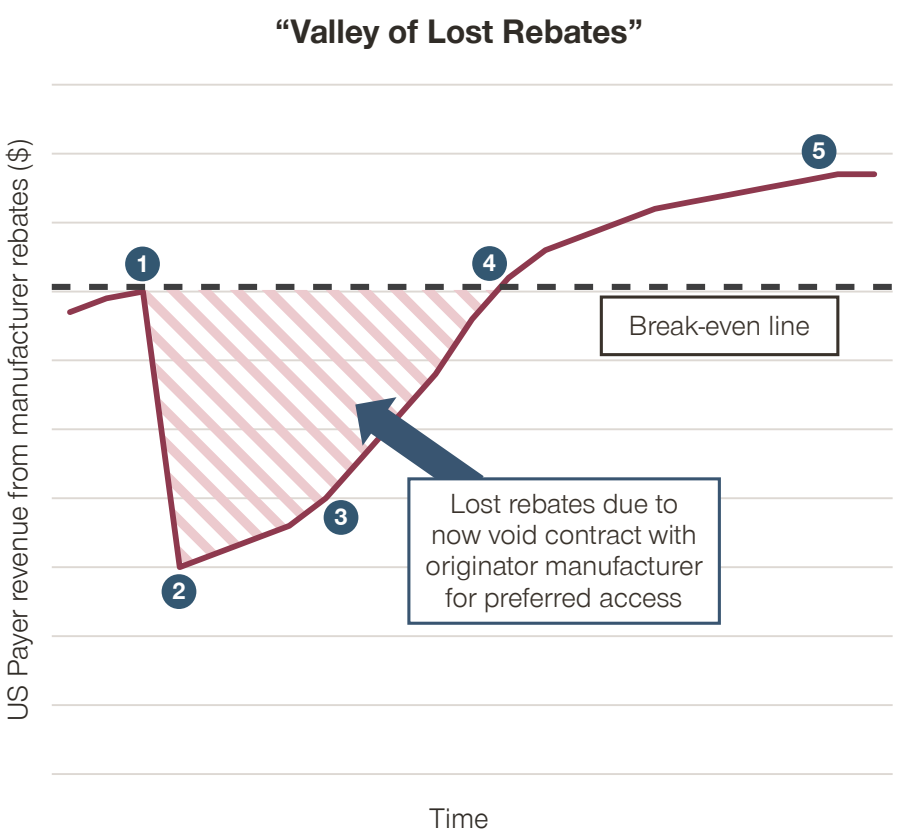


Figure 1: Top ten pharmaceutical products by 2017 US sales



1. **Pre-biosimilar entry:** Payer gets large revenue from manufacturer rebates for giving preferred access to the originator
2. **Biosimilar added to formulary:** Originator contract for preferred access is now void and payer no longer receives rebate revenue from manufacturer
3. **Payer begins switching patients:** As patients are moved to biosimilar, payer receives rebate revenue from the biosimilar manufacturer
4. **Breakeven point:** Critical mass of patients switched to biosimilar such that biosimilar rebate revenue exceeds rebate level from originator contract
5. **Long-term additional revenue:** Payer receives higher rebate revenue from biosimilar than what would have been achieved from staying with originator contract

Figure 2: Valley of Lost Rebates

The losses will continue until payers can switch over a critical mass of patients from the originator to the biosimilar. A visualization of the "valley of lost rebates" can be seen in (figure 2). While the exact monetary amount at stake will vary between payers, this general concern is shared by most major health plans across the US. With this in mind, Simon-Kucher conducted interviews with seven US payers to better understand how they expect to manage upcoming biosimilars and what strategies they are discussing to avoid or minimize this valley of lost rebates.

When discussing biosimilars, payers expressed doubt about the promise of cost savings, and will require more evidence before they begin to fully support wide-spread biosimilar adoption. On top of this initial doubt regarding costs savings, payers are unsure of the specific pricing strategy that biosimilars will take at launch. One potential strategy would be to launch with a low WAC (wholesale acquisition cost), and offer little to no additional contracting on top. The other strategy could be to launch with a WAC near parity to the originator biologics, yet offer large contracts with high rebates to bring the net cost down for payers. With this uncertainty surrounding biosimilar launch pricing, many payers across the US are taking a "wait and see" approach to understand exactly how the different strategies will play out before they make any important management decisions (figure 3).

In 2017, the top 10 biologic pharmaceutical products accounted for ~$45 billion in US revenue combined. Biologics also represent 5 of the top ten highest selling pharmaceutical products based on US revenue (figure 1), and managing their costs is a top priority for all US payers.

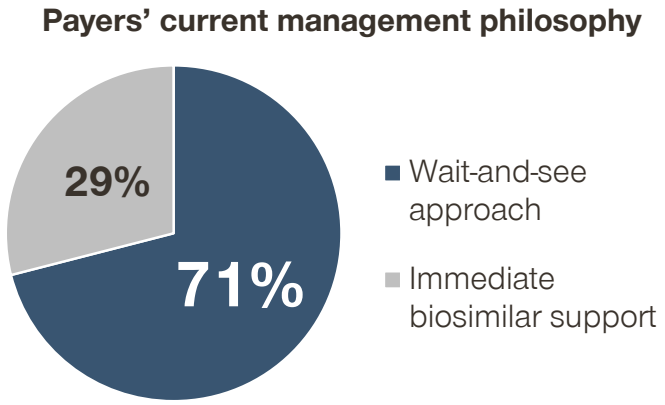


Figure 3: Payers' current management philosophy

"We have been talking about biosimilars for 10 years now and still don't have [many of] them. Most likely we will put them on formulary if they show up, but no decision will be made until they are on the market and can be sold."

– Pharmacy Director, Regional MCO

While many payers are waiting for more information before making any concrete management decisions, the majority agree that they expect biosimilars to compete similarly to how branded products compete now. There is a consensus among payers that biosimilars will not be managed like generic products and instead will compete with originator biologics just as any new branded product would compete when entering the market. When asked about clinical differences between the biosimilars and their originator products, most payers stated they are comfortable with the clinical aspect of the discussion, believing that FDA approval is sufficient to justify the efficacy and safety profiles of new biosimilars. Given this, the ultimate management decision for new biosimilars will likely center on one main topic: net price.quire additional data to support rewarding the innovation.

"We are looking for X% net difference from the originator product, and don't care how we get there. Whether it's a rebate or WAC discount, we're just looking at the net difference in the end."

– Pharmacy Director, Regional MCO

When asked which pricing metric is the most impactful for evaluating new biosimilars, payers confirmed that net cost realized by the plan is the key metric for US payers. This net cost includes all up-front discounts, as well as forthcoming rebates that are offered by manufacturers in order to gain preferential access on payer formularies. In many cases, these rebate dollars represent a major revenue stream for health plans, directly affecting their bottom line. The significance of these rebate dollars is further amplified when considering that many of these biologic agents have extremely high utilization in the US. As such, any management decision that could potentially reduce these incoming rebates will have substantial financial implications. When asked how the current incoming rebates for branded biologics impact their ultimate decision making with biosimilar adoption, payers largely agreed that rebate considerations will heavily influence their final decision making (figure 4).

Influence of rebate considerations in the decision to adopt biosimilars

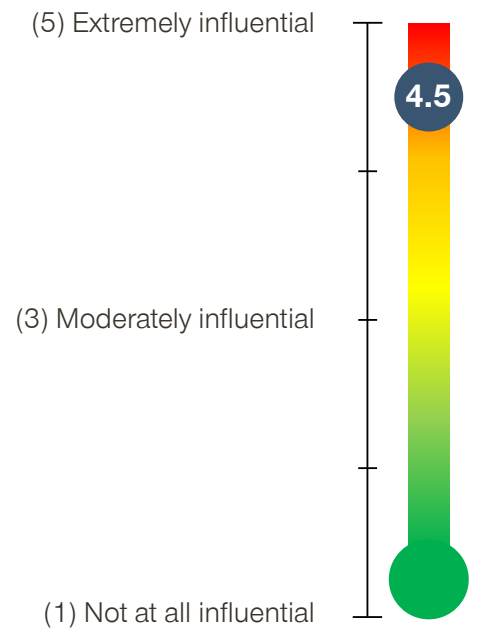


Figure 4: Influence of rebate considerations in the decision to adopt biosimilars

With significant potential rebate losses at stake, payers will need to see substantial cost savings from biosimilars in order to consider adding them to formulary. We asked payers what specific net price difference they need to see to consider adding biosimilars to formulary. The responses varied, but on average, payers are looking for ~30% savings from biosimilars, meaning 30% lower (net price) than their originator therapies. This 30% may, however, vary by indication, as some indications see much higher utilization than others. Therefore, in certain indications, a smaller percentage difference will still yield high savings, due to higher volume. For example, if biosimilars indicated to treat rheumatoid arthritis (RA) were hypothetically priced only ~15% lower than their originator counterparts (half the cost savings payers are anticipating), this ~15% would be magnified by high patient volume, and may ultimately yield sufficiently high savings for payers to warrant adoption of the biosimilar. However, if biosimilars do not

offer an adequate level of total savings, payers may prefer to stick with the current rebate streams coming from branded biologics, and choose not to adopt biosimilars.

After factoring the pricing and rebate considerations of biosimilars, payers are faced with the challenge of synthesizing this information to form a management strategy. In general, payers are opposed to management strategies that would completely exclude biosimilars, because they hope that biosimilar inclusion will effectively drive down future biologic pricing. However, if manufacturers of originator products offer substantially increased discounts to remain exclusive on formularies, then payers may consider excluding biosimilars.

"In Europe, J&J lowered the price of Remicade because everyone was switching to the biosimilar. I don't know if manufacturers will do the same thing in the US, and I don't really care. If they want to lower the price then we will probably leave it [branded biologics] on there because we are familiar with it and physicians and patients are familiar with it"

– Medical Director, Regional MCO

Many payers expect that the manufacturers of originator products will be willing to renegotiate existing contracts, as these biologic products often represent a substantial portion of the manufacturer's total revenue. But payers are largely unaware of the specific amount of additional discount that manufacturers will offer.

"We will approach the manufacturer with whatever offer we get from biosimilar and say 'Here is the offer we have. What are you going to do about it?'"

– Pharmacy Director, National PBM

If payers do add biosimilars to formulary, their responses suggest they are more inclined to grandfather patients in, meaning they will allow patients to finish their current course of therapy with originator products, as opposed to switching all patients to the biosimilar immediately. This is mainly due to logistical issues with immediate switching, a variety of state laws on how switching may be accomplished, as well as expected resistance from both physicians and patients. Several payers also noted that grandfathering may occur at the indication level for each product, noting that switching RA or psoriasis patients over may happen quickly, while gastrointestinal (GI) patients may prove more difficult to switch and thus be grandfathered instead.

Ultimately, the decision to add biosimilars to formulary will come down to the launch strategy, the indications in question, and the willingness of manufacturers of originator products to re-negotiate current discounts / rebates to stave off biosimilars. The heart of this dilemma lies in payers' willingness to take on sharp, short-term rebate losses from voided contracts in order to see more cost savings long term with biosimilar-originator competition. While we now better understand what high level factors are top of mind for payers, there are still additional considerations that may impact payers' final decision making: how large of an increased rebate will manufacturers of originator products need to offer to keep biosimilars off formulary, how might copay assistance programs impact the affordability of biosimilars for patients, and how might biosimilar interchangeability status affect total utilization? It will be several years before these questions are all answered, but scrutiny will intensify with every step towards biosimilar introduction into the US market as payers make this one of their top priorities moving forward. There is too much money at stake not to. ◂

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Will Trump's Blueprint have Pharma 'Singing the Blues' or is it just "Fake News"?

By Nathan Swilling, Madelane Teran, Vivek (Victor) Sivathanu, and Aishwarya Jayagopal

Drug pricing in the US has been a topic of increasingly intense discussion in the past few years. Although many government leaders and candidates have spoken about the rising costs of prescription drugs, all proposed changes have either faced significant hurdles or have had little to no impact on drug prices. On May 11, 2018 the White House put forward President Donald J. Trump's Blueprint to Lower Drug Prices. The plan, called "American Patients First," aims to lower prescription drug prices by increasing competition, improving negotiation, and creating incentives to lower list prices and out-of-pocket (OOP) costs to patients[1].

While the Blueprint introduces many different proposals, here we chose to focus on three areas to discuss the potential impact and likelihood of implementation:

1. Reducing manufacturer rebates and/or passing rebates to patients
2. Enhancing Medicare Part D plans' negotiating power with manufacturers
3. Increasing price awareness of physicians and patients

1. Reducing manufacturer rebates and/or passing the rebates to patients

Manufacturers employ contracting with insurance providers, Pharmacy Benefit Managers (PBMs), and employer groups to secure optimal formulary positioning for their drugs (e.g., a confidential rebate is offered in exchange for having their drug be one of the preferred drugs on formulary). Even though rebates lower the overall drug expenditure for the payers, most often these discounts do not get directly passed on to the individual patients purchasing that specific drug. Some patients have a benefit design where they are responsible for a percentage co-insurance of the drug cost. These patients are typically paying a co-insurance on the Wholesale Acquisition Cost (WAC) of the product, which could be as high as twice the payer's actual net cost for the medication after their negotiated discounts. Similarly for patients who have a deductible, they are responsible for the full WAC of the product, even if the payer's net cost is substantially lower. The net result is that some patients are paying for a larger proportion of their medication's cost due to what many consider to be an 'inflated' list price that, in some circumstances, is far from the medication's true cost to the payer.

Below we delineate two relevant proposals highlighted in Trump's Blueprint aimed to tackle high OOP costs that are perceived to come from 'artificially' high list prices:

A) Requiring at least one third of rebates to be applied at the point of sale: Point-of-sale rebates would have an immediate short-term impact on OOP costs for *some* patients, as those who pay a co-insurance or have a deductible would see some immediate cost relief. This would be a large proportion of Medicare Part D patients, but will likely impact only a minority of commercially insured patients.

In the long run, however, the impact from this change could be significantly muted. The revenue that payers receive from rebates is currently used to offset premium costs. If a proportion of the rebates are passed directly to patients, payers would likely make that up by either increasing premiums, or by simply increasing the % co-insurance and/or deductible. For example, rather than employ a benefit design where a patient is responsible for 25% of the cost, the revised benefit design could require patients to be responsible for 35% of the price.

Table 1. Example of a potential benefit design change a payer could implement to offset lost rebate dollars. In this example, one third of the rebate is credited to the patient, but the benefit design has been changed so that both the patient's and payer's net cost are unchanged.

	Original design (25% co-insurance)	**New design** (35% co-insurance)
WAC of Drug X	$100	$100
Payer rebate	($30)	**($20)**
Patient cost-share	($25)	**($35)**
Patient rebate	$0	**$10**
Payer net cost	$45	$45

In this political environment, we believe that legislative action to implement this sort of change is highly unlikely. However, simply using the 'bully pulpit' of the White House and focusing attention on this issue could be enough to see changes in the industry. Already, we have seen Aetna and United Healthcare voluntarily announce policies for a portion of rebates of select medications to be passed on to patients. While this trend is not widespread, if it continues, it would have a significant impact for manufacturers.

First, we would potentially see a new level of net price transparency. If net prices are to be disclosed to patients, they would evidently become publicly available. This is currently tightly guarded information within manufacturers due to competitive reasons. Second, if % co-insurances do increase as mentioned above, this could create even more cost sensitivity on the side of patients. Lastly, for commercially insured patients, co-pay support programs are very often used to reduce patients' OOP exposure. If these changes do come to pass, manufacturers would need to potentially allocate a larger proportion of their list price (WAC) to patient support programs, although on a net basis the investment would be the same; i.e., in the above example patients OOP is actually unchanged, just a larger % of the WAC.

B) Capping or completely eliminating rebates that fall under the anti-kickback discount safe harbor: A more drastic change to the industry would be changes to the interpretation of the anti-kickback discount safe harbor laws. Because this is based on an interpretation of the law, the White House has stated that this change could be implemented through executive action. As the current rebate system is a key component of the insurance industry, and particularly the PBM industry, any move to make rebates illegal would almost certainly result in litigation. However, as mentioned above, even the threat of this change could be enough for the industry to voluntarily make changes.

The impact of such a massive change to the US drug pricing & contracting environment is difficult to predict. Manufacturers would still be able to compete on price, but they would be competing on a list price level with a price that would be applicable across all channels. Under the current system, manufacturers provide targeted rebates to specific payers in return for specific access advantages and even different rebates for different channels (commercial vs. Medicare Part D). With the abolition of rebates, a lower price could result in an access advantage at some plans, but there would be no guarantee. The net result could be a lower interest on the part of manufacturers to compete on price, especially since any price action would be visible to competitors and potentially result in a price war.

2. Enhancing Medicare Part D plans' negotiating power with manufacturers

Currently, CMS regulatory guidance mandates that Medicare Part D plans (PDPs) cover at least two chemically distinct drugs per class. Additionally, federal law requires PDPs to cover all or substantially all drugs in the following six protected classes: HIV/AIDS treatments, anti-depressants, anti-psychotics, anti-convulsants, immunosuppressants, and anti-cancer drugs. While these PDP formulary coverage policies aim to ensure sufficient coverage and choice for Medicare beneficiaries, they can limit the payers' ability to negotiate rebates with manufacturers.

Trump's Blueprint proposes to amend the protected class policy to provide more flexibility for payers to manage costs. While the Blueprint does not provide clarity on what "more flexibility" could mean, possible changes include: a) non-coverage or b) changing the clinical appropriateness standard used by plan sponsors to determine formulary

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inclusion. To implement such a change to the protected classes, Congress would need to amend the current statute or CMS would need to issue new regulatory guidance. In addition to this proposal included in the Blueprint, the administration's FY2019 budget proposes to relax the PDP coverage requirement from the current two-drug per class minimum to one- drug per class. A change in the two-drug per class requirement could be directly implemented by CMS through issue of new regulatory guidance.

While a statutory amendment might appear to be more challenging to achieve, introduction of new CMS regulatory guidance could also face significant hurdles, especially for the protected classes. For instance, in 2014 CMS proposed the removal of anti-depressants, anti-psychotics, and immune-suppressants from the protected classes and projected potential savings of $720 million over 5 years[2]. However, this change faced unsurmountable opposition from lawmakers (bipartisan) and industry groups, citing hampered drug access to seniors, and was abandoned.

A change to either the two-drug per class policy or the protected-class policy has the potential to increase payers' negotiating power and introduce downward price pressure by increasing the risk of non-coverage. While these policies could theoretically lead to lower net prices, there are additional humanitarian and public perception implications that government officials will have to consider. Even in the cases of oncologics and anti-retrovirals, which have significantly higher per-prescription costs than other protected classes[2], it is questionable if plans would enforce such policies due to the potential public pushback. Even though a revision of the protected-class policy may seem to be a logical place to increase Part D sponsors' negotiation power, and subsequently lower drug prices, the overall impact could be minor.

3. Increasing price awareness of physicians and patients

Trump's Blueprint also includes a bevy of proposals to increase public awareness of pharmaceutical prices aimed at helping patients and physicians make more informed decisions.

A) Public listing of Medicare Part B, Part D, and Medicaid drug prices and price increase history on the CMS Drug Spending Dashboard: As of May 2018, CMS has already implemented this change by releasing an updated drug price dashboard. The website contains gross prices and Medicare and Medicaid spend on a few thousand drugs as well as aggregated information on rebates provided by manufacturers. However, it is unclear how much of an impact government listing of prices and price increases on a website might have. The AARP for a number of years has published a list of more commonly used drugs and their price increases. An additional website with this information could spotlight manufacturers even more for price increases, but our opinion is that it will likely have little direct impact.

B) Expansion of the Explanation of Benefits (EOB) provided by PDPs to include price history and lower cost alternatives: Expansion of the EOB documents is likely straightforward to do under the authority of CMS. However, it is unclear what inclusion of "lower cost alternatives" would entail, as Medicare plans are already required to substitute generics where possible to minimize patient OOP costs. Like the public listing of prices on the CMS dashboard, this proposal is likely to be immediately actionable.

   Including price increase information in Part D patients' EOB could potentially have a greater impact than the dashboard, as the information will be more readily available to patients. Some patients are likely to respond to communication on price increases by at least having a conversation with their physician about whether there is a lower-cost alternative. We do not believe, however, that CMS suggestions of specific, lower-cost alternatives is likely to be a viable proposal. Apart from generic substitution, there is no simple algorithm for switching patients to another therapy without considering their specific health situation, co-morbidities, other medications, etc. We would expect significant pushback from the medical community of any proposals for CMS to suggest patients take a different medication than the one prescribed by their physician.

C) Evaluation of the possibility of including list prices in direct-to-consumer advertising: It is unclear whether the FDA has the authority to require companies to include prices in advertisements and whether such a requirement would run into legal issues with respect to free speech rights.

   However, manufacturers are already required to include information on potential side effects in their marketing, so requiring information on price could potentially be legal as well. However, a crucial challenge here is: which "price" would they be required to communicate? Would that be a price per monthly supply? Per year? Per course of therapy? What about drugs that have varied dosing schedules, or prices depending on patient weight or other patient characteristics? What would patients be expected to do with that information as they wouldn't readily have the tools to compare prices across alternatives? On the other hand, one possible impact could be that patients would potentially be less likely to "ask their doctor about" a drug they saw in an advertisement if they believed the medication was very expensive. However, overall, we believe the challenges in implementing this policy might turn out to be just too difficult.

Overall, it is unclear how much impact the changes proposed in the Blueprint could have on drug prices and patient OOP costs. While some of the proposals in the Blueprint are likely to face significant hurdles to implementation, drawing attention to the current system may spur players to make changes on their own. We just recently observed how this increased spotlight can spur change as Pfizer recently reversed course on mid-year price increases for 40 drugs after a Trump tweet and a call from the White House. It will be interesting to observe whether other manufacturers alter their usual pricing strategies. ◂

Abbreviations:
CMS = The Centers for Medicare & Medicaid Services; EOB = Explanation of Benefits; FDA = The Food and Drug Administration; PBM = Pharmacy Benefit Manager; PDP = Part D plan; OOP = Out-of-pocket; WAC = Wholesale Acquisition Cost.

References:

1. American Patients First, The Trump Administration Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs, 2018
2. http://www.pewtrusts.org/en/research-and-analysis/fact-sheets/2018/03/policy-proposal-revising-medicares-protected-classes-policy

Simon-Kucher opens new office in Chicago

On May 15, 2018, Simon-Kucher expanded its US operation with a new office in Chicago, located right in the Loop (30 S. Wacker Dr., Suite 2214). With the new office, Simon-Kucher continues to grow its US presence and plans to further build its relationship with Chicago- and greater Midwest-based clients. The Chicago Life Sciences team will be led by Dr. Nathan Swilling and Stephen Dunbar. Please feel free to direct inquiries to either Nathan.Swilling@simon-kucher.com or Stephen.Dunbar@simon-kucher.com.

Simon-Kucher opens new office in Zurich

On July 1, 2018, the HealthCare practice of Simon-Kucher expands its European operation with a new office in Zurich, Switzerland, located right in the city center (Loewenstr. 1, 8001 Zuerich). With the new office, the Simon-Kucher Health-Care specialists continue their growth path. The Swiss HealthCare team will be led by Dr. Jens Mueller. Jens is a Partner in the HealthCare practice of Simon-Kucher for about a decade. He worked for Simon-Kucher in Asia, Europe and North America. Please feel free to direct inquiries to Jens.Mueller@simon-kucher.com.

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, and 30 of the top 35 medical technology companies. We combine analytical rigor with strategic insights and employ highly sophisticated methodologies that integrate quantitative and qualitative findings. Our recommendations are based on empirical data, thorough research, and extensive experience.

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