Comprehensive commercial alignment: the key to brand forecast accuracy
Actual sales miss the revenue forecast by an average of 50 percent – an alarming number. What can pharmaceutical companies do to achieve their desired commercial performance and improve forecast accuracy?

Account for ATU status in France when building your local and European P&MA strategy
The Temporary Authorization for Use (ATU) program allows manufacturers to generate revenue even before a drug is officially launched. However, the program is undergoing significant changes in France – particularly in terms of eligibility criteria. How should companies effectively integrate ATU in a European P&MA strategy?

Key account management: tackling the challenges of a dynamic pharma market
The market environment for pharmaceutical companies is constantly changing, requiring a new approach to key account management. What are the key measures to make use of revenue potential and drive growth by improving KAM?

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Annual European Medical Technology Strategy Forum

Advanced revenue models for profitable growth:
Monetizing value in a new era

Radisson Blu Zurich Airport, Switzerland, February 11, 2020

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- Practical approaches on how to monetize beyond the core
- Industry best practices on new revenue models
- Successful implementation of new revenue models

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Senior Director Sales
EMEA SPI
Johnson & Johnson

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SVP Managing Director
Germany
Medtronic

Dr. Cosmin Bordea
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Fresenius Medical Care

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CMS drug price negotiation: Is it truly a negotiation?

The House Democratic leadership is pushing forward with a proposed plan to reduce drug prices: the Lower Drug Costs Now Act of 2019, released on September 19th, 2019. This bill includes the establishment of several programs and requirements, primarily aiming to limit the prices of top-spending drugs. One of the key programs proposed by this bill is the Center for Medicare and Medicaid Services (CMS) negotiation of maximum prices for certain drugs, which is currently prohibited by law. Under this program, the CMS must negotiate the maximum prices for insulin products and at least 25 single source, brand name drugs that do not have generic competition that are among the 125 drugs that accounts for the greatest national spending or greatest spending under Medicare Part D and Medicare Advantage. The US prices would be tied to six international markets: Canada, Australia, the UK, Japan, Germany, and France. The negotiated US price should not exceed 120% of the weighted average price, i.e., average international market price (AIM price), across these six countries and should target at the lowest net average price in any one of the six countries. The penalty for not reaching a price agreement with the CMS within a defined period of time would be additional tax that starts at 65% of sales in the US for the drug in negotiation and rises by 10% for every three non-compliant months until the excise tax reaches 95% of its US sales.

If enacted, this bill would essentially force the drug manufacturers into price agreement with the CMS, with a likely much lower price tag for the US, possibly lower than the AIM price, unless that price is lower than 95% of the current US price. Further analyses need to be conducted to understand the true impact of this bill. For example, the negotiation-eligible drugs only include single source drugs. However, this may exclude some brand name medicines that have generic competition but the prices are not impacted in a significant way. As the proposed bill targets the top 125 drugs by spend it is unlikely to impact newly launched products. Knowing that a significant price reduction may be in the future once the sales build up to a certain threshold, would manufacturers launch at even higher prices in anticipation of the effect of this bill on the future prices of their products? How will this impact their international pricing strategies?

France
Changes to nATU program

Over the years, the ATU program in France has become one of the key considerations for a manufacturer’s EU P&R strategy. In an evolving P&R environment, where the path to market access can be long and complicated, ATU status granted by the French National Agency for Medicines and Health Products Safety (ANSM) provides rapid access opportunities for drugs without a marketing authorization or those undergoing P&R negotiations. Only drugs that target serious or rare indications without available appropriate treatment alternatives and presumed efficacy and safety data can benefit from the ATU program. Besides obtaining a rapid market access, the ATU program also enables a manufacturer to set the drug price freely. This generates substantial strategic appeal for manufacturers, considering the international price referencing implications across EU and the potential for early revenue.

Typically, two types of ATU can be granted: nominative ATU (nATU) or cohort ATU (cATU). While nATU is patient-specific and granted at the request of individual physicians, cATU is designated for a group of patients at the request of the drug manufacturer. The requirements and eligibility criteria differ slightly between the two, with cATU being somewhat more restrictive.

With the growing strategic importance of ATU status, both the number of drugs granted ATU and their prices have risen, leading to a significant budget impact with costs exceeding >€1B per year for the French healthcare system. In an effort to offset the burden and continue this program
sustainably, the French authorities have been slowly introducing initiatives to reform the program. In its most recent iteration, French Social Security Law (LFSS) for 2020 implemented two new changes for the nATU program:

1. **Additional monitoring mechanisms / conditions:**
   Stricter eligibility criteria have been rolled out for nATU, mirroring requirements for cATU status. For example, nATU will now require drug safety and efficacy to be “strongly presumed” (instead of “presumed to be favorable”) and the clinical trial to be “ongoing” in France (instead of “ongoing or submitted”). Additionally, the number of nATUs authorized per product will now be capped.

2. **Repeal of “free pricing” for nATU:** The Ministry of Health will now determine the compensation rates for nATU drugs rather than the manufacturer, but this price is not expected to be published. Manufacturers should still be able to freely set the price charged to hospitals, but will have to pay back the difference versus the compensation amount set by the MoH (free pricing will still apply for drugs with cATU status).

The nATU program serves more than 2.5 times the patients in cATU program. The high prices set by the recent nATU drugs propelled the above changes, which may now impact P&R negotiations in France. It remains to be seen if the French ATU program can preserve its strategic appeal.

For an in-depth overview of recent ATU changes and its implications, please refer to page 22 of this issue.

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Spain

**The Spanish Ministry of Health has published an action plan to promote the use of generics and biosimilars**

The key priorities and work streams of the Spanish Ministry of Health are uncertain, due to current political instability in Spain. With four general elections and four different Ministries of Health in the last years, the Spanish Healthcare System has needed to adapt to the changing political environment.

However, having a sustainable Healthcare System remains a key priority for the Ministry of Health. In this context, the Ministry has proposed an Action Plan to promote the use of generic and biosimilar drugs. This is expected to lead to an increase in competition among manufacturers and eventually reduce pharmaceutical expenditure.

The key measures proposed in the Plan are the following:

**Actions related to P&R setting of generic and biosimilar drugs:**

1. **Voluntary discounts within the Fixed Reference Price (FRP) System:** Products within the same reference group will no longer be required to have the same price. Upon creation of the group, all products (originator and generics/biosimilars) will need to have the same price (reference price), but afterwards, manufacturers can offer discounts. These voluntary discounts will not be considered for the reference price recalculation the next year.

2. **Dynamic prices:** Price of the drugs within an FRP group will be re-negotiated based on volume of original and biosimilar sales vs. the total sales of the active substance.

3. **Reference groups by ATC-4:** The Plan would create reference price groups based on ATC-4 drug classification (i.e., chemical subgroup) instead of ATC-5 (i.e., chemical substance). For example, currently infliximab drugs, including the originator (Remicade) and its biosimilars (Inflectra, Zessly, Remsima, Flixabi, etc.) are grouped following ATC-5 classification L04AB02. The new system would have a reference price group based on the broader ATC-4
classification L04AB, and include drugs for the same indication, such as infliximab drugs (Remicade and its biosimilars), etanercept drugs (Enbrel and its biosimilars), adalimumab drugs (Humira and its biosimilars), certolizumab drug (Cimzia) and golimumab drug (Simponi).

4. Lower price for generics and biosimilars vs. originator: Generics and biosimilars’ prices would be fixed to a lower price vs. originator drug. Additionally, this price will be based on the originator’s real acquisition price (instead of list price).

Actions related to the prescription of generic and biosimilar drugs:

5. Prescription by active substance: It will become mandatory for physicians to prescribe by active substance.

Actions related to dispensation of generic and biosimilar drugs:

6. Pharmacy substitution: It will become mandatory for pharmacists to dispense the less costly drug, allowing automatic substitution of the originator by generic/biosimilar if needed. Together with the prescription by active substance, this aims to foster competition among manufacturers and lower prices.

7. Clawback system: Pharmacy discounts negotiated between the pharmacy and the manufacturer will need to be refunded by the pharmacies to the National Health System.

The Plan has not been well received by the majority of pharmaceutical industry stakeholders, who criticize that they have not been involved in the development of these initiatives. Many have publicly opposed the plan:

- Pharmaceutical manufacturers contend that the Plan may damage drugs’ competitiveness without generating savings to the system, as originator drugs already have the same price as generics/biosimilars due to the fixed reference price system. The Plan could risk the continuity of innovative companies as their incentives would be tempered.

- Physicians ask for the NHS to respect their responsibilities and decisions as prescribers, and oppose prescription by active substance. Additionally, they argue that this change could lead to drug substitutions that may result in medication errors by patients who are used to a certain presentation.

- Pharmacies reject the clawback system as it disincentivizes them from negotiating discounts and their sustainability could be at risk.

- Patients are afraid of experiencing safety and quality issues when prescribed generics and biosimilars.

So far, this Action Plan only constitutes a list of ideas. Approval and implementation details are still to be defined. In the meantime, the Ministry of Health has welcomed feedback from industry stakeholders.

There are many uncertainties regarding the Action Plan, due to Spanish political instability which makes it difficult to approve new measures, as well as pushback from the industry. Although it is uncertain whether or not the different measures of this Plan will ever come into existence, it is clear that the Spanish Ministry of Health continues to consider potential solutions to mitigate expenditure and guarantee the future sustainability of the Healthcare System.

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4 The price revision date will be set on the resolution of the drug inclusion in the National Healthcare System.
5 Except for unsubstitutable drugs: (i) biologics; (ii) drugs which active substance is considered of narrow therapeutic margin, if they do not have intravenous administration; (iii) drugs which active substance is subject to special medical control or tracking; and (iv) respiratory system drugs administered via intravenous injection or infusion.
6 Originator drug manufacturers realize that their drugs are no longer profitable when generics or biosimilars enter the market, due to their price reduction. Thus, these manufacturers would be incentivized to focus on the launch new originator drugs that are profitable.
Switzerland

Current status and future developments in innovative therapy funding in Switzerland

Innovative therapies with curative potential, such as cell or gene therapies, are being brought to thousands of patients around the globe. These therapies usually target a limited patient group that are affected by rare diseases, and often require just one injection. However, they are associated with a high price tag that is a challenge for healthcare systems (see table), who are often not ready or structured to support such costs. This is especially the case in Switzerland, where healthcare costs are mostly covered by private insurances on a regional level. These insurances are subject to a national framework set by the BAG/OFSP\(^a\), which publishes a limited list of drugs (List of Specialties – LS) that insurance companies have the obligation to reimburse. LS is built on the principles of cost-effectiveness, adequacy and efficacy. Given that these limited criteria could make it hard for some of the innovative products to make the list, the Swiss government has built some flexibility into the system, through the article 71b, c of the health insurance regulation. According to this article, insurance companies must still cover the costs of a treatment that is not on the LS if two conditions are met: The treatment must bring an important therapeutic benefit to the patient, and there is not an alternative, efficacious treatment included on the LS. Insurance companies have challenged this rule, which has led to an uncertain reimbursement situation.

However, yet another pathway does exist for some specific patients through the invalidity insurance (managed by the BSV/OFAS\(^b\)), which must legally pay for any drugs indicated for “congenital defects” for patients younger than 20 years old, as defined by a list edited by the Federal Council (highest executive authority). The criteria for coverage are similar to the inclusion on the LS, even if less formalized and transparent. In some cases, this pathway has proven to be successful, such as for Spinraza in spinal muscular atrophy, but it is still not ideal. Indeed, patients older than 20 years old at treatment onset or suffering from conditions that are not on the list of congenital defects cannot get any funding through this pathway. This has led to several cases that gained attention in the media, such as a successful crowdfunding for Spinraza by a 31-year-old patient\(^c\).

This partial funding of innovative therapies is not an ideal situation, as it keeps manufacturers from giving patients access to the care they need. Several attempts have been made to solve the issue, such as the decision of santé-suisse, an association of insurance companies, to fund Novartis’ Kymriah outside of any framework with a lump sum of CHF 200,000\(^d\). There have also been some individual parliamentary interventions to increase/suppress the 20-year-old limit (although all have been turned down or withdrawn). However, these are all too limited to restore trust in the funding of these therapies, which is certainly not encouraging manufacturers to invest the costs related to a Swissmedic approval (Swiss EMA/FDA equivalent). Nevertheless, this situation may be resolved soon, as there are ongoing discussions in the Federal Commission for Healthcare Services and Principles to make a fundamental decision on how these therapies should be more systematically funded. Conclusions are expected in the first semester of 2020. ▶
<table>
<thead>
<tr>
<th>Product</th>
<th>Indication</th>
<th>Price</th>
<th>One time therapy</th>
<th>Target Patient Age</th>
<th>Congenital defect</th>
</tr>
</thead>
<tbody>
<tr>
<td>Luxturna</td>
<td>Retinal dystrophy</td>
<td>€690,000 (Germany)</td>
<td>Yes</td>
<td>None, but the younger the better</td>
<td>No</td>
</tr>
<tr>
<td>Strimvelis</td>
<td>ADA-SCID (immunodeficiency)</td>
<td>€594,000 (Italy)</td>
<td>Yes</td>
<td>1-6 years old</td>
<td>No</td>
</tr>
<tr>
<td>Kymriah</td>
<td>Leukemia, lymphoma</td>
<td>€320,000 (France)</td>
<td>Yes</td>
<td>&lt;25 years old</td>
<td>No</td>
</tr>
</tbody>
</table>
| Spinraza         | Spinal muscular atrophy     | Year 1: €420,000 (France)  
Year 2+: €280,000 (France) | No                | None, but the younger the better | Yes               |
| Yescarta         | Lymphoma                    | €327,000 (France)      | Yes              | All ages           | No                |
| Zolgensma        | Spinal muscular atrophy     | $2,130,000 (USA)       | Yes              | <2 years old       | Yes               |
| Zynteglo         | Beta-thalasemia             | €1,580,000 (Europe)    | Yes              | >12 years old      | No                |

*Federal Office for Public Health  
Federal Social Insurance Office

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### NHS England draft commercial framework

#### Background
The Pharmaceutical Price Regulation Scheme expired at the end of 2018, and was replaced by the Voluntary Pricing and Access Scheme (VPAS) as the new agreement between the Department of Health and Social Care and the Association of the British Pharmaceutical Industry. VPAS aims to create some stability in an environment of uncertainty through incentivized innovation, fairer access, and greater affordability. It committed NHS England (NHSE) to publishing a framework setting out their approach for commercial activity in relation to branded medicine, and a draft was issued in November.

#### Objectives
The draft framework describes how NHSE, the National Institute for Health and Clinical Excellence (NICE) and pharmaceutical companies could work together flexibly to support rapid patient access and fair funding for clinically and cost-effective branded medicines.

#### Role, responsibilities and commissioning route
NHSE is expanding its influence and increasing collaboration with NICE. NICE will be responsible for clinical and cost-effectiveness assessment of all new indications (with a small number of exceptions), while NHSE will decide if commercial arrangements can support mitigating economic issues (including cost-effectiveness and affordability), if any.

#### Commercial options
The framework supports NHSE and pharmaceutical company collaboration on identifying commercial solutions for affordability challenges:

- **Patient Access Schemes (PAS):** Simple, confidential discounts remain the preferred option and must be consistent across indications. Only when discounts have been demonstrated unsuitable should a more complex non-confidential PAS be considered.

- **Confidential Commercial Agreements (CCAs):** NHSE will consider CCAs on a case-by-case basis in the two following circumstances:
  - Companies wanting to enhance their value-offer (e.g., value at or below the lower end of the standard NICE threshold or other applicable thresholds). The framework confirms openness to financial schemes

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[https://www.santesuisse.ch/fr/detail/content/santesuisse-souhaite-une-solution-rapide-pour-rembourser-les-therapies-geniques](https://www.santesuisse.ch/fr/detail/content/santesuisse-souhaite-une-solution-rapide-pour-rembourser-les-therapies-geniques)
such as budget capping, price-volume agreements, risk-sharing, and outcomes-based agreements.

- Unusual and unique circumstances when a launch is considered particularly challenging or commercially unviable (i.e., when there is clear differentiation in health gain between indications, significant loss in revenue without commercial flexibility, and the impossibility of recovering from revenue loss in later years). By not clearly defining those elements, the discretionary terms on which NHSE decides on offering a CAA are retained.

- Managed Access Agreements (MAAs): MAA should be considered if there is a plausible potential for a drug to satisfy the criteria for routine commissioning but clinical and financial uncertainty remain. A time-limited data collection agreement is added to the PAS or CAA and treatment is offered at a cost-effective price for the duration of the MAA.

- Budget impact test: Even if a medicine is cost-effective, costs greater than £20 million in any of the first three years of launch will result in NHSE engaging in commercial negotiation to address affordability.

Next steps
Overall, the draft framework emphasizes the increasing influence of NHSE and signals that complex commercial schemes will likely be more frequent going forward. The finalized framework is expected in early 2020 and feedback can be provided until January 10th, 2020.

日本

Potential rule changes in the 2020 NHI price revision
The next regular NHI price revision is approaching in April 2020, and the Japanese Ministry of Health, Labour and Welfare (MHLW) has recently published information about potential changes coming in 2020.

One proposed change is an update to the so-called “post-launch premium” system. This system allows manufacturers to receive a price premium for an already-launched product when new data are made available (either by further demonstrating the clinical usefulness for the existing indication or supporting an expansion to a pediatric or orphan indication). As part of the update, MHLW is considering granting premiums for indication expansions other than orphan or pediatric use. For example, MHLW is looking to reward data demonstrated in the elderly patient group (especially >75 years). Additionally, the update may allow the summing up of price premiums, if a product qualifies for more than one at the same time, which is currently not possible. All of these changes to the post-launch premium system would be new incentives, rewarding additional research and development efforts.

However, MHLW outlines other proposed changes that target new ways to realize cost savings. One example involves changing the rules for the Comparator pricing method. Currently a new drug receives the same daily price as the pricing comparator (plus a potential price premium). With the new pricing rule, a discount will be possible for the new drug if it does not qualify for the so-called “Price Maintenance Premium” (PMP), while the pricing comparator does qualify. The PMP protects products from the regular NHI price cut and is granted to products meeting certain criteria (e.g. orphan drug indication or qualifying for a price premium due to clinical usefulness). The pricing rule change would result in a lower launch price for products not meeting these criteria for innovation or clinical necessity.

The discussed changes suggest that MHLW is willing to reward products that are innovative, while strictly restricting the budget for products that are not. This policy is a consequent step in responding to a healthcare budget that is too limited to distribute without differentiation, and should continue for the foreseeable future.

中国

2019 NRDL price negotiations concluded with 70 drug inclusions
The result of China’s 2019 national drug price negotiation was announced by the National Healthcare Security Administration (NHSA) on November 28, 2019. The 2019 NRDL negotiation targeted single-source drugs which were launched in China before December 31, 2018. Out of 119 drugs negotiated, 70 were successfully added to the National Reimbursement Drug List (NRDL), including 52 medicines from MNCs and 18 Chinese medicines.
Additionally, out of 31 drugs which were added to the NRDL in 2017, 27 re-negotiated successfully, including 22 medicines from MNCs. The outcomes of the 2019 NRDL negotiation will become effective on January 1, 2020, and be valid for two years until December 31, 2021.

The average price cut was 61% for the 70 products which were negotiated for the first time, whereas it was on average 26% for the 27 products re-negotiated. For some therapy areas the price cut was particularly high: the average price cut of HCV drugs was more than 85%; prices of oncology and diabetes drugs were cut by approximately 65% on average. For the first time manufacturers can choose not to disclose the negotiated prices publicly. Out of 74 medicines from MNCs added to the NRDL, post NRDL prices of 46 drugs are confidential.

The 2019 NRDL negotiation prioritized therapeutic areas including oncology, rare diseases, chronic diseases and pediatrics as well as essential drugs. As a result, all 5 national essential drugs were included in the NRDL. Looking at the split by therapeutic areas, 22 oncology drugs, 7 rare disease drugs, 14 chronic disease drugs (including diabetes mellitus, hepatitis B, rheumatoid arthritis, etc.), and 4 pediatric drugs successfully negotiated. From 5 PD-(L)1s launched in China, only one local novel PD-1 inhibitor was included in the NRDL. With the inclusion of 7 orphan drugs, the NRDL increased coverage of rare diseases such as pulmonary arterial hypertension (PAH), Niemann-Pick disease type C (NPC), and multiple sclerosis (MS).

According to the NHSA, a dynamic adjustment mechanism for NRDL will be put into place in the future that allows review and inclusion on a yearly basis. Once it becomes effective, drugs that failed to be added to the NRDL this year may have the chance to be included in the NRDL the following year.

Brazil

Outcomes-based agreements

The newly-elected government in Brazil is expected to bring changes to the health care system landscape, with a higher focus on more affordable and fair public reimbursement. Denizar Vianna, the appointed head of SC-TIE (Science, Technology and Strategic Input Secretariat), is expected to lead these changes. He has made public statements regarding his focus on defining public priorities, budget constraints, considerations of unmet needs and the future technologies landscape, and is also a strong advocate for the implementation of risk sharing agreements (RSA) in Brazil. The first RSA pilot was closed in June 2019 for Spinraza in Spinal muscular atrophy (SMA) types II and III.

SMA is a rare genetically-inherited neuromuscular disease that causes progressive muscle weakness and loss of movement, and is the most common genetic cause of death in infants. There are 4 types of SMA, and type I is the most severe and common. Type I patients never develop the ability to sit unsupported, and typically do not survive after the first 2 years if no intervention is provided. Spinraza is the first treatment approved beyond supportive care, and got a fast-track approval 3 months after submission by ANVISA (the Brazilian Health Regulatory Agency). Access was granted in November 2017.

The first submission for public funding happened in January 2018 for SMA type I, however CONITEC (the Brazilian HTA agency) gave a negative preliminary recommendation due to fragile clinical evidence, lack of demonstrated clinical improvement, inconsistent cost-effectiveness relation, and evidence that it could compromise the financial sustainability of SUS (The Unified Health System) financial sustainability. In January 2019, Biogen made a new submission proposing a 62% discount vs. list price and achieved a positive funding recommendation 3 months later for SMA type I. The fast assessment by CONITEC was a result of the high awareness and perceived unmet needs for SMA. The public consultation for the first submission achieved a record of 37K contributions, followed by 42K contributions for the second public consultation, which received 95% in favor of incorporation.
For SMA types II and III, due to uncertainties on efficacy and budget impact, the MoH decided to implement the first RSA pilot in the public setting, which is the biggest innovation in the public sector since the early days of tech-transfer. For Denizar, it is important that each contract is tailored case-by-case and with transparency. He also gave public statements about being open to discussing ideas and building future RSA models. The RSA reached with Biogen consists of a patient cap based on epidemiology, a negotiated price discount, and payment based on performance, which will be monitored by the MoH through Albert Einstein Hospital. The data will be used by CONITEC for a new assessment in three years. Since the beginning of November, patients with SMA types II and III have been able to request access to Spinraza and be directed to a reference center by the MoH.

Although there are still several challenges for rolling out outcomes-based contracts, including infrastructure availability for results monitoring, patient database development, and legal constraints (e.g., the MoH cannot receive paybacks in the case of treatment underperformance), this is a new access opportunity in Brazil that is especially relevant for orphan drugs. Offering the MoH support for developing the required capabilities and having high public awareness, perception of unmet needs, and indication severity can improve chances of success. Denizar highlights the importance of the MoH and industry engaging in discussions to improve access that guarantees the sustainability of the public system.
Comprehensive Commercial Alignment: The Key to Brand Forecast Accuracy

By Nick Keppeler, Tyler Perez, and Jeremy Winkler

Actual sales miss the revenue forecast by an average of 50 percent – an alarming number. What can pharmaceutical companies do to achieve their desired commercial performance and improve forecast accuracy?
The success of mid- to long-term planning in pharma relies heavily on the commercial alignment and accurate forecasting of future revenue from new product launches. However, this continues to be a difficult exercise to predict. From 2015 to 2018, 65% of new products across the pharmaceutical industry failed to achieve their forecasted revenues, with 14 of 23 new oncology products failing to reach their forecasted revenue by an average of 50% (Figure 1).a There continues to be debate around what is considered to be an acceptable variation in actual vs. forecasted peak sales two-years prior to launch. The general consensus from industry experts considers a 6-15% variation in forecast vs. actual peak sales to be acceptable, however market share assessments from primary research more often than not overstate the real world share that is actually captured.b To successfully achieve desired commercial performance, companies must go beyond just capturing health care provider preference share estimates by taking a multi-faceted approach to develop alignment across several real world factors. Poor outcomes are due to a lack of alignment between patients, payers, prescribers, and the brand, causing forecasts to be unrealistic and critical brands falling short in terms of value and sales potential. While we don’t believe that major pharmaceutical companies neglect any of these four key stakeholders in isolation, poor planning across activities for these customers can significantly derail a new product launch (and by extension its forecast). For example, a brand team might capture prescriber perception and preference share for a new brand without accurately capturing how payer access and authorization requirements will impact provider decisions. Therefore, planning across these diverse commercial activities needs to be carefully carried out and accounted for to improve commercial performance and forecast accuracy.

One way that Simon-Kucher focuses on getting commercial alignment correct is by analyzing an event that we refer to as the “Prescribing Epicenter”. The “Prescribing Epicenter” captures four key drivers or cornerstones of

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* Figure based on data taken from Globaldata.com
* Simon-Kucher & Partners Chicago Forum Survey 2019
brand strategy that serve as the pivotal juncture where patients can be helped by a new brand (Figure 2). These four drivers include: 1) brand differentiation and the customer journey, 2) dynamic patient events that create opportunities to start or change therapy, 3) physicians’ willingness to prescribe based on brand interest and experience, and lastly 4) available access through payer and organized customer engagement. Balancing these elements requires a complete assessment of the levers across all relevant stakeholders and segments. By comprehensive commercial alignment and optimization across each of the four drivers of the Prescribing Epicenter, companies can maximize the potential value for a new brand while ensuring commercial performance matches forecasts.

“From 2015 to 2018, 65% of new products across the pharmaceutical industry failed to achieve their forecasted revenues, with 14 of 23 new oncology products failing to reach their forecasted revenue by an average of 50%.”

The Prescribing Epicenter for each product is unique and may require different activities to ensure balance is achieved across the four cornerstones. Each cornerstone requires different key considerations to help determine which activities are needed to ensure a comprehensive commercial alignment. The first Prescribing Epicenter cornerstone is the brand differentiation of a new product. A product’s brand must articulate the differentiating factors between alternatives, highlight key value messages...
and engage stakeholders at the right time to achieve success. Patients and prescribers might display an interest in a product, but if the brand is not agreeable with payers, then restricted access can limit commercial performance at launch.

The cornerstone around dynamic patient events is the next key driver that can easily fall out of alignment within the prescribing epicenter. Events such as the diagnosis of a new disease or when a prior therapy has been identified as not meeting the patient’s needs are the natural start, stop, or inflection points in the patient journey. When a relevant event occurs, it is critical that the product is both clinically appropriate and available to the customer. For example, if the brand is not top of mind for physicians at the time of an event, readily accessible from payers or amenable to patient needs, this could derail product adoption. To deal with these challenges it is important to assess how elements such as digital engagement, direct to consumer marketing or patient support programs can help overcome these gaps. In order for adoption to fit into the natural progression of care, products must be marketed effectively across patient segments so that they are in the decision set at the right time of the patient journey.

Next, when considering the “willing prescriber” cornerstone, it is helpful to think both of the prescriber as an individual but also the environment in which they operate. For example, most commercial organizations track the communication preferences of their physician targets. However, what is less common is looking at how the environment in which they operate affects the way the physician is engaged with the manufacturer. Take as an example two specialists who both prefer digital communications, but one practices in City A and the other in City B. Now, consider that City A has access challenges for your product and only 20% of lives have unrestricted access to your product. In this geography, it would be more impactful to prioritize communications related to the strength of access support programs and approaches to help patients initiate treatment onto a product quickly while they are working through the authorization process. For the alternative physician in City B (assuming very good access) those same messages may be of lower priority. What might be unique about City B is the low level of patient events in the area relative to the size and demographics of the population. This might create a scenario where messaging on the importance of accurate diagnosis and early treatment to help bring the disease under control should be prioritized for physicians in City B. Shifting focus across different commercial activities to account for these differences across geographies can make the difference between achieving high levels of prescribing from both providers versus only achieving high levels of prescribing from one. The winning result is prescriber strategies and education that reinforce the brand in the context of that prescriber’s local Prescribing Epicenter.

The last cornerstone is focused on available access for a new product. While this is an area that all pharma companies prioritize, payer activities need to be carried out mutually in conjunction with the other three cornerstones. Often times there is misalignment within the manufacturers’ teams at this step – for example when a brand team positions the product as a first line option while the vast majority of payers expect to have access requirements of two or more competitor therapies. Companies should be cognizant that gaining access alone will not guarantee the best commercial performance of a new product. If the product gains access but doesn’t account for the other three cornerstones, patients and prescribers could fail to see the need for the new product even if payers do.

Creating harmony across all four cornerstones of the Prescribing Epicenter allows for a new brand to be launched at its maximum potential. Identifying short-comings ahead of time helps commercial activities and forecasts to be adapted for potential suboptimal factors and reasonably account for future commercial performance. These exercises require investment across multiple groups within a given company to prevent future miscalculations that can damage the commercial performance of a new product.
Case 1: What do you mean I won’t hit my forecast? Missing the mark

It is well understood that physician-stated preference share from market research needs to be adjusted to create more realistic expectations for real world market share. While there are a variety of approaches to do this, there are still a number of manufacturers who only conduct physician research and then apply an off-the-shelf haircut of 50% to their preference shares to help adjust forecast estimates. This approach is a common mistake and can be a big contributor to why so many forecasts significantly miss the mark. Simon-Kucher applies a different approach – by developing custom estimates of actual market factors across the Prescribing Epicenter for each brand and competitive situation. In the following blinded example, four key market-based adjustments were used to help achieve a more accurate real world share expectation including: (1) Payer access, (2) sales force reach, (3) physician uptake and (4) awareness and impact of competition. These factors were then applied for one brand across four possible patient events. The key findings were that the “haircut” factor a) ranged from 50-75% and b) varied across patient events for the same product. By an order of magnitude, applying a typical 50% adjustment factor rather than Simon-Kucher’s comprehensive commercial alignment approach would have led to an overestimate of >$1 billion per year in peak revenue forecast.

**Peak preference shares by patient event pre- vs. post-market factors**

<table>
<thead>
<tr>
<th>Event Description</th>
<th>Pre-market</th>
<th>Post-market</th>
<th>Impact of market factors</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 “Naïve” patients</td>
<td>10%</td>
<td>40%</td>
<td>25%</td>
</tr>
<tr>
<td>2 Switching to or adding Class A product</td>
<td>15%</td>
<td>44%</td>
<td>34%</td>
</tr>
<tr>
<td>3 Changing within Class A products</td>
<td>19%</td>
<td>39%</td>
<td>49%</td>
</tr>
<tr>
<td>4 Switching within Class B products</td>
<td>2%</td>
<td>6%</td>
<td>33%</td>
</tr>
</tbody>
</table>

Figure 3: Percent peak preference share by pre-/post-market factors
Case 2: Predicting regional pockets of opportunity

As a brand gets closer to launch, forecasting and strategic planning needs to be taken a step further to look at how the business will perform in a local sales region. Simon-Kucher uses a quantitative regional assessment known as the Top Line Power Commercial Engine to elucidate the effects of comprehensive commercial alignment on prescribing. In this example, advanced analytics (Tableau for data management and visualization, Python for prediction models) is used to assess competitor performance in the market environment to draw competitive insights for the product of interest. Data from US census data, CDC prevalence, MMIT formulary status, # of specialists & TRx data (IMS), CMS open payment data and Google was used to evaluate the variation in prescribing as it relates to factors such as sales / marketing spend to prescriber, % of covered lives facing no step edits, number of specialists in an area, and Google searches for the competitor product. Given the power behind this approach, there is the flexibility to use a range of data inputs including a client’s sales force effectiveness data, target call lists, and advertising spend to name a few.

This Top Line Power Commercial Engine approach serves two important functions. First, it helps better refine forecasts closer to launch as sales estimates are rolled up from a detailed geographic territory view to an aggregate whole. Second, it helps advance from strategic planning to comprehensive commercial alignment readiness, in order to make a launch as successful as possible. This approach serves as a quantitative bridge to launch readiness and critical success factor planning.

In the graphic below, this detail illustrates tremendous variation across the USA in terms of launch environment including: a) drivers of competitors’ commercial performance, b) areas of opportunity with low treatment rates today, c) geographies where the competitor seems to focus less on its sales and marketing efforts and d) relevant actions around payer strategy, physician targeting and disease awareness. For example, one takeaway was that competitors were facing access hurdles in Alabama – most likely caused by access of the product at Prime / BCBS Alabama. We estimated that 40% of the competitor volume was untapped due to this access position (Figure 4). Another key insight from this type of analytical approach debunks the use of traditional physician targeting based on prescriber deciles to identify markets. The result could be rather than targeting competitor entrenched areas that will put the manufacturer head to head with its competitor, focus on opportunities in low disease treatment areas or low marketing spend areas with high untapped potential. New tools are making it easier to evaluate this type of added complexity and return more targeted and actionable opportunities for manufacturers.

**Categorization of launch environments based on Competitor Y performance vs. expectations**

- **800-lb gorilla areas**
  - 60 ZIP3s; 49% of TRx
  - High use vs. expected cases

- **Average areas**
  - 247 ZIP3s; 35% of Competitor Y TRx
  - Use in line with expectations

- **Under marketed areas**
  - 93 ZIP3s with low marketing / sales focus
  - 17% of cases vs. 9% TRx

- **Payer limited areas**
  - 68 ZIP3s with access policies that affect TRx potential
  - 11% of cases vs. 6% TRx

- **Low penetration areas**
  - 98 ZIP3s with minimal Competitor Y use
  - 15% of cases vs. 2% TRx

- **Geography excluded**

**Figure 4: Categorization of launch environments based on competitor Y performance vs. expectations**
Future challenges and opportunities

Redefining a multifaceted approach for strategic initiatives and tactics is vital for successful commercial performance as well as creating a path forward. With a huge percentage of new products failing to reach their forecasted numbers, expanding the considerations in commercial activities for a product launch can improve accuracy and help to identify blind spots in launch readiness planning. Strategies around the four cornerstones of the Prescribing Epicenter all contribute to the potential success of a launch and accuracy of forecasting commercial performance. Systematically evaluating the Prescribing Epicenter for a product helps to identify short-comings of a product’s go-to-market strategy and improve the ability to more accurately forecast and prepare mid- to long-term planning. We strongly believe that comprehensive commercial alignment is a critical factor to both significantly improving forecasting accuracy and creating a solid foundation for long-term brand performance.

“For comprehensive commercial alignment and optimization across each of the four drivers of the Prescribing Epicenter, companies can maximize the potential value for a new brand while ensuring commercial performance matches forecasts.”

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ATU in France: the case for early consideration in local and European P&MA strategy

By Diane Cosset, Clementine Legros, Jonathan Haugen, Lilia Meddeb

Examining the recent changes in France’s early access program and its implications for manufacturers’ European P&MA strategy.
Time to access in France, with an average duration of 209 days after marketing authorization in 2018, continues to exceed the European directive of 180 days. However, the ATU (Temporary Use Authorization) early access program enables reimbursed access to drugs prior to marketing authorization. Since its implementation in 1994, the ATU program has garnered symbolic importance, and today serves as an emblem of France’s pioneering position in this field. Although this program represents an opportunity for patients and pharmaceutical companies alike, manufacturers must carefully consider the impact on their future negotiated prices in France and in other European countries when setting prices for ATU drugs. This is even truer considering this program has been on French health authorities’ radar for the past few years and has been subject to increasingly strict pricing rules, in particular with the recent repeal of the free pricing policy for nominative ATU.

What is the ATU program?

ATU status is granted by the French National Agency for Medicines and Health Products Safety (ANSM) to promote fast access to innovation, before marketing authorization and conventional pricing and market access process completion. In order for a drug to be granted ATU status, three key criteria must be met:

1. The drug must be intended for a serious or rare indication
2. There must be no other appropriate therapies available for this indication in France
3. The drug must have presumed efficacy and safety in light of the available scientific data, and the treatment cannot be delayed for patients

Within this program, two types of ATU can be granted. A nominative ATU (nATU) is for one specific identified patient at the request of his or her physician. A cohort ATU (cATU) is designated for a group of patients at the request of the drug manufacturer (with requirements and eligibility criteria differing slightly between the two).

ATUs allow early access for thousands of patients each year; roughly 22,000 patients benefited from the ATU program in 2018 alone including over 230 different drugs (nATUs: 217 drugs and 15,987 patients; cATUs: 20 drugs and 5,642 patients) which underscores just how extensive the program is.

The ATU program was initially designed to guarantee early access mainly to new HIV therapies, but now mostly covers oncology and hematological products as well (see Figure 1).
For some ATU drugs, such as Yescarta, the P&R process can be rather quick, and may be completed within a year of their MA. However, the average post-ATU status duration is approximately 630 days\(^c\) (see Figure 2), which is significantly longer than the average time of 209 days\(^d\) between marketing authorization and P&R completion in 2018, despite the priority review given to these drugs by the TC.

By their very nature, ATU drugs address diseases with high unmet need for which there may not be any alternative treatment available, implying a lack of price benchmarks and comparators which often results in challenging and lengthy price negotiations with the Economic Committee for Health Products (CEPS). Therefore, benefiting from the ATU/post-ATU status is a key advantage for manufacturers, as it prevents major delays in products’ commercialization and therefore loss of revenue. It also contributes to explaining why the post-ATU phase is longer than average. The fact that patients already have early treatment access implies limited pressure for health authorities to complete the P&R process quickly and may be another explanation for the longer P&R process of ATU drugs.

\(^c\) Average time between marketing authorization and post-ATU expiration date of all ATU drugs with a post-ATU effective date between 2014 and November 2019

\(^d\) 2018 CEPS report
There are several products that have remained in post-ATU status for more than two years. Among these products, there are some drugs that are still in ongoing P&MA negotiations (see Figure 3), while others have paused CEPS price negotiations or may be waiting for new data and re-evaluation by the TC.

One gap from post-ATU status was the impossibility to benefit from this early access program without having previously been under ATU status (i.e., there was no possibility of applying after the granting of marketing authorization). This gap was addressed by the December 2018 legislation Article 65 (application decree published in August 2019), which enables drugs that are not under cATU to benefit from early access through post-ATU status.

**Increased scrutiny and pricing regulation for ATU drugs**

The ATU scheme has progressively become a structured early access program for large volumes of patients, whose cost to health insurance has been significantly increasing over the past years and now exceeds €1 billion per year. This brought the ATU program onto payers’ radar, and resulted in the implementation of multiple recent initiatives from French authorities to control this program more closely in order to guarantee its sustainability.

**Additional monitoring mechanisms/conditions**

The recently-passed annual French Social Security Financing Law (LFSS) for 2020 implemented additional monitoring mechanisms/conditions for nATUs. Eligibility criteria for nATUs are now stricter and more in line with those for cATUs; for instance, drug efficacy and safety must be “strongly presumed” (instead of “presumed to be favorable”), and clinical trial programs must be “ongoing” in France (instead of “ongoing or planned”).

On top of that, there will be a cap set by the Ministry of Health (MoH) and Social Security on the number of nATUs authorized per product. Notably, once a product
has reached the nATU cap, which is yet to be defined, the manufacturer is still able to apply for cATUs for that product.

**ATU annual sales capping**
Currently, the ATU and post-ATU programs are 100% funded through the Social Security Pharmaceutical Innovation Fund (similar to T2A-excluded and retrocession drugs). The manufacturer can supply drugs under ATU/post-ATU status for free or freely set a price. It is also possible for a manufacturer to decrease or increase the ATU/post-ATU price; for instance, Ledaga took a ~40% price increase post-ATU after transitioning from Actelion to Recordati, highlighting the degree of flexibility granted to manufacturers in regards to ATU pricing so far.

However, for ATU drugs exceeding €30 million in annual sales during the ATU or post-ATU period, a “cap” of €10k/patient/year is set for the net price, and everything above the cap is paid back. This capping rule was part of the LFSS 2017, and was created as a tool to control the ATU free pricing policy. As a result, manufacturers must carefully monitor ATU sales and manage their cash flows accordingly. So far, however, this threshold has not been reached*.

**Repeal of the free pricing policy for nATU**
With the recent approval of the LFSS 2020 (applicable as of March 2020), the government decided to repeal the “free pricing” law, leaving the MoH to unilaterally determine compensation rates for nATU drugs (existing drugs pricing rules should still apply, though real-life implementation remains to be seen). Manufacturers should still be able to freely set the price charged to the hospitals, but will have to pay back the difference versus the compensation amount set by the MoH. This decision was driven by the high prices set for some nATU drugs (i.e., up to ~€2,000,000 for one injection), which significantly increased the ATU budget impact and raised concerns regarding the financial sustainability for the health system. Despite this change, free pricing will still apply for cATU drugs.

This legislative change will likely have a negative impact on the pharmaceutical industry in France, since these compensation determinations may set new, lower benchmarks for future price negotiations with the CEPS. With nATU likely becoming less attractive to manufacturers, patient access may also be negatively impacted.

**ATU and post ATU price: a ceiling for negotiated prices?**
The ATU price is referred to as a starting point (and likely as a price ceiling) during negotiations with the CEPS. An analysis of ATU drug prices before and after CEPS negotiations shows that the negotiated price is usually significantly lower than the ATU price (see Table 1), with an average price decrease of 17%.

The price decrease tends to be larger for drugs with ASMR IV/V (~20%) than those with ASMR III (~10%), likely resulting from the International Price Referencing (IPR) guarantee granted to ASMR III drugs (which assures that the price cannot be lower than the lowest price in Germany, Italy, Spain and the UK). However, no clear pattern can be outlined between ASMR rating and level of negotiated price discount, since the latter mainly depends on the manufacturer’s ATU pricing strategy. In rare cases (e.g. if IPR applies), the negotiated price could be set above the ATU price (e.g. Lutathera, where the negotiated price was a 26% premium vs. ATU price).

If the price negotiated with the CEPS is lower than the ATU price, the manufacturer can be asked to pay back all or part of the difference between the ATU price and the reference net price (calculated based on a 3-year sales forecast including all negotiated paybacks). And in the case where no agreement is reached during pricing negotiations or if the drug is not reimbursed in France, the CEPS can decide alone on a reference price and then ask the company to pay back the entire difference from the ATU price for previous sales.

Taking all of this into consideration, manufacturers should consider setting the ATU price at the upper price limit (or even slightly higher) of the target price when developing their P&MA strategy for France. Manufacturers should also be cautious and may need to expect paybacks depending on their ATU pricing strategy; the CEPS continu-

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* Threshold not hit in 2017 nor in 2018 – information not publicly available for 2019
ally faces issues collecting paybacks from manufacturers who did not anticipate this possibility in their budgets. However, the LFSS 2020 has expanded on potential solutions for manufacturers struggling with paybacks by providing the option to pay in installments over two years, or to renegotiate for up to 3% payback relief.

**ATU for indication expansions: a new opportunity for early access**

As of August 2019 (publication of the December 2018 Article 65 application decree), ATU status can now be granted for products undergoing indication expansions, as opposed to only for initial launch indications as was previously the case. This measure, designed specifically with cancer immunotherapies in mind (due to their efficacy across multiple cancers and promising indication expansions), addresses a major gap in the ATU program and should allow for additional early access to innovative products.

ATUs for indication expansion drugs and initial launch indication drugs have similar eligibility criteria, but vary significantly in regards to pricing. The selling price for an ATU indication expansion is the existing public price for the already reimbursed indication(s). At the net price level, similarly to the future new pricing rules for nATU, the MoH sets the compensation amount (which is only applicable to units sold under the ATU indication expansion, with tracking enabled by the hospital delivery or administration of ATU products).

Once indication expansion ATU status is granted and the request for compensation is submitted, the manufacturer is notified of the total compensation amount within 45 days, with no possibility to negotiate. The same rules described previously apply in the case where the negotiated price ends up being below the compensation amount; the difference between the public price and the total compensation per unit must be paid back at the end of the year.

### Table 1: Differences between ATU prices and CEPS negotiated prices in France

<table>
<thead>
<tr>
<th>Product</th>
<th>Active Substance</th>
<th>SMR/ASMR</th>
<th>Date of price publication in the Official Journal</th>
<th>List ex-manu price vs. ATU price % difference</th>
</tr>
</thead>
<tbody>
<tr>
<td>UPTRAVI</td>
<td>selexipag</td>
<td>Weak / V</td>
<td>28/12/18</td>
<td>-36%</td>
</tr>
<tr>
<td>IBRANCE</td>
<td>palbociclib</td>
<td>Important / IV</td>
<td>23/03/18</td>
<td>-33%</td>
</tr>
<tr>
<td>DARZALEX</td>
<td>daratumumab</td>
<td>Important / IV</td>
<td>18/06/19</td>
<td>-32%</td>
</tr>
<tr>
<td>ZEJULA</td>
<td>niraparib</td>
<td>Important / IV</td>
<td>16/05/19</td>
<td>-22%</td>
</tr>
<tr>
<td>LYNPARZA</td>
<td>olaparib</td>
<td>Important / IV</td>
<td>24/01/18</td>
<td>-22%</td>
</tr>
<tr>
<td>ENTRESTO</td>
<td>sacubitnl/valsartan</td>
<td>Important / IV</td>
<td>11/10/18</td>
<td>-20%</td>
</tr>
<tr>
<td>HEMLIBRA</td>
<td>emicizumab</td>
<td>Important / II</td>
<td>07/02/19</td>
<td>-16%</td>
</tr>
<tr>
<td>SPINRAZA</td>
<td>rusinersen</td>
<td>Important / III</td>
<td>18/04/19</td>
<td>-16%</td>
</tr>
<tr>
<td>VENCLYXTO</td>
<td>venetoclax</td>
<td>Important / V</td>
<td>12/06/18</td>
<td>-16%</td>
</tr>
<tr>
<td>TECENTRIQ</td>
<td>atezolizumab</td>
<td>Important / IV</td>
<td>20/02/19</td>
<td>-16%</td>
</tr>
<tr>
<td>TAGRISSO</td>
<td>osimertinib</td>
<td>Important / V</td>
<td>26/07/19</td>
<td>-15%</td>
</tr>
<tr>
<td>DUXIPENT</td>
<td>dupilumab</td>
<td>Important / III</td>
<td>08/03/19</td>
<td>-13%</td>
</tr>
<tr>
<td>OCRRELIZUMAB</td>
<td>ocrelizumab</td>
<td>Important / III</td>
<td>28/02/19</td>
<td>-13%</td>
</tr>
<tr>
<td>WAKIXI</td>
<td>pitolisant</td>
<td>Moderate / IV</td>
<td>16/05/19</td>
<td>-11%</td>
</tr>
<tr>
<td>NUCALA</td>
<td>mepolizumab</td>
<td>Important / IV</td>
<td>08/02/18</td>
<td>-9%</td>
</tr>
<tr>
<td>GALAFOLD</td>
<td>migalastat</td>
<td>Important / IV</td>
<td>02/05/17</td>
<td>-8%</td>
</tr>
<tr>
<td>YESCARTA</td>
<td>axicabtagene ciliocele</td>
<td>Important / III</td>
<td>13/07/19</td>
<td>-7%</td>
</tr>
<tr>
<td>BLINCYTO</td>
<td>blinatumomab</td>
<td>Important / III</td>
<td>05/05/17</td>
<td>-7%</td>
</tr>
<tr>
<td>IMBRUVICA</td>
<td>ibritunib</td>
<td>Important / III</td>
<td>01/08/17</td>
<td>-7%</td>
</tr>
<tr>
<td>CABOMETYX</td>
<td>cabozantinib</td>
<td>Important / III</td>
<td>15/02/18</td>
<td>0%</td>
</tr>
<tr>
<td>LUTATHERA</td>
<td>lutetium (177Lu)</td>
<td>oxodotretide</td>
<td>Important / III</td>
<td>07/08/19</td>
</tr>
</tbody>
</table>

Comprehensive list of products with both ATU prices and negotiated list prices published between 2017 and November 2019 (ATU drugs provided for free were not considered in the pricing analysis); SMR: Medical benefit rating; ASMR: Therapeutic improvement rating over existing treatments; ASMR II: important; III: moderate; IV: weak; V: no therapeutic improvement.
This again endangers the attractiveness of the ATU program for the pharmaceutical industry, given the fear that unilaterally-set compensation will have a negative impact on drugs’ current prices.

A few drugs are currently under indication expansion ATU (see Table 2) and have been provided by manufacturers for free. Some of these manufacturers submitted a request for compensation to the MoH following the publication of the decree in October 2019 specifying the documents and information to be included in the compensation request dossier.

### ATU price considerations: how is Europe affected?

For the last few years, ATU prices have been published on the MoH’s website. The published price is the maximum amount of compensation that the manufacturer charges to hospitals, with price publication occurring three times per year. These prices are referenced at the national level by the CEPS during negotiations, but they may also be used as benchmarks by other countries within the IPR. As a result, when building the French ATU P&MA strategy, manufacturers should not only consider the price potential of their drug in France, but also its price potential in other EU countries, in order to make sure that the ATU price set in France will not jeopardize price potential throughout the region.

Although there is a general trend where manufacturers adapt their French ATU pricing strategy based on their European/Germany pricing strategy, important price differences are observed for some products. For more than half of ATU drugs, the price in Germany before AMNOG (free pricing) was roughly in-line with the French ATU price (+/-10% difference). Accordingly, the average percentage decrease between free and negotiated prices in Germany versus France is roughly the same (22% in GE vs. 17% in FR). Interestingly, ATU prices are typically published several months after Germany’s free prices are set. As such, several manufacturers do not take full advantage of the ATU program, as they provide the drug for free during the whole period before German price publication, despite being able to charge for the drug and generate revenue much earlier.

### Conclusion

Overall, the ATU program contributes to revenue generation for manufacturers before the completion of P&R negotiations, accelerates treatment uptake, and enhances French physicians’ familiarity with the treatment ahead of a drug’s official launch. However, the ATU program is currently undergoing significant changes, particularly in regards to eligibility criteria and pricing. Some of these aspects are still uncertain and are being discussed (e.g., the exact approach and process for compensation-setting of nATUs and indication expansion ATUs). Lastly, with the French authorities becoming stricter towards the ATU program, there is a distinct possibility that the MoH compensation structure for nATUs could be extended to cATUs, which would further alter the pricing landscape for ATU drugs and likely trigger fierce resistance from the pharmaceutical industry. In all, the ATU program merits early, thorough consideration for local and European P&MA strategy.

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1. Analysis of the price difference between Germany launch visible net ex-manu price (source: LAUER-TAXE) and French ATU price (source: MoH) for a selection of drugs with both prices published
2. Average % discount between ATU price and negotiated list ex-manu price in France vs. average % discount between launch and post-AMNOG visible net ex-manu prices in Germany for the same selection of drugs having all prices published
Key Account Management: Tackling the Challenges of a Dynamic Pharma Market

By Raf Onclin and Jens-Christian Oelker

The market environment for the pharmaceutical industry is in a state of constant change, making it more challenging than ever to foster long-term relationships with important customers. What’s required is a more systematic approach to KAM. Raf Onclin and Jens-Christian Oelker explain how companies can often unlock significant revenue potential and address the challenges of a dynamic and increasingly competitive marketplace.
Increasing pressure on healthcare systems is leading to the professionalization of purchasing approaches on the customer side. With specialty business growing in importance for manufacturers and spill-over effects from secondary care impacting primary care, effective key account management (KAM) is essential, particularly as a means of addressing marketplace challenges and maximizing business opportunities. By running a key account excellence program, assessing their current KAM approaches, identifying potential improvement areas, and implementing changes, they will be able to drive impact and sustain growth.

Current market dynamics call for effective key account management

The market environment for pharmaceutical companies is in constant flux. Increasing cost pressure and consolidation are now a common occurrence in many countries. Smaller customer accounts are strengthening their buying power by joining group purchasing organizations and healthcare providers and payers are investing in professionalizing their purchasing processes. In response to EU procurement guidelines, tendering and contracting are becoming widespread practices.

This dynamic market environment presents three challenges for the pharmaceutical companies in managing their key accounts:

- **No clear direction on where to go:** Without structured guidance and proper intelligence, key account managers may miss information on important customers or lose sight of business opportunities. Not prioritizing most attractive key accounts or overlooking important stakeholders can hinder business growth.

- **No clear ownership:** Key account excellence is not always on top of the management agenda. Allocating responsibility and assigning ownership and decision making is not always clearly defined, particularly when sales teams deal with products across several business units. As such, it may not be clear what authority individual key account managers have, requiring them to seek approval or consensus and slowing down decision-making.

- **No clear guidance on what to do:** Not all pharmaceutical companies have well-defined account development strategies - many lack account development planning and appropriate KAM toolboxes to support execution. Objectives are rarely set on a per-account or per-segment basis. As a result, monitoring and incentivization efforts are often ineffective.

![Improving KAM in Pharma](image-url)
Five measures to improve key account management

Before launching any improvement initiative, companies should assess the strengths and weaknesses of their current approach as well as the specifics of the market segments in scope. Initiatives that incorporate one or more of the following five measures can often lead to considerable improvements with a significant revenue impact.

1. **Achieve transparency over your key accounts and provide efficient data access**
   First, collect data on all relevant key accounts in order to identify their stakeholders, understand their current business situation and challenges, and determine their decision-making processes. Then, use this data to segment the key accounts and prioritize them. KAMs need to have easy access to account data to be able to properly design offers and manage interactions with customers. Due to market dynamics, data needs to be continually collected and updated, while segmentation should be reviewed on a regular basis.

2. **Define an account strategy and perform account development planning**
   Setting strategic objectives for key account business will support alignment and coordination between all relevant stakeholder groups and serves as the basis for determining resource requirements. Account development planning should aim to improve the performance of individual accounts and that of your company as a whole. To improve quality and impact, define key performance indicators (KPIs) to help monitor progress and achievements.

3. **Optimize your offer design to address key accounts’ needs**
   Every key account is different and has specific requirements. Significant revenue potential can be unlocked by following a tailored rather than a one-size-fits-all approach. Use account profiles and development plans to create individualized offers for each key account.

4. **Ensure appropriate KAM governance**
   Key account management requires senior management support. Within individual KAM teams, roles and responsibilities must be clearly defined to ensure smooth workflows. Key account managers should have a specific level of authority to be able to make decisions about the offering. Alternatively, an approval framework can be developed to handle offers efficiently.

5. **Develop KAM infrastructure and provide comprehensive training**
   The role of a key account manager is shifting from a purely sales-oriented position to that of a business partner for key accounts. Key account managers increasingly develop business models with the customer, sell products by demonstrating their value, and ensure products and services are optimally used within the customers’ organizations. Successfully carrying out these tasks involves hiring the right people and training them accordingly. Continuous competency development is needed in order to tackle the complexities and demands of this role. In addition to properly training the workforce, using the appropriate support tools can be valuable in KAM. For example, a CRM system can support teams by improving coordination if more than one person is in contact with a key account.

Similar to links in a chain, a company’s key account management is only as strong as its weakest part. A compromise on any of the five elements can result in a loss of effectiveness of your key account management and a loss of business opportunities.

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New office location: Chicago

Simon-Kucher & Partners new Chicago office is located in the heart of downtown along the west bank of the Chicago River. The building itself, Riverside Plaza features its own public park, amphitheater, and riverwalk, and has become one of the most-awarded towers in the city, receiving both national and international acclaim. Located on the 41st floor, Simon-Kucher’s office suite faces both west and south Chicago, with spectacular views of the river and downtown area. Currently, the office holds 13 fulltime employees and will soon grow to 21 fulltime employees in the coming year.
Simon-Kucher & Partner’s Boston office has moved from One Canal Park to a 31,444-square-foot U.S. headquarters at One Boston Place. “The tremendous pool of talent and remarkable eruption of innovative companies calling Boston home definitely contribute to our continued success and growth here,” Nick Keppeler, Simon-Kucher’s Boston-based Managing Partner said. “This new space provides substantial office capacity to comfortably accommodate the growth of the team, right in the heart of the city.” The Boston location has about 100 employees now, but the new office has capacity for an additional 60 workers, the amount Simon-Kucher intends to hire over the next five years.
Introducing our new colleagues

**Simone Seiter**

Simone is a Partner in the global Pharma & Biotech practice within Simon-Kucher & Partners Life Sciences Division since beginning of 2019. She is working out of the company’s office in Frankfurt, Germany. Her focus is on strategic pharmaceutical commercialization, launch- and brand excellence, portfolio- and lifecycle-management, including go-to-market strategies, P&MA strategies, product lifecycle strategies and orphan diseases. She has supported many of the current top-20 pharma and medtech companies in successfully planning and commercializing their healthcare innovations in Europe and the USA.

Previously, she has worked as the VP Brand / Commercial Strategy/ Launch Excellence with IQVIA for 13 years and 6 years with Capgemini. She also worked as a postdoctoral fellow at the NCI/ NIH and a dermatologist at the university hospitals Heidelberg and Homburg/ Germany as well as several dermatology offices. She holds a position as an independent director of a stock-listed ophthalmology gene therapy company since 2017.

**Wolfram Lux**

Wolfram is a Senior Director in the global Pharma & Biotech practice within Simon-Kucher & Partners Life Sciences Division, and joined the company in 2019. He is based in Munich, Germany and specializes in strategic pharmaceutical commercialization, launch- and brand excellence, portfolio- and lifecycle-management, including go-to-market strategies, P&MA strategies, product lifecycle strategies and orphan diseases. During his career, Wolfram supported many of the current top-25 pharma and medtech companies, always focusing successfully planning and commercializing healthcare innovations, especially in the European and American markets.

Before joining Simon-Kucher & Partners, he acted as General Manager of a Life Sciences Consultancy in Dusseldorf for 3 years and prior to that he was a senior principal in IQVIA’s Launch and Commercial Strategy division. Wolfram held industry positions as Medical Liaison, Marketer and as Business Unit head in the onco-pharmaceutical industry too. Wolfram received his diploma degree in Chemistry from ETH Zürich and a bachelor in business administration from the University of Hagen, Germany in 1996, respectively 1999. He got his PhD in 2001 from the Free University of Berlin in Molecular Biology.
Sabrina Salomon

Sabrina serves as a Director in the global Pharmaceutical & Biotech practice within Simon-Kucher & Partners’ Life Sciences Division, working out of the company’s office in Cologne, Germany. Sabrina has over 8 years of healthcare consulting experience in the global market. She specializes in commercial strategy and launch excellence, including stakeholder communication and engagement strategy, organizational structuring, go-to-market strategy, commercial excellence, and performance evaluation. Sabrina has supported clients in a wide range of disease areas, predominantly within the areas of immunology, cardiovascular, and dermatology.

Prior to joining Simon-Kucher, Sabrina was an Associate Principal at IQVIA Consulting Services and a Manager Executive Insight Healthcare Consultants and gained industry experience with Boehringer Ingelheim and BASF before committing herself to consulting. Sabrina received a Master’s degree in Business Administration and a post-graduate degree in Health Care Economics from EBS University in Wiesbaden, Germany. She is a guest lecturer at EBS University, lecturing on performance evaluation in the pharmaceutical industry.

Henrik Hedstorm

Henrik is a Senior Director in Simon-Kucher’s New York office. He has more than 20 years of consulting and industry experience in the US and global healthcare markets. Henrik is a member of the global Pharmaceuticals & Biotech practice within Simon-Kucher’s Life Sciences Division. Specializing in corporate, commercial, marketing and brand strategy formulation, he supports clients in executing new product development, as well as the launch of new products/indications. In addition, Henrik assists his clients with process improvements and resource optimization.

Henrik was a Principal at IQVIA Consulting Services and Capgemini Consulting prior to joining Simon-Kucher and Partners. He spent more than a decade in marketing/brand & sales management at a top-5 international pharmaceutical company where he held many roles in both the global and the US organization. Henrik received his diploma in International Business from University of Stockholm / University of London and his Business Administration from CTU.
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.

Simon-Kucher’s global Life Sciences presence:
over 200 dedicated professionals in 20 offices worldwide

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