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An in-depth analysis of major pricing and reimbursement changes in Spain

The importance of pricing and market access in asset valuation

Three ways over-the-counter manufacturers can boost their bottom lines

Strategies for the successful launch of orphan drugs

and much more...

How to mitigate the risk of price cuts in European payer markets

By Amelie Scheffler, Diane Cosset, and Nady Sfeir

Pharmaceutical companies are facing more frequent and substantial price cuts for major products in most European payer markets. Indeed, as austerity measures across Europe have spread, pharmaceutical expenditures have become particularly appealing cost-cutting targets. In France, the 2013 social security financing law defined an objective of 800 million euros of savings from pharmaceuticals and medical devices price cuts. Portugal decided to cut the prices of some branded drugs by approximately 7% and expects to save 85 million euros this year through the annual price revision and new reference countries.

Price cuts have the potential to seriously erode pharmaceutical companies' profits, which could in turn lead to unforeseen consequences. A price cut on a major product that represents a high percentage of revenue could necessitate restructuring, decreasing investments, and closing manufacturing sites or offices for small- or mid-sized pharmaceutical companies. Moreover, the impact of a price cut in one European country can have a ripple effect in other countries through international price referencing rules (e.g., in the Netherlands, international price referencing is conducted twice annually).

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HITting it out of the park in the USA: Succeeding in a digital age

What does Health IT (HIT) use in the United States mean for the future of pharmaceutical companies?

By Brian De & Allison Capone

Until recently, health care practices in the United States were slow to widely adopt computerized systems, despite their potential benefits. As medical records have evolved from their earliest forms, they have come to include more complex information, making it increasingly cumbersome to keep track of all information on the traditional paper records. Usage of electronic medical records (EMR) has been linked to potential cost containment and outcomes accountability – several studies have documented their ability to reduce hospital lengths-of-stay, nurses' administrative time, and drug and imaging usage, among countless other benefits. Despite these advantages, uptake of such systems in the United States was not financially attractive for physicians or hospitals until the federal government began to provide significant incentives for adoption. As in many other countries, electronic medical records systems are here to stay in the US – here's what you should know to stay ahead of the curve.

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SIMON • KUCHER & PARTNERS

Strategy & Marketing Consultants

Executive Editor

Dr. Nathan Swilling

Assistant Editors

Stephen Dunbar

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Graphic Design

Anek Schumann

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Editor-in-Chief

Jennifer DeBerardinis

Associate Editors

David Bower

SiQi Chen

Jackie DiLorenzo

Chris Kramer

Marsha Pelletier

Brad Rubin

Lucas Toffoli

Clotilde de Vaux

Bonn Office

Willy-Brandt-Allee 13

53113 Bonn, Germany

+49 0228 / 9843-0

Boston Office

One Canal Park

Cambridge, MA 02141

+1 617 231 4500

Please send inquiries to:
LSCcommunications@simon-kucher.com

<http://www.simon-kucher.com/en/content/pharmaceuticals-biotechs>

Recent developments in global pricing & market access



Brazil: Coverage of oral oncology drugs and subcutaneous anti-TNFs by private payers becomes very likely

The private payer regulator ANS published a draft resolution on May 28 with a list of 36 oral oncology drugs to be covered by January 2014. This list includes Tykerb, Votrient, Zytiga, Sutent, Tassigna, and Afinitor, which currently lack regular coverage in both the public and private settings. ANS also recommended coverage of subcutaneous anti-TNF therapies, which until now were only covered in the public setting.

This potential private coverage presents a significant opportunity for the pharmaceutical industry in Brazil, as there are more than 47 million privately covered lives: equivalent to the entire population of Spain.

Currently, most private payers only cover drugs requiring supervision or administration by a healthcare professional. Oral and subcutaneous drugs are not regularly covered unless they are given to hospitalized patients. However, a significant number of patients obtain access to drugs not covered by private or public payers through legal injunctions.

A day after the ANS published the draft resolution, a proposed national law (PL 3,998/12) that requires coverage of oral oncology drugs by private payers was approved by a second commission in the Brazilian Congress, after having been approved by the Brazilian Senate last year. This means the proposed law only needs to be approved by the Commission for Constitution, Justice, and Family in the Congress and be signed by the Brazilian president to come into effect. This draft law specifies that coverage of oral oncology drugs will be regulated by ANS.

ANS is now collecting feedback from stakeholders on its draft resolution. One issue currently being discussed is whether ANS will only update the list of covered oral oncology drugs every 2 years, which could leave drugs launched during the time between list updates without coverage.

CONITEC increases funding barriers for gefitinib, erlotinib, natalizumab, and tiotropium

April was a tough month for branded drug manufacturers trying to access the large Brazilian public market. CONITEC, the new HTA commission that recommends funding decisions in the public healthcare system, has issued for public review negative HTAs for gefitinib, erlotinib, natalizumab, and tiotropium.

The HTAs for EGFR inhibitors erlotinib and gefitinib were requested by Roche and AstraZeneca, targeting first-line treatment for NSCLC EGFR+ patients. Despite the separate appraisals, CONITEC's conclusion was similar for both drugs: the HTA commission rejected public funding due to

a lack of efficacy gains in overall survival, which was stated as the primary outcome for the evaluation of oncology drugs. Though the HTA commission recognized the efficacy of the EGFR inhibitors in disease-free survival, this was classified as a secondary outcome, as it does not represent an improvement in a patient's condition.

CONITEC also complicated the plans of Biogen Idec to increase public access for natalizumab. The biologic already holds public funding for third-line treatment of multiple sclerosis but was denied broader coverage for second-line treatment. The HTA commission argued that the observational studies provided by the manufacturer presented weak consistency-of-efficacy evidence in this indication. In addition, the economic studies were considered limited and based on evidence for first-line treatment. CONITEC noted that the public system already has structured guidelines in place that are consistent with the international consensus for treating the disease.

Tiotropium's HTA was requested by the Public Ministry of Paraná, a southern State of Brazil. The drug is already covered for COPD patients with persistent symptoms and high risk of exacerbation in some of the states in the country, including the two most populous that capture a third of the Brazilian population: São Paulo and Minas Gerais.

CONITEC rejected funding on the grounds that clinical studies have not demonstrated significant efficacy of tiotropium over the publicly covered long-acting β_2 -agonists. The national funding refusal creates uncertainties over the future coverage of tiotropium by the states, given that they may follow the national guidance of the HTA commission.

The final HTA report still needs to assess public collaborations, usually written by physicians' societies, reference treatment centers, patients' associations, and drug manufacturers. However, given prior HTA decisions, CONITEC is unlikely to change its initial appraisals of the drugs.

Canada: Legislation enacted to cap generic drug prices

The Canadian provinces recently enacted a collaborative agreement that places limits on the prices of some widely used generic drugs. Controlling the prices of generic drugs has been a top priority in Canadian health policy since the issue garnered national attention in the 2000's, when several studies showed that Canadians were paying substantially more for generic drugs than were healthcare consumers in other countries.

Ontario was the first province to take action, and in 2010 capped the prices paid by the Ontario Drug Benefit (ODB) Program for generics at 35% of the bio-equivalent branded drug prices as of April 2011, and at 25% as of April 2012. These acts led to an estimated savings of C\$200 M/year on prescription drug costs. The province has since further reduced the maximum price of ODB price for the top 10 most commonly prescribed generics drugs to no more than 20% of their branded equivalents, resulting in a further C\$55 M savings. The savings achieved in Ontario

prompted other provinces to implement their own measures to limit generic prices paid by public plans and led to widespread capping of generic prices at 25 to 40% of branded equivalents.

Canada's provinces and territories took an even more drastic step in April 2013: they not only enacted legislation capping generic prices of specific drugs at 18% but also did so collaboratively. This 'pan-Canadian' agreement extends to six widely prescribed generic drugs: atorvastatin (high cholesterol), ramipril (high blood pressure), venlafaxine (depression), amlodipine (high blood pressure and angina), and omeprazole and rabeprazole (both for ulcers and acid reflux). Provincial governments project that this move will collectively save public drug plans up to C\$100 M/year. Although Quebec neither participated in negotiations nor signed the legislation, the province will nevertheless benefit from the new scheme because regulations dictate that Quebec drug prices must be equal or less than the lowest public prices in other provinces.

Despite industry fears that the agreement might also introduce tendering – whereby a single manufacturer would capture all public plan purchases of a multi-source molecule – concerns over drug shortages limited political willingness to implement a tender process. Instead, provinces have agreed to consider agreements with all manufacturers willing to supply the market with generics at 18% of the prices of their branded equivalents.

The recent pan-Canadian agreement on generic drug prices is the first of its kind for multi-source drugs. However, if the provinces see substantial savings as a result of this first collective generic price-cutting agreement, it will not likely be the last.

Canadian Purchasing Alliance leverages higher volumes to achieve lower prices

Despite its genesis several years ago, the pan-Canadian Purchasing Alliance (p-CPA) has only recently gained traction as a means for provinces to centralize price negotiations for publically reimbursed drugs. Unlike generics, the prices of branded drugs in Canada are already in essence "capped" by the Patented Medicines Price Review Board (PMPRB). Nevertheless, there are significant latent incentives for provinces to negotiate branded drug prices via a pan-Canadian approach (i.e., improving consistency of branded drug prices and patient access across all provinces, leveraging larger utilization volumes to achieve lower drug prices, and minimizing duplication of resources required for the negotiation of listing agreements by individual provinces).

These factors prompted provinces (except Quebec) to establish the p-CPA in 2010, with the goal of centralizing the price negotiations for publicly reimbursed drugs. However, the p-CPA initially gained little traction as a means of negotiating branded drugs; provinces have historically been individually responsible for these negotiations, and

as a result proved resistant to change. In fact, so deep-rooted is the idea of province-by-province branded price negotiations, that in its first two years, the p-CPA was utilized only twice for branded drugs, and then only for very high-cost innovative therapies.

However, premiers and provincial health ministers publicly declared their support for the collective negotiations approach for branded drugs in 2012. Following these public re-affirmations, there was mounting evidence of increased acceptance and adoption of the collective negotiation approach. As of spring 2013, joint negotiations had become decidedly more commonplace – although neither universal nor mandatory – and had been completed for 8 brand-name drug products, with 13 more drugs in active negotiations.

The provinces also reached consensus with regard to key p-CPA directives, such as agreement that all branded drugs evaluated by the Common Drug Review (CDR) or the pan-Canadian Oncology Drug Review (p-CODR) would be considered as potential candidates for collective price negotiations, although the general consensus at the moment points to p-CPA negotiations being limited to innovative, higher cost therapies. These initial decisions represent the first steps toward establishing a formal operating structure, which provinces have agreed is the next step for the further development of the p-CPA.

All in all, the p-CPA appears to have reached a tipping point that signals more frequent usage of collective negotiations for branded drugs – especially expensive, innovative branded drugs – seeking public reimbursement. Nevertheless, this is far from a sure bet: without specific timelines for the implementation and roll-out of formal operating procedures or support from federal leadership, whether such collective negotiations of branded drug prices are a passing trend or whether they are here to stay and be further developed remains an open question.

Germany: Bundestag passes AMNOG amendment to ease benefit evaluation

Germany's lower house of parliament, the Bundestag, recently passed a key amendment to the relatively new AMNOG process. With its passage, the amendment moves to the Bundesrat for approval. If approved, new technologies reviewed by the G-BA will no longer be compared to the lowest cost comparator during the AMNOG benefit evaluation. Instead, the manufacturer will be able to choose its technology's comparator from a list approved by the G-BA. The goal of the amendment is to prevent an automatic "no benefit" for technologies that do not have a specific trial versus the lowest cost comparator. Opponents of the amendment claim manufacturers would be able to achieve a higher price despite offering "no benefit"; however, supporters argue that the opponents do not fully understand the AMNOG process. The pricing negotiations are separate from the benefit evaluation, and the amendment only applies to the benefit evaluation. Technologies that offer

"no benefit" will still be required to have a price comparable to the lowest cost comparator. Nevertheless, when the conversation starts in terms of a higher cost comparator, it is possible that the same comparator will be carried over into the price negotiations.

G-BA publishes new selection process for retrospective benefit assessment

The G-BA recently published the algorithm for the selection of drugs subject to retrospective benefit assessments. In a first step, 188 relevant active substances have been identified according to the following criteria:

- Launched prior to January 1, 2011 (prior to AMNOG)
- New active substance that is still patent protected (if the drug contains more than one active substance, at least one has to be patent protected)
- Not chosen as appropriate comparator therapy by the G-BA in a previous benefit evaluation
- Not included in an FRP group or excluded from reimbursement

In a second step, the identified active substances were ranked according to their importance to the health care system: expected sales until loss of exclusivity. Revenue (i.e., economic burden) accounts for 80%, and frequency of prescriptions (i.e., market diffusion and prevalence) for 20% in this ranking.

In a third step, drug groups were created around the lead substances. Regardless of the length of patent protection, pharmaceutical agents, which have at least one indication with the respective lead substance in common, are assigned to the group.

While the G-BA highlighted that the approach contributes to transparency and fairness in the evaluation process, industry associations claim that it was not put up for scientific discussion before implementation. They also contend that the differences across substances/groups regarding revenue and sales development have not been appropriately reflected in the algorithm.

For further retrospective benefit evaluations, the G-BA resolved to put forth at least one group every six months. However, not all drug groups included on the list will have to face a retrospective benefit evaluation, since they might lose their patent protection beforehand.

The G-BA put forward six drug groups for retrospective benefit assessment (Table 1). Manufacturers of these drugs are therefore asked to submit a dossier to the G-BA; if a dossier is not submitted on time, an additional benefit will not be granted.

Table 1: Product groups subject to retrospective benefit assessments

	Active ingredient (brand name)	Joint therapeutic indication	Deadline for dossier submission
Product groups (ranked by importance)	1 Tapentadol* (Palexia)	Intense chronic pain	15 Oct. 2013
	2 Denosumab* (Prolia)	Osteoporosis	15 Oct. 2013
	Ranelic acid, distrontium salt		
	Recombinant parathyroid hormone		
	Teriparatide (Forteo)		
	3 Rivaroxaban* (Xarelto)	Atrial fibrillation, stroke prophylaxis, and cardioembolic diseases; deep venous thrombosis	15 Dec. 2013
	Dabigatran (Pradaxa)		
	4 Liraglutide* (Victoza)	Diabetes mellitus type 2	1 Jan. 2014
	Exenatide (Bydureon)		
	5 Agomelatin* (Valdoxan)	Depression	1 Feb. 2014
Duloxetine (Yentreve)			
6 Tocilizumab* (RoActemra)	Rheumatoid arthritis	1 March 2014	
Golimumab (Simponi)			
Certolizumab pegol (Cimzia)			

*lead substance

QoL may play a greater role than PFS in early benefit evaluations for oncology drugs

The most important endpoint for oncology treatments is the overall survival (OS). Yet, an improvement in the overall survival vs. a competitor treatment is often difficult to show at treatment launch, e.g., due to the necessary study length or cross-overs. Thus, progression free survival (PFS) is often used as the primary endpoint in clinical trials, especially for oncology treatments used in early lines of treatment. But with PFS as a primary clinical trial endpoint, demonstrating a drug’s patient-relevant benefits in early benefit evaluations – which the G-BA does not believe PFS delivers – can be challenging for manufacturers.

Recently, the G-BA determined that improvement in OS could not be shown for crizotinib, a treatment for ALK-positive NSCLC, due to the cross-over of patients to the crizotinib arm. Thus, the key question was to what extent an additional benefit can be granted based on PFS as the primary endpoint. PFS is regarded as a combined endpoint by the G-BA – consisting of mortality and morbidity. In the case of crizotinib, the GBA granted an additional benefit based on symptomatic morbidity data (e.g., tumor-related symptoms and health-related quality of life). The G-BA did not analyze PFS as a surrogate parameter to assess the benefit of the drug. The significant reduction in non-fatal symptoms and a significant improvement in quality of life led to a significant additional benefit in comparison to best supportive care.

The case of crizotinib suggests that if morbidity and quality of life data are measured, they will feature more promi-

nently in G-BA considerations than PFS. Yet, it remains to be seen how the G-BA will evaluate a drug that has only PFS and no symptom/quality of life data.

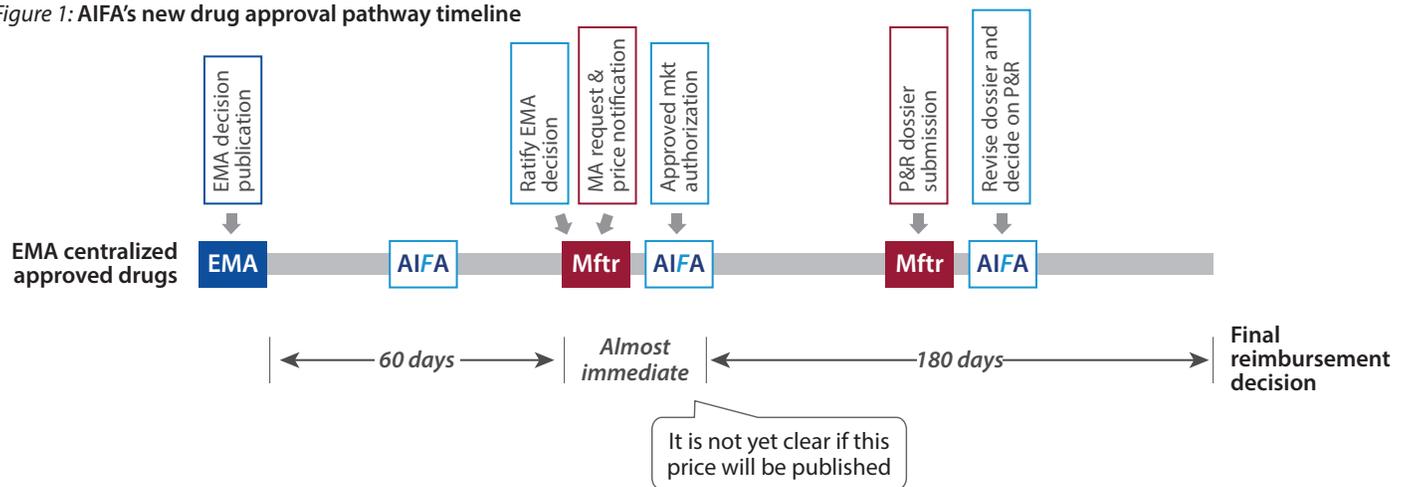
Italy: AIFA establishes new drug approval pathway

AIFA recently implemented law 189/2012, intended to provide immediate market authorization to EMA-approved drugs that are awaiting pricing and reimbursement negotiations and thereby making them almost immediately available to patients, who would pay OOP (Figure 1). As stated by the law, all EMA-approved drugs will be temporarily placed on a sub-list of non-reimbursed drugs and will be classified as class C (Class C (nn)). In order to get access to the class C (nn), manufacturers must submit a request for market authorization that communicates their planned public price. Then, the drug can be commercialized and purchased by patients out-of-pocket. Manufacturers can submit a request for reimbursement only after having received market authorization.

Special exceptions for this law are orphan drugs, drugs of exceptional therapeutic importance selected by AIFA (it is not clear how AIFA will select this drug category), and hospital-distribution-only drugs. Manufacturers of these drugs may instead submit their P&R requests in parallel with their market authorization request.

Currently, the updated list of all drugs included in the category as well as a list of drugs that are waiting to be included in the class are available on AIFA’s website.

Figure 1: AIFA's new drug approval pathway timeline



Approved: http://www.agenziafarmaco.gov.it/sites/default/files/Lista_farmaci_inseriti_classe%20C_27%2005%202013.pdf

Waiting: http://www.agenziafarmaco.gov.it/sites/default/files/farmaci_valutazione_CTS_11062013.pdf

This reform has important implications for pharmaceutical manufacturers, as it dictates that once a drug is placed in class C (nn), manufacturers can commercialize the drug in Italy after they communicate the public price to AIFA. The initial price communication must be carefully elaborated given that it could be dangerous for the drug's image. However, the price also has the potential to be beneficial for future P&R negotiations; it could be used by the manufacturer as an anchor for price negotiations, forcing AIFA to review its negotiation strategy.

Nevertheless, companies are not obligated to commercialize the drug before they negotiate the reimbursement, since this could present drawbacks. For example, for expensive drugs with indications addressing high unmet needs or with high social/payer awareness, the price is likely to play an important role on both the manufacturer and the drug's perceived image. Cases of particularly high public interest could put pressure on the company to shorten negotiation times by offering discounts that will obtain AIFA's buy-in.

On the other hand, the new class could be advantageous given that companies will be allowed to start promoting drugs before having reimbursement, thereby preparing the market for the arrival of the drug once the negotiation process is over and accelerating market penetration.

Japan: MHLW aims to increase share of generic drugs to over 60% by 2018

The Ministry of Health, Labor, and Wealth (MHLW) announced in April 2013 a "Roadmap for further promotion of the use of generic medicines" to ensure the sustainability of the national healthcare system by increasing the efficiency of medical spending.

Though the MHLW aimed to increase the share of generic

drugs to exceed 30% by the end of 2012, the share has only reached approximately 26% (based on the old calculation method: generic volume over total drug volume). Though off to a slow start, MHLW's roadmap set an ambitious new target for Japan's generic share: over 60% (defined as generic volume over the combined volume of long listed and generic drugs) by 2018: similar to the current generic share in France and Spain. Based on the old calculation method, the 2018 target generic share would be 34.3%, but the roadmap redefined the share of generic drugs to align with international practices.

The national and prefectural governments, as well as generic manufacturers and health insurance providers, are leading 6 key initiatives that aim to overcome hurdles impeding the use of generics.

1. Securing a stable supply of generics

The supply of generic drugs has been unreliable due to manufacturing freezes, quality control problems, and bulk drug shortages. To alleviate this problem, the MHLW will reference the best practices of other countries on generic drug supply management and the procurement of bulk drugs. Generic manufacturers are also asked to create and follow operational manuals to maintain stable supply based on guidance provided by the Association of Generic Medicine Manufacturers.

2. Building trust in product quality

Many Japanese physicians still doubt the quality of generic drugs and refrain from prescribing them over branded alternatives. To combat this preference, the MHLW and the prefectural governments will continue to provide prescribing guidance, conferences, and trainings that highlight the value of generic alternatives. Additionally, the MHLW will send inspectors to generic manufacturing sites to confirm that quality standards are met.

3. Promoting complete information delivery of generic drugs to physicians

Though the MHLW has worked to provide reputable information supporting the use of generics, information such as supplementary documents on drug characteristics are

not effectively reaching medical practitioners. The prefectural governments will collect information and provide lists of generic medicines to local medical institutions and pharmacies. In addition, the Association of Generic Manufacturers will improve the Generic Medicine Information System, and generic manufacturers will provide training to their medical representative and medical marketing specialist teams to further improve the quality of information delivery.

4. Improving the environment for further utilization

The MHLW will provide technical advice to prefectural governments on the development of effective plans to manage medical spending by promoting the increased use of generic drugs. Prefectural governments will set targets for the share of generics and work on initiatives to expand the use of generic drugs locally. Additionally, health insurers will more actively provide information on price differences between generics and their branded alternatives.

5. Changing the insurance system

The MHLW has increased the incentives given to pharmacies and medical institutions for dispensing generic options over their branded alternatives in the past few years. Because past measures did not bring expected results, further incentives must be developed to increase the prescribing of generics by doctors, dentists, and pharmacists. For doctors and dentists, incentives are tied to share of generic drug use at a medical institution, while for pharmacists, health insurance points are also given based on percentage of generic drugs dispensed. Since Japan is a prescription market and current practice relies heavily on branded drugs, however, these initiatives do meet resistance. As such, the Central Social Insurance Medical Council (CSMIC) will consider additional changes to the medical insurance system to further incentivize the use of generics.

6. Monitoring progress toward roadmap targets

The generic share in foreign markets will be monitored on an ongoing basis, and the MHLW plans to adjust the 2018 target generic share based on any major changes in the generic landscape abroad.

UK: DoH aims to promote nationally uniform treatment through CDF

The CDF has faced many popular criticisms since its inception in 2011, particularly for its inability to decrease locality-based treatment inequity ('postcode' prescribing). The Department of Health took action to end this regional variation in access by making NHS England responsible for the operational management of the CDF. As of April 2013, there is one national list of approved "fast-track" drugs. This means that there is now a single national system for deciding which cancer drugs are available for which conditions, resulting in uniform access to treatment.

NHS England has also established a national CRG (Clinical Reference Group) for Chemotherapy, which helped to improve the CDF list. The Chemotherapy CRG will take the

lead on reviewing new treatments and making recommendations for funding.

The single national list will contain 28 products that treat 70 cancer conditions (Table 2). Specialists will still be able to apply for any cancer treatment through the CDF on behalf of their patients, even if the drug is not on the fast track list via Individual Funding Requests. Specialists are also able to request a fast-track cohort policy for drugs to be reviewed. Given the dynamic nature of the CDF, the national list will be reviewed quarterly by the Chemotherapy CRG.

Any patient currently receiving funding for a cancer drug that is not listed on the nationally approved list or who has received confirmation that they will receive funding for one of these drugs will continue to receive treatment as long as their specialists consider it clinically appropriate.

As for the roles of former bodies, the Cancer Networks will continue their work in supporting commissioners to achieve the goals of the quality outcomes framework;

Table 2: The UK's national CDF list

Drugs	Indication(s)
Abiraterone	Metastatic castration-resistant prostate cancer
Aflibercept	Metastatic colorectal cancer (second line)
Axitinib	Advanced renal cell carcinoma
Bendamustine	Chronic Lymphocytic Leukemia, low grade lymphoma (first line, relapsed, or refractory to Rituximab), mantle cell non-Hodgkin's lymphoma (first line or relapsed), multiple myeloma (relapsed)
Bevacizumab	Advanced breast cancer, advanced colorectal cancer, advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer
Bortezomib	Mantle cell lymphoma (relapsed or refractory), Waldenstrom's Macroglobulinemia (relapsed)
Brentuximab	Systemic anaplastic lymphoma (refractory), CD30+ Hodgkin lymphoma (relapsed or refractory)
Cabazitaxel	Metastatic castration-resistant prostate cancer
Cetuximab	Advanced head and neck cancer, metastatic colorectal cancer
Clofarabine	Acute lymphoblastic leukemia (relapsed or refractory), acute lymphoblastic leukemia (relapsed or refractory)
Crizotinib	ALK +ve advanced or metastatic non-small cell lung cancer
Dasatinib	Philadelphia chromosome positive (Ph+) acute lymphoblastic leukemia and lymphoid blast crisis chronic myeloid leukemia, chronic phase chronic myeloid leukemia, accelerated phase chronic myeloid leukemia, blast crisis chronic myeloid leukemia
Eribulin	Advanced breast cancer
Everolimus	Advanced breast cancer, pancreatic neuroendocrine carcinomas, metastatic renal cell carcinoma
Imatinib	Gastrointestinal stromal tumor
Lapatinib	Advanced breast cancer
Lenalidomide	Multiple myeloma (second line)
Nelarabine	Refractory T-cell acute lymphoblastic leukemia or refractory T-cell lymphoblastic non-Hodgkin's lymphoma
Ofatumumab	Chronic lymphocytic leukemia
Pazopanib	Advanced non-adipocytic soft tissue sarcoma
Pegylated Liposomal Doxorubicin	Angiosarcoma, sarcoma in patients with cardiac impairment, sarcoma of the heart and great vessels, fibromatosis (2 nd line)
Pemetrexed	Advanced non-squamous non-small cell lung cancer (2 nd line, maintenance)
Peptide Receptor Radionuclide Therapy (Lutetium177 Octreotate or Yttrium90 Octreotide/Octreotate)	Neuroendocrine tumors
Pertuzumab	Locally advanced or metastatic breast cancer
Ruxolitinib	Symptomatic splenomegaly in primary myelofibrosis, post polycythaemia vera myelofibrosis or post essential thrombocythaemia myelofibrosis
Sorafenib	Advanced hepatocellular carcinoma, papillary or follicular thyroid cancer, pancreatic neuroendocrine carcinomas
Temsirolimus	Advanced renal cell carcinoma
Vandetinib	Medullary thyroid cancer

however, their role is muddled by their overlapping responsibility with the new NHS England.

NICE will continue to review new big budget impact medications. Should NICE support the use of a cancer drug that is already on the national list, it will be removed from the list within 90 days of the NICE review's publication and become routinely commissioned by the NHS. In instances where a new oncology therapy receives a negative appraisal, decisions to fund the drug via the CDF will be made by NHS England, provided that the fund is still in operation.

'Commissioning through evaluation': Is this the practical approach to specialized commissioning we were looking for?

In the House of Lords on February 26, the UK commissioning board clinical director for specialized services, James Palmer, said: "The process that we are putting in place is called 'commissioning through evaluation', which allows us to start using a treatment, evaluate its effect and ensure that it aligns to a research protocol on the way." This pragmatic approach to commissioning is intended to provide 'a specific budget to rapidly test and evaluate innovations that have the potential to deliver high impact changes'. The 44 clinical access policies released on April 4 are the first examples of this new UK commissioning approach. This initial commissioning on a limited basis will allow earlier market entry for new treatments. Eventually, a final commissioning decision regarding future use will be made based on additional evidence. The NHS commissioning board has a duty to promote innovation and research, and 'commissioning through evaluation' could provide a fast entry option for treatments that struggle to gather strong evidence and that otherwise may not be routinely funded by the NHS.

Ireland's Health (Pricing and Supply of Medical Goods) Bill 2012 to introduce reference pricing and pro-generic initiatives

Recently passed Health Bill 2012 will establish reference pricing and pro-generic initiatives in Ireland. The Irish parliament's (Oireachtas) new legislation aims to reduce both overall drug spend and out-of-pocket patient spending. The bill will create a reference pricing system: patients will pay costs that exceed the reference price for a branded drug out-of-pocket, unless the brand is clinically necessary. For drugs at or below the reference price, the Health Service Executive (HSE) will pay for General Medical Services (GMS) provided products. On the pro-generics initiative front, the bill will allow pharmacists to substitute generic medicines with their branded alternatives, if the generic is certified by the Irish Medicines Board (IMB) as interchangeable and if the physician has not indicated a medical reason the prescription must be branded.



US: Florida passes Cancer Treatment Fairness Act

On June 7, Governor Rick Scott of Florida signed into law the Cancer Treatment Fairness Act, which will go into effect in July 2014 and requires private health insurance agencies to cover oral chemotherapies in the same manner as intravenous chemotherapies. The new law aims to make oral cancer therapies more affordable for many of Florida's large elderly population who receive supplemental insurance in addition to Medicare insurance. Florida is the 23rd state (not including District of Columbia) to pass an oral chemotherapy parity law.

Texas rejects State Medicaid expansion

Texas opted out of Medicaid Expansion at the end of May, led by Governor Rick Perry. State Medicaid Expansion, a tenet of the Patient Protection and Affordable Care Act, extends State Medicaid coverage to those earning under 138% of the federal poverty level, or about \$31,000 for a family of four. Expansion would be heavily federally subsidized: The federal government would pay entirely for expansion between 2014 and 2016, reduced to 90% by 2020, for a total subsidy of almost \$200 million annually. Medicaid expansion is especially contentious in Texas, a heavily Republican state with the highest rate of uninsured in the US (26%, or 6 million residents). Supporters of Medicaid expansion cite the high rate of uninsured and the economic gains federal subsidies would lead to, including a healthier population and a more robust healthcare system. Legislators who oppose Medicaid expansion cite current inefficiencies in Medicaid as well as the importance of state sovereignty. Though Texas opted out of Medicaid expansions, supporters say that the fight for health coverage is not over.

GSK prices its two new melanoma therapies at a discount to Zelboraf

At the end of May, the FDA approved both of GSK's new melanoma therapies: Tafinlar and Mekinist. Both therapies were priced at a discount to Roche's BRAF inhibitor, Zelboraf. Mekinist, a MEK inhibitor, displayed similar PFS to Zelboraf, yet it was priced at a 20% discount. And, Tafinlar, which has the same mechanism of action as Zelboraf but slightly inferior PFS data, was priced at a 30% discount. Tafinlar and Mekinist both received monotherapy indications; however, GSK is currently conducting trials to determine the efficacy of both therapies in combination. If the two are eventually approved in combination, then their total cost would be 50% more than that of Zelboraf.

Pricing and reimbursement in Spain: An analysis of national level P&R decisions from January 2011 until April 2013

By Kathrine Kartach

As the Spanish economy strives to recover from the economic crisis, the pharmaceutical industry faces challenges in the Spanish market. First, austerity measures (initiated in 2010 as a response to pressure to meet European deficit targets) continue to limit public healthcare spending. Moreover, drugs correspond to over one-third of the estimated healthcare budget deficit (€15.5 billion)ⁱ. Increases in healthcare spending, especially for hospital drugs, drove this healthcare deficit: prior to 2010, hospital drug spending registered inter-annual increases of 10-15%ⁱⁱ and currently accounts for approximately 40% of pharmaceutical spendingⁱⁱⁱ. For these reasons, the pharmaceutical industry has become a walking target for the Spanish government.

As a result, the former socialist government began to implement various healthcare cost-containment measures. Within the span of two years (mid-2010 to mid-2012), the government approved four Royal Decrees focused on cost-containment measures, including reductions on the prices of generics, across-the-board obligatory discounts for innovative drugs, higher drug co-pays, delisting of 400 drugs from reimbursement, and a centralized purchasing platform for drugs and healthcare products. These measures have saved an estimated €13 billion. Healthcare spending has been cut by 10.6% in the last three years (€6.7 billion)^{iv} in order to meet deficit targets (1.6% in 2012 and 0.7% for 2013)^v. The regional healthcare budgets for 2013 have been cut on average by 5.62% vs. 2012 whilst the pharmaceutical budget has been cut on average by 13.55% vs. 2012 (for Valencia and Murcia these cuts are >30% and in nine of the 17 regions >15%)^{vi}. These figures lend insight into the depth and breadth of planned healthcare spending cuts; meeting spending targets will not be easy for the healthcare sector, and these cuts will also create major challenges for pharmaceutical companies.

The remainder of this article will concentrate on analyzing two consequences of the budgetary pressure on pharmaceuticals related to pricing and reimbursement of new drugs at the national level:

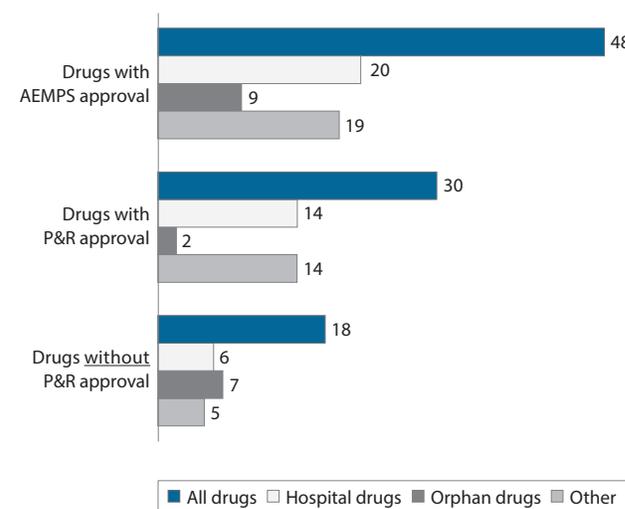
1. P&R delays for new drugs
2. Changes to pricing policy and their impact on pricing decisions for new drugs at the national level

This article will not discuss pricing and access decisions on a regional and local level or pricing decisions for drugs seeking approval for new indications.

P&R delays for new drugs

The following analysis focuses on P&R delays in Spain for new drugs between January 2011 and April 2013. It is based on all new drug market authorization approvals from the Spanish Medicine's Agency (AEMPS) up to September 2012 (allowing for the 180 day standard time window for P&R approval in Spain).

Figure 1
Overview of P&R approvals in Spain: January 2011-April 2013



Drugs with AEMPS approval: until Sept. 2012
 Drugs with/without P&R approval: until Apr. 2013
 Hospital dispensation drugs do not include orphan drugs
 Other includes retail and non-reimbursed products

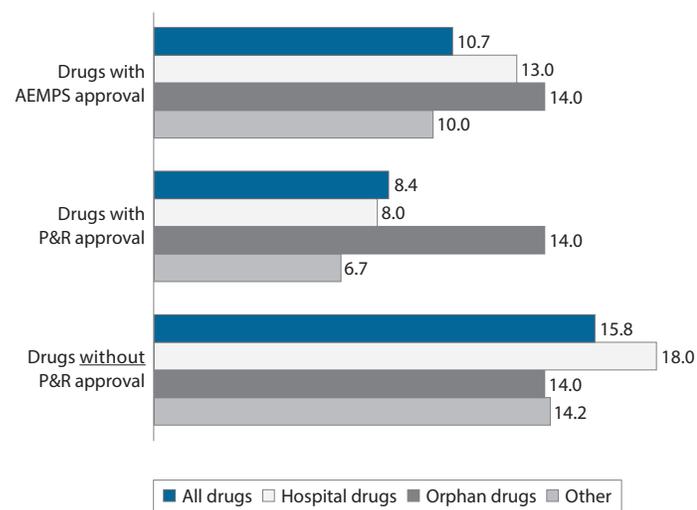
A total of 48 new drugs received market authorization from AEMPS between January 2011 and September 2012 (Figure 1). Almost 20% (9) of these new drugs are designated with orphan drug status. An estimated 42% are drugs with hospital use or hospital dispensation status (excluding the orphan drugs). Of these 48 drug approvals, 63% of them (30) have received P&R approval from the Ministry of Health. Almost half (47%) are hospital-use or hospital-dispensation drugs, and only two are orphan drugs. By April 2013, eighteen drugs (37%) still had no P&R resolution, seven of which (39%) were orphan drugs. If no P&R decision can be reached, these drugs may remain without NHS reimbursement in Spain.

What about approval times and P&R delays?

The EU Transparency Directive establishes a maximum time period for P&R approvals of 180 days (6 months). In the case of those drugs with P&R approval, the approval process by the Ministry of Health took on average 8.4 months from the date of market authorization until inclusion in the national health system^{vii} (Figure 2). The minimum time was 3 months, and the maximum, 17 months. Fourteen drugs (47%) were approved within the stipulated six month time period. Included in this group are drugs such as Victrelis and Incivo for hepatitis C. In these cases, the clear clinical benefit for Hep C patients drove swift approval. A total of seven products were in P&R negotiation for more than 12 months until obtaining approval. Five of these seven products are hospital use or hospital dispensation used in HIV, oncology, neurology and dermatology; the remaining two drugs are the orphan drugs.

In the case of the eighteen drugs (37%) that still haven't received P&R approval, on average they have been awaiting approval for 15.8 months (until April 2013) with a maximum approval delay of 24 months. Except for one drug, all have been in P&R negotiations for 11 months or longer. Examples of drugs in this group are Halaven (breast cancer), Zelboraf (melanoma), Esbriet (idiopathic pulmonary fibrosis), Vyndaqel (familial amyloid polyneuropathy), Caprelsa (thyroid cancer), and Fampyra (multiple sclerosis).

Figure 2
Overview of P&R approval times (in months)



Drugs with AEMPS approval: until Sept. 2012
 Drugs with/without P&R approval: until Apr. 2013
 Hospital dispensation drugs do not include orphan drugs
 Other includes retail and non-reimbursed products

Several factors drive these delays and differences in approval times:

1. **Inclusion of regional representation in the national pricing commission in mid-2012:** Before mid-2012, P&R decisions (national competency only) and drug budget management (regional competency) were clearly disconnected. The inclusion of the budget holders (i.e., the regions) in national P&R decisions led to greater discussion around what should be approved, under what conditions, and at what price, leading to the delays observed.
2. **Political changes have slowed decision-making:** A change in the leading political party, along with other political factors, led to more infrequent pricing committee meetings where P&R decisions were taken.
3. **A high share of hospital and orphan drugs among all agents awaiting approval:** Given that hospital drugs, including orphan drugs, represent approx. 40% of the total pharmacy budget, payers are delaying decisions for hospital and orphan drugs in order to maintain the decreases in hospital drug spending (deficits - 2010: 8.1%, 2011: 3.4%).
4. **Low perceived additional clinical benefit in relation to the high price requested:** The MoH has stated that it will follow the criteria of "denying public funding for some biologics and cytostatics when companies are requesting unreasonable prices, especially for drugs which lengthen survival only by three months"^{viii}.

Pricing policy and pricing decisions for new drugs at national level

For many years, there have been three key cornerstones to pharmaceutical price setting in Spain:

1. Internal price referencing with available therapeutic alternatives
2. External price referencing with other EU countries
3. Consideration of budget impact

What has changed in the last three years? (Table 1)

On the one hand, there has been a change in emphasis of each of these three decision criteria on P&R approval for new drugs:

On the other hand, as a result of budgetary pressure and an objective to remain one of the countries with the lowest drug prices in Europe, changes have been made to pricing policy:

1. Obligatory discounts/rebates for all new drugs:

"Our European counterparts are doing it, why not us?" As a result, in 2010 Spain introduced its own discounting approach: a discount of 7.5% for new drugs and 4% for orphan drugs.

Table 1
Changes in the past 3 years

Criteria	Change in emphasis	Rationale for change in emphasis
Internal price referencing:	 Increase	More emphasis on making sure that prices of new drugs are aligned with those of existing therapeutic alternatives in Spain
External price referencing:	 Decrease	EU price referencing is no longer explicitly mentioned as a factor for price decision, allowing for greater emphasis on internal price referencing
Budget impact:	 Strong increase	The main driver, at least in the short term



2. Introduction of a double pricing system:

“Our European counterparts negotiate further (e.g. confidential price-volume agreements), why not us?” With the last Royal Decree in April 2012, the Spanish government opened the door to a “double pricing” system that focuses on drugs dispensed in the hospital setting. The double-pricing system may be applied when the MoH considers the requested list price for a new drug from a pharmaceutical company too high for reimbursement within the NHS. This system allows pharmaceutical companies to request a non-reimbursed list price (notified price), taking into consideration EU price references but requiring the pharmaceutical companies to negotiate a confidential discount with the MoH in order to be reimbursed within the NHS (funded price). Although the actual level of discount is supposed to be confidential, to date the negotiated funded prices for three newly approved drugs (Lustrate, Yervoy and Xgeva) have been published in the Spanish press^x. The funded prices are -20%, -30% and -20% compared to the notified list prices, respectively^x. In addition, publically available sources^{xi} reveal that the recently approved drug, Eviplera, has double pricing, though the actual level of discount remains confidential. Although public sources can currently be used to establish which drugs are subject to double pricing, for future double pricing agreements, it is expected that the actual level of discount will remain confidential.

How have these pricing policy measures affected pricing decisions in Spain

A comparison to the EU-4 (France, Germany, Italy, and the UK)

The following analysis is based on those drugs with price and NHS reimbursement approval since January 2011 and with price approval in at least two other EU-4 markets.

When comparing ex-manufacturer list price in Spain with the EU-4, Spain is already the country with the lowest prices on average (-7%) (Figure 3). When comparing on a visible net price level^{xii}, the picture does not change significantly (-5%). However, in the EU-4 there are many cases with additional confidential agreements in place that cannot be reflected in this analysis. Given that payers in Spain are aware of the existence of such agreements and are under pressure to meet budget deficit targets and remain the EU-5 country with the lowest prices, national payers implemented the double pricing system. When looking at the price differences between the EU-4 for Yervoy and Xgeva (two newly approved drugs with double pricing and publically available information on the funded price), Spain is on average 20% below the EU-4. The average P&R approval time for new drugs with double pricing (Lustrate, Yervoy, Xgeva, and Eviplera), was 13.75 months, which is ~5 months above the average (8.4 months). Although approval times were longer, positive outcomes were reached. This either may not have been possible or would have resulted in even more delays without double pricing. It is still early to draw solid conclusions about double pricing; however, payers seem to be requesting significant discounts for new drugs, especially in the hospital setting, in order to remain the country with the lowest net price within the EU-5.

In summary, healthcare spending, especially hospital drug spending, is under attack from the array of cost-containment measures implemented by the Spanish government that aim to curb spending and reduce the healthcare deficit. The consequences of these deep budget cuts for the pharmaceutical industry are numerous with specific consequences for the P&R approval of new drugs. There are significant delays (over one year) in P&R approvals for (high cost) hospital and orphan drugs in particular. In terms of pricing new drugs, on average, Spain

is the lowest priced country in the EU-4, both on a list price and visible net price level. Given the high pressure to significantly reduce deficits and the fact that payers are aware of the existence of additional discounts or pricing agreements that can further lower the net price of new drugs within the EU-4, Spain has jumped on the bandwagon in an attempt to remain the country with lowest prices in the EU-5. As a result, additional pricing agreements, such as those described above, may be required for new drugs at the national level in order to obtain reimbursement.

How can pharmaceutical companies mitigate the effects of pricing pressure and P&R delays?

Some selected lines of action are:

1. Consider the tough P&R environment and prepare a robust value story that addresses budget sensitivity and supports the price request.
2. Establish both visible net and non-visible net internal pricing policies for the European price corridor, and have a clear walk-away price across the markets at the list, visible net and non-visible net price.
3. Be proactive internally with double pricing for drugs dispensed in the hospital setting. Already incorporate this into the price negotiation strategy at both the global and local level as a fall back option for P&R negotiation.

4. Track expected policy changes in order to optimize P&R strategies for new drugs. Looking to the future, the Ministry of Health stated that it is considering a conditional reimbursement system for new drugs^{xiii}.

Endnotes

ⁱhttp://www.consoft.es/noticias/news_text.asp?id=40030

ⁱⁱIMS Health

ⁱⁱⁱIMS Health

^{iv}El País 16th February 2013 "6.700 millones menos para sanidad"

^vEl Global 14 -20 January 2013 "El presupuesto en Farmacia para 2013 cae más del doble que el del total de la partida sanitaria"

^{vi}El Global 14 -20 January 2013 "El presupuesto en Farmacia para 2013 cae más del doble que el del total de la partida sanitaria"

^{vii}Due to lack of public information on CIPM approval dates in some cases the date of commercialization was taken

^{viii}Elglobal.net 7 June 2013: El real decreto de precios y evaluación de medicamentos se conocerá a lo largo de junio

^{ix}Portalfarma database. Cofares. El global.net. "El precio notificado llega a las farmacias pero el sector aún no sabe cómo actuar". February 18, 2013. "BMS comercializara Yervoy 5,304 euros más caro para los hospitales privados que para el SNS". January 22, 2013. Correo Farmacéutico. "Sanidad busca cómo compensar a las boticas y consolidar el doble precio". January 28, 2013; *PVL notificado; PVL facturación

^xEl global.net. "El precio notificado llega a las farmacias pero el sector aún no sabe cómo actuar". February 18, 2013. "BMS comercializara Yervoy 5,304 euros más caro para los hospitales privados que para el SNS". January 22, 2013. Correo Farmacéutico. "Sanidad busca cómo compensar a las boticas y consolidar el doble precio". January 28, 2013

^{xi}Portalfarma; Botplus – "notified price"

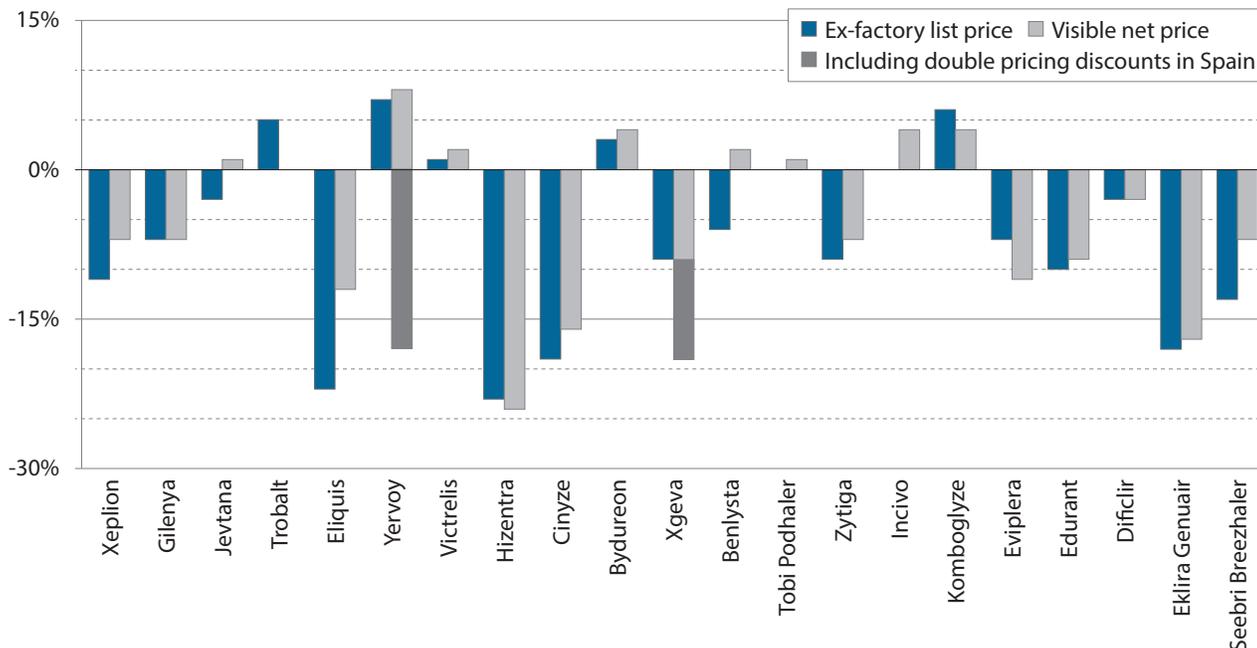
^{xii}Only including compulsory discounts of 7.5% or 4% (orphan drugs) for drugs in Spain – not including the effects of double pricing

^{xiii}El Global 17-23 December 2012: La nueva regulación sobre precios traerá consigo la evaluación única y compartir los riesgos.

For correspondence related to this article, please contact **Kathrine Kartach** at Kathrine.Kartach@simon-kucher.com

Figure 3

Price comparison on Spain vs. EU-4 (*only publically known discounts considered)



Sources: Spain: Portalfarma; France: Codage; Germany: Lauertaxe; Italy: Codifa; UK: BNF; * Germany: 16% discount and AMNOG rebates/price cuts for drugs which have finalized the process, France: net = list; Italy: 5% or 5%+5% where applicable; UK: net = list; Spain: 7.5% or 4% (orphan drugs)

Three ways OTC manufacturers can boost their bottom lines

By Ram Subramanian, Matt Adkins, and Dan Greenwald

Manufacturers of OTC medications need to find new ways to drive additional growth and profitability

The OTC/consumer healthcare industry faces numerous challenges which threaten the profitability of manufacturers. National retailers have more power than ever to negotiate lower prices. Competition from private label brands continues to intensify: in 2011, private-label OTC brands sales grew 8.7% and accounted for over a quarter of the overall OTC market¹. Rx-OTC switches and the launch of innovative new OTC products typically drive market growth for the OTC industry but such new launches occur on average only between 2-3 times per year for the entire industry (Table 1). Indeed, if this analysis is limited to only new brands (i.e. not new formulations of existing OTC products) the number is even lower – only 1-2 new OTC brands have been launched per year over the last decade.

Table 1: Rx-OTC switch/ New OTC approvals in the US (2000-2010)

Year	Rx-OTC switch / New OTC approvals
2000	4
2001	1
2002	5
2003	2
2004	0
2005	1
2006	4
2007	3
2008	0
2009	3
2010	1
2011	3
Average:	2.3

Furthermore, the bulk of these new OTC innovations occurred in a small handful of categories. Cold/Cough related, Heartburn, and Allergy categories accounted for over 50% of the new OTC products (Figure 1)¹.

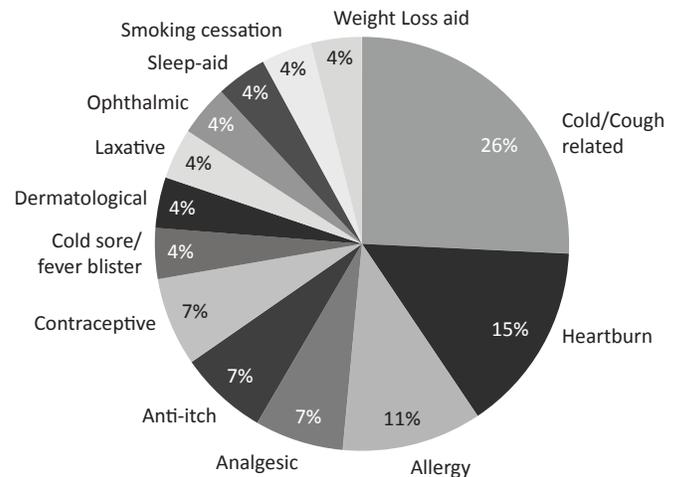


Figure 1: Share of Rx-OTC switch/ New OTC approvals in the US by product category (2000-2010)

Simon-Kucher & Partners, the world's leading pricing consulting firm, has identified three ways to address the challenges looming over OTC manufacturers in the consumer healthcare industry². They are:

1. Limit self-inflicted wounds to product profitability
2. Map the road to profitability over the life of the product and align pricing strategy with the overall brand strategy early on
3. Align the organization via a dedicated "Pricing & Profitability" role, and involve the C-suite in pricing decisions

Given the size of the market, improvement in profit margins can lead to substantial financial upside. Based on findings from in-depth interviews conducted by Simon-Kucher with OTC industry executives, as well as pricing project experience in the consumer healthcare industry, we will examine how manufacturers can improve their bottom-line.

1. Limit self-inflicted wounds to product profitability

Manufacturers often adopt practices that limit their profitability. Two examples of such practices are:

1 http://www.chpa-info.org/pressroom/Retail_Sales.aspx

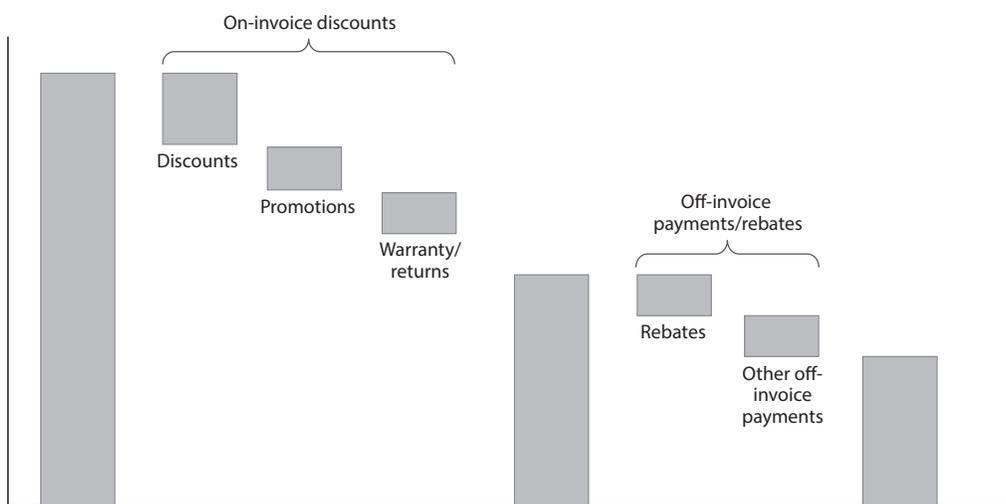
2 Simon-Kucher analysis; http://www.chpa-info.org/media/resources/r_4620.pdf

3 The Economist Books

- Unnecessary discounting and overuse of favorable terms and conditions
- Ineffective retailer incentives and terms

Unnecessary discounting and overuse of favorable terms and conditions leaves millions of dollars in potential profits on-the-table every year. Consumer healthcare manufacturers, like their counterparts in other industries, often have robust knowledge and firm control of where all of their costs are incurred and how top-line revenue is whittled down into bottom-line profitability. Very few manufacturers have the same level of knowledge and governance in place to oversee the pricing waterfall from list prices to net prices paid by the retailer (Figure 2).

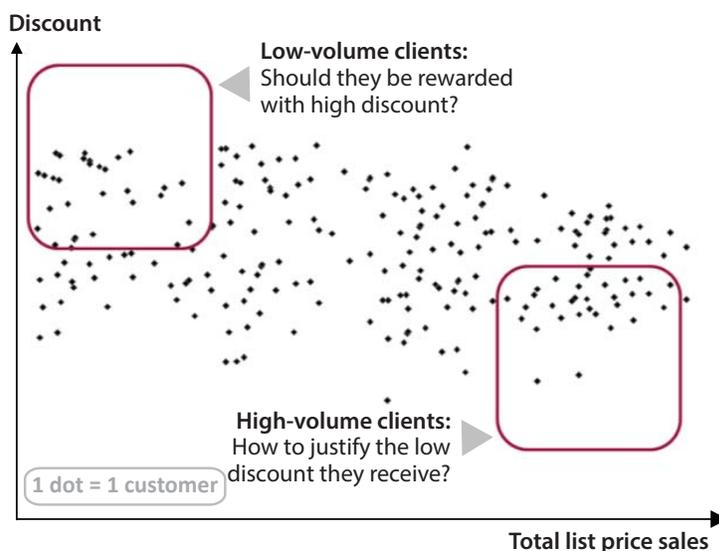
Figure 2: Price waterfall



Simon-Kucher’s experience suggests that larger players in the market stand to gain tens of millions of dollars in additional profitability every year by regularly auditing pricing practices within their organizations. The source of the potential profit improvement can come from several areas. Simon-Kucher pricing audits often uncover that manufacturers frequently give some of their worst customers—those with minimal sales and poor loyalty—some of the best discounts and most favorable terms and conditions. Taking a close look at these customers and putting policies in place to force sales to better justify high discounts to “bad customers” can lead to significant additional profit through capturing higher net prices with these customers.

Pricing analytics often uncover patterns like the one shown in Figure 3. This distribution pattern shows there is little to no correlation between the pricing that a customer gets and that customer’s sales volume. Customers, in this case retailers, have little incentive to sell more volume.

Figure 3: Distribution of customer pricing vs. customer size for a typical company



Putting the aforementioned policies in place to limit discounting to underperforming customers can create a strong incentive for customers to grow. Figure 4 shows the impact of implementing a more consistent customer pricing framework.

Pricing analytics often uncover that certain discounting mechanisms are well-governed and monitored, limiting misuse, while other mechanisms remain un-monitored, increasing the risk that sales-reps unnecessarily give away potential profits. In the absence of regular pricing analytics and monitoring, such “loopholes” may not even be known to management.

Ineffective retailer incentives and terms are another potential cause of profit leaks. Simon-Kucher’s experience in other retail focused industries has shown that manufacturers often provide discounts or trade terms that either do not incentivize the right behavior from retailers or that have a much larger impact than originally intended on a company’s bottom line.

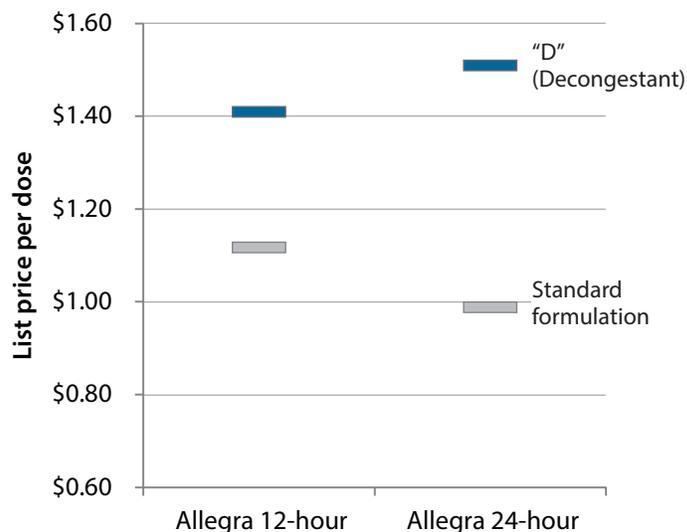
Figure 4: Consistent customer pricing framework



Routine pricing analytics can also identify other potential pricing problems such as unintentional list price inconsistencies among SKUs within a brand and unprofitable SKUs. For example, a recent Simon-Kucher Mystery Shopper study of retail pharmacy prices uncovered an example of a pricing inconsistency in over-the-counter Allergy drugs. Sanofi /Chattem markets both a 12-hour and a 24-hour version of Allegra in a standard formulation as well as in a decongestant formulation (Allegra-D). On a per unit basis, the 12-hour standard product is priced higher than the 24 hour standard product; however, this trend is reversed for the “D” formulations, where Allegra-D 12-hour is priced lower than the 24-hour version (Figure 5). These types of price inconsistencies can cause unintended consumer behavior and are potentially a source of lost profits for manufacturers.

Many of the corrective actions identified through this type of analysis are readily implementable and can lead to

Figure 5: Pricing: Allegra®



near-term profit realization with little upfront investment. However, most OTC manufacturers do not consistently perform this type of advanced pricing analytics and as a result may be leaving millions of dollars in unrealized profits on the table.

2. Map the road to profitability over the life of the product and align pricing strategy with the overall brand strategy early on

Companies with world-class pricing set and execute pricing against a corporate pricing strategy. These companies carefully position products within their portfolios and craft a strategy that fits within that context. However, for OTC manufacturers pricing is most often a decision taken by the brand manager and is not always optimized in the context of the manufacturer’s broader portfolio.

There are two critical areas that deserve more attention:

- Launch pricing
- Managing prices after launch

Getting the price right at launch is critically important and decisions must be made which align the pricing strategy with the overall brand strategy over the full lifecycle of the product. In launch pricing too much emphasis is often placed on uptake at launch in order to achieve volume targets for the brand. In-depth interviews conducted by Simon-Kucher with OTC industry executives uncovered that pressure from larger retailers can make it very difficult to change prices on leading products once they are set in the market, effectively locking companies into suboptimal pricing.

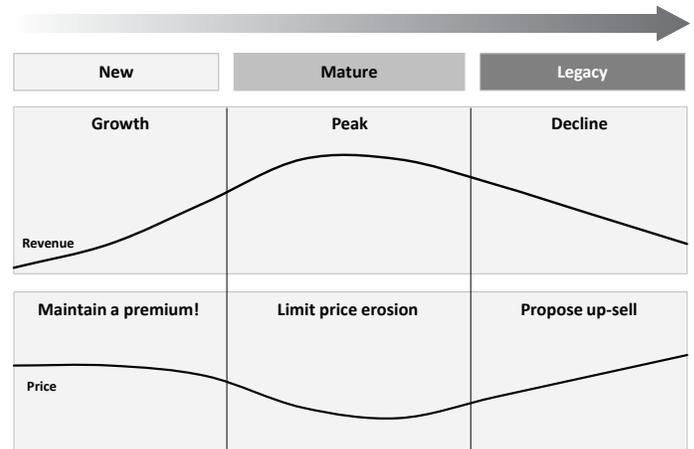
In order to optimize launch pricing, manufacturers need to fully understand the value proposition of their new products. Manufacturers do not always fully understand the complete value proposition of their products in the context of the broader portfolio at launch, which makes

determining the optimal price extremely difficult. By making an investment prior to launch to better understand the value story of new products, manufacturers can more effectively position products within their broader portfolios and develop the right pricing strategy to execute that positioning at launch.

Managing prices after launch is as important as launch pricing because the value proposition of products can change drastically over the lifecycle of the product, and manufacturers must adjust products' pricing strategy accordingly to account for such market changes. For example, in product categories with recent Rx-OTC entrants, former market leaders such as Zantac® (heartburn) and Benadryl® (allergy) now play significantly different roles in the market than they did before the launch of newer generation products. Thanks to the launch of next-generation OTC medications like Prilosec® (heartburn) and Claritin® (allergy), Zantac® and Benadryl® now each have a more niche position and their pricing should reflect this change. Not adapting a brand's pricing strategy to changes in its value proposition and market positioning represents a tremendous wasted opportunity for additional profit growth. Figure 6 shows a framework Simon-Kucher uses to maximize profits by pricing brands over different stages of the product lifecycle.

A product's pricing strategy should depend on both the value provided as well as the stage in the product lifecycle. New, innovative Rx-OTC switches should aim to maintain a high net price by limiting channel promotion. As the product progresses through its lifecycle, concessions can be given on price and discounting. However, when a product nears the end of its lifecycle or becomes a legacy product, manufacturers should look to raise the price and limit discounting. Simon-Kucher's experience shows that end-of-lifecycle and legacy products present a tremendous unrealized opportunity to boost profitability.

Figure 6: Pricing framework for brands over different stages of the product lifecycle

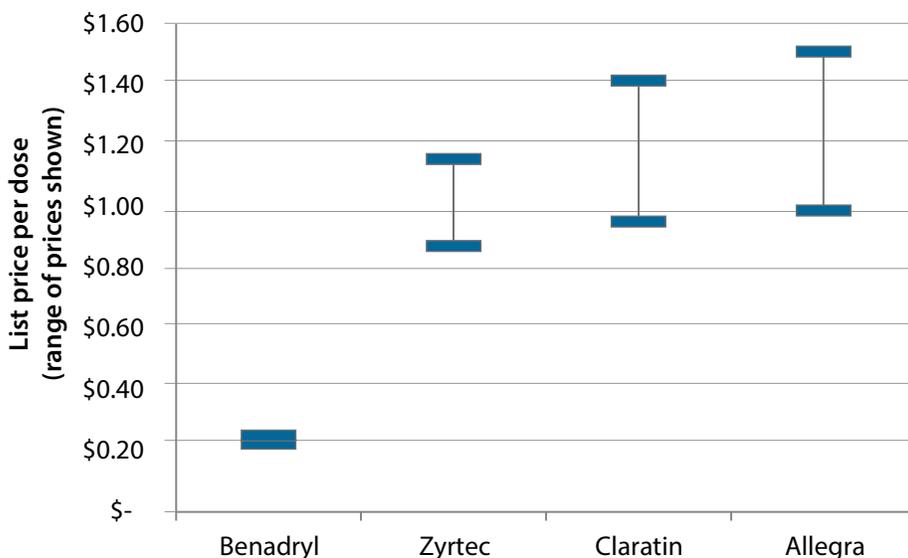


Significant price increases on these products can lead to higher profitability as remaining users tend to have high brand loyalty while some converters will switch to higher-margin, next generation products. Manufacturers can also more easily implement such price changes as they are isolated and focus primarily on brands that are often not top spend items for retailers.

The case of Benadryl® provides an excellent example of this opportunity. Next-generation allergy medications have launched at significant price premiums and have converted the vast majority of the market over to these newer products in the past several years. However, a recent Simon-Kucher study of retail pharmacy OTC pricing revealed that Benadryl® has maintained its significant price discount with respect to the next-generation products. This disconnect represents an opportunity for the manufacturer of Benadryl®, McNeil Consumer Healthcare, to gradually reduce the price gap through consistent price increases on Benadryl®, especially given that McNeil markets one of the next generation Allergy medications and can potentially benefit from converting customers to the higher-margin next generation Zyrtec®.

OTC manufacturers will improve profit margins by mapping the road to profitability, which starts at launch by prioritizing profitability with a well-understood value proposition and which continues over the course of the product lifecycle by adapting to changing market conditions.

Figure 7: Pricing: Benadryl® vs. other OTC brand families



3. Align the organization via a dedicated “Pricing & Profitability” role, and involve the C-suite in pricing decisions

Within OTC manufacturers today there is generally no single function/department that is responsible for sophisticated pricing analytics. This leads companies to overlook pricing as a potential area for profit growth. Profitability gains are likely to erode over the long-term if an organization is not set up to incorporate a pricing function as a core component of product and portfolio strategy

OTC manufacturers usually think of pricing not as an organizational function but as an activity; pricing is typically one among several activities that fall under the responsibilities of the Brand Manager. Brand Managers may spend time on product pricing at the launch of a new product and as part of updates to the annual brand plan but this focus on pricing is not a sophisticated analysis. OTC manufacturers risk not *crafting a pricing strategy that is aligned with the overall brand strategy but instead simply determining a price.*

Furthermore, pricing at the portfolio level and price positioning within a portfolio of brands probably receives even less attention than individual product pricing. The lack of a dedicated pricing and profitability function prevents tracking of product profitability across a franchise in a systematic way, with the end result that profit gains erode in the long-term and the organization does not capitalize on the full potential of their product portfolios.

Marketing and sales departments within most OTC manufacturers typically divide up pricing responsibilities

and often do not collaborate enough to align strategy setting with strategy execution. Marketing teams craft the value story for a brand and manage the P&L. They are responsible for product positioning and recommending an appropriate launch price. However, the sales team manages discounts and rebates and the overall channel strategy, which has a direct impact on product margins. Without a pricing and profitability function that spans the marketing and sales teams, it is extremely difficult to coordinate an optimal strategy for the franchise. Success in a pricing and profitability function requires a very analytical and data-driven approach to problems that combines financial rigor with marketing creativity. The goal of a pricing and profitability role is one of ensuring highest profitability that is in line with the long-term franchise strategy and detecting and eliminating any “profit leaks” in the portfolio.

A recent global study conducted by Simon-Kucher & Partners with over 2,700 executives and managers from over 50 countries across a variety of industries shows that a dedicated pricing function gives companies their greatest chance to survive and prosper in today’s low-growth climate (Figure 8). Companies with a dedicated pricing organization are:

- More likely to have “high pricing power”
- More often successful in achieving price increases
- More likely to command higher margins after a price increase

Figure 8

Pricing organizations make a clear difference

Companies with dedicated pricing organizations are...

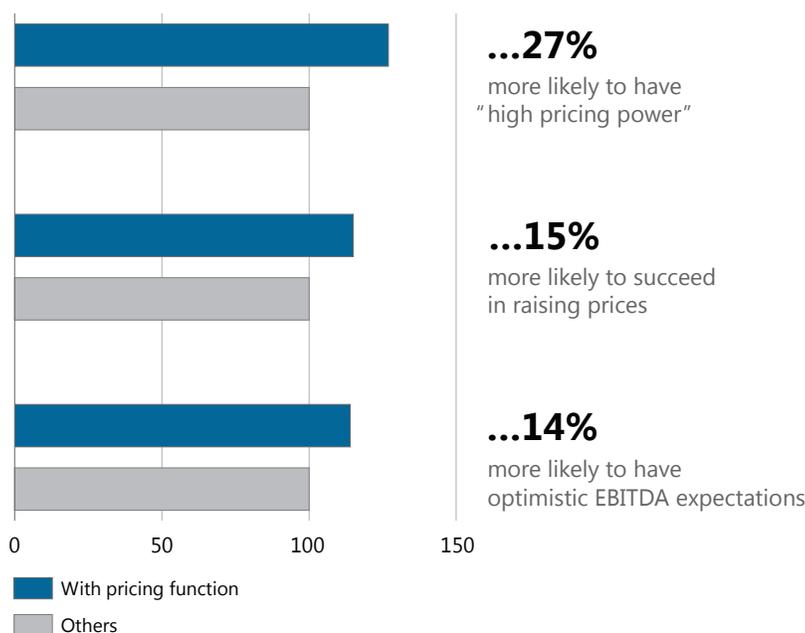
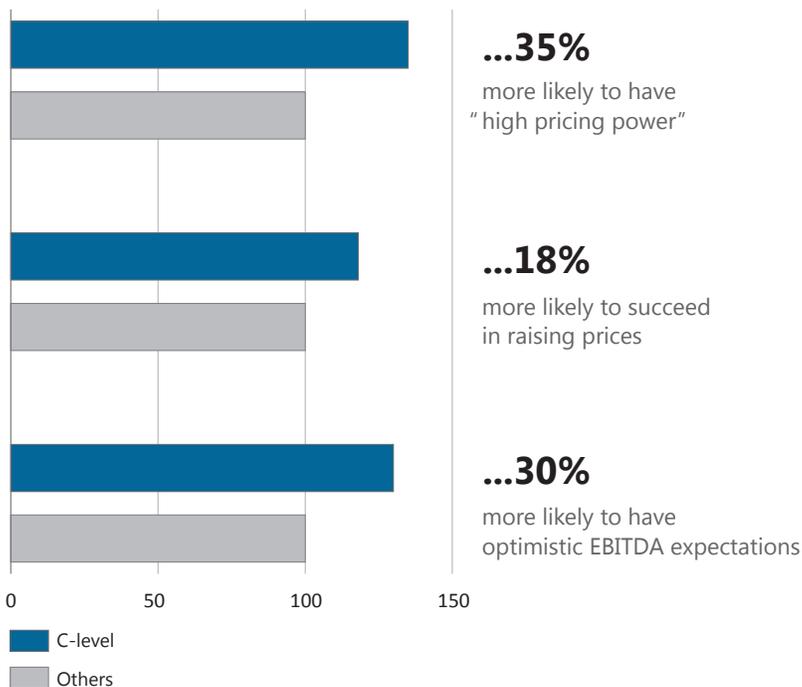


Figure 9

C-level involvement drives pricing performance

Companies with increased C-level involvement in pricing are...



High pricing power results when C-level executives take an active role in pricing. High pricing power makes companies more likely to raise prices, more likely to make those increases stick, and more confident about future profit growth.

Additionally, companies where C-level executives are directly involved in pricing are much more likely to have created a dedicated pricing function than companies in which top management does not have pricing on their agenda (Figure 9). A dedicated pricing role or function within the organization needs to do the day-to-day pricing work that ensures that strategic pricing decisions are implemented.

Taking advantage of high pricing power via a dedicated pricing function is a crucial asset at a time when over 80% of companies face increased pricing pressure from customers or their competitors.

Conclusion

Pricing is simultaneously one of the most powerful and underutilized tools for profit improvement among OTC manufacturers. In order to capitalize on this opportunity, manufacturers must take three steps:

1. Limit self-inflicted wounds to product profitability, by bringing discounts in line with customer loyalty and incentivizing retailers to increase their volume.

- 2. Map the road to profitability over the life of the product and align pricing strategy with the overall brand strategy early on.** A product's pricing strategy should depend on both the value that it provides as well as the stage in the product's lifecycle
- 3. Align the organization via a dedicated "Pricing & Profitability" role, and involve the C-suite in pricing decisions.** A centralized "Pricing & Profitability" function spanning marketing and sales is the most effective way to coordinate portfolio strategy, achieve and defend price increases, and develop a pricing strategy which optimizes profit margins across the portfolio. Following our recommendations OTC manufacturers can increase their pricing power and find new sources of profit growth even at a time when the market is becoming more competitive and less forgiving.

A Q&A based on the findings of this paper previously ran in OTC bulletin on April 12, 2013

For correspondence related to this article, please contact
Ram Subramanian at
Ram.Subramanian@simon-kucher.com

Licensing & Partnering: The importance of pricing and market access in asset valuation

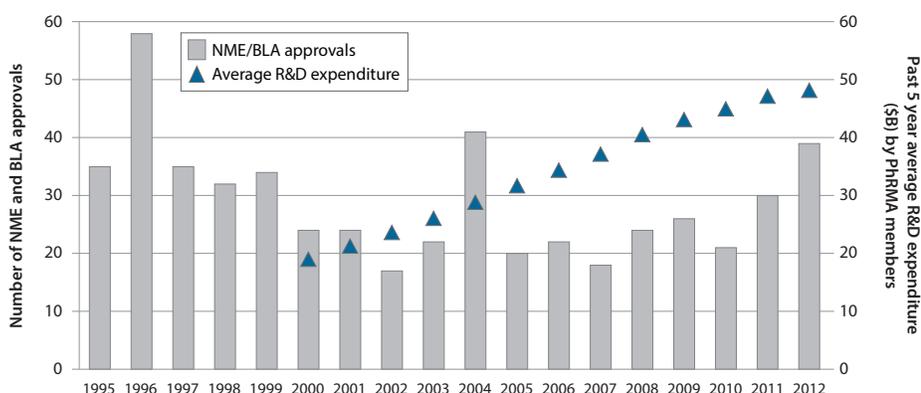
By Michael Kuehn and Alex Ettinger

Healthcare reform is now a global phenomenon: Among the many worldwide changes are the United States' Affordable Care Act, Germany's AMNOG, and the United Kingdom's switch from Primary Care Trusts to Clinical Commissioning Groups. While healthcare markets may be in flux, large pharmaceutical companies continue to have a great demand for licensing new products.

Big Pharma's Appetite to In-License

There are various reasons for pharmaceutical companies' substantial demand for in-licensing new products. A Simon-Kucher & Partners research study with 40 industry experts from leading pharmaceutical and biotechnology companies identified three major trends. The first trend was the deficits in large manufacturers' current pipelines. While the 1990's saw 30-40 New Molecular Entities (NME) and New Biologic License Applications (BLA) approvals per year, this number dropped to 20-25 on average in the 2000's (Figure 1). The second trend was an overall decrease in productivity of pharmaceutical companies' research and development (R&D). In 2000 the Pharmaceutical Research and Manufacturers of America (PhRMA) averaged under \$20 billion per year on R&D while generating 24 NME/BLA approvals compared with an average of over \$30 billion annual R&D spend with even fewer approvals in the 2000's. The third trend underlying pharmaceutical companies' demand for in-licensing involved the continuing impact of loss of exclusivity (LOE)/patent loss of blockbuster drugs.

Figure 1: New Biologic License Applications approvals by year



Biotech's Need to Out-License

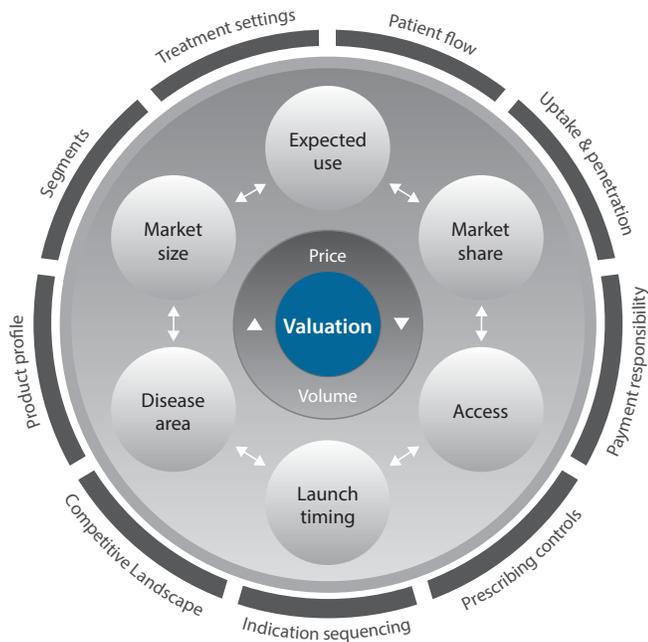
While large pharmaceutical companies have a real need to in-license new assets, smaller pharmaceutical or biotechnology companies possess an equally large desire to out-license their products in development. Bringing a new product to market requires a great deal of experience and an even larger investment, but many biotechnology companies lack both the experience and R&D budgets needed to get their asset through late-stage clinical development, regulatory approval, and reimbursement approval. Instead of looking for outside funding, they see partnering and/or licensing as a quick and easy win.

Common Challenges during Licensing Discussions

Although large pharmaceutical companies are keen to acquire new products and biotechnology companies look to license their assets, both sides often experience challenges during the negotiation process. In order for the buy-side (often large pharmaceutical company) and sell-side (typically biotech or smaller pharmaceutical company) to agree to a licensing deal, they need to agree on a value for the asset in question. The valuation of the asset requires due diligence on a number of market variables, including market size, expected use, market share, market access, launch timing, current competitive products, competitive products in development, growth trends, time to maximum market penetration, and achievable price level (Figure 2). Asset valuation is a key obstacle to optimal licensing and partnering.

Price and market access are crucial aspects of an asset's value. According to Simon-Kucher & Partners research, however, expected market access and achievable price level were considered to be the least accurate variables during licensing discussions. The same survey found that biotechnology companies commonly made mistakes regarding the lack of consideration for pricing and market access, leading to an unrealistic valuation of their asset. As a result of this uncertainty, pharmaceutical and biotechnology business development

Figure 2: Input variables considered for the valuation of an asset



executives agree that pricing and market access assumptions are often not sufficiently robust. Licensing dealmakers must add more emphasis to pricing and market access assumptions, as they are more and more a contentious cornerstone for asset valuation calculations.

Moreover, in-licensing target assets often occurs early in the clinical development process and/or may target novel and rare diseases. This results in greater uncertainty regarding the clinical performance of the asset in pivotal late phase trials and a lack of clear clinical and price comparators. While these targets may generate future revenue, they also have the distinct potential to fail before reaching the market. This means that assumptions regarding the price potential and market access of early stage compounds and/or assets targeting rare diseases are extremely complex and challenging to develop.

In addition to the market variables is another layer of complexity – geography. Different markets have different sizes, products, growth trends, disease trends, and in particular, distinct price and achievable market access/reimbursement potential. In order to properly evaluate each individual market, it is imperative to have local experts who are up to date with local healthcare reforms as well as clinical initiatives. Oftentimes mid-size and development-stage companies are in a difficult position outside of their market due to smaller global commercial resources and typically no established affiliates to whom they can reach out for local input.

Price & Market Access Are Key Assumptions

Because asset valuation depends on price and market access, proper assumptions are essential for optimal licensing deals. A pharmaceutical product's price has a direct influence on the drug's market access, and a drug's

market access has a direct influence on the potential sales volume.

Often, once certain price thresholds are crossed, specific restrictions apply that will severely limit access. A clinically valuable drug with broad access is likely to be prescribed much more than a drug with restricted access. Market access is a key variable when determining a drug's potential volume as payer management is increasingly influencing physicians' prescription choices. Hence, one can see the link between price, market access, and volume. When evaluating the future revenue for a pharmaceutical product, models will often utilize various combinations of price and volume to give best case, base case, and worst case projections.

Case Study

Simon-Kucher & Partners recently leveraged its extensive pricing and market access expertise to help value an asset for a biotechnology company. After conducting interviews with US managed care payers, Simon-Kucher & Partners recommended a range of prices with specific rebate levels, resulting in a small range of net prices for the asset. The recommended net prices corresponded to unrestricted or lightly restricted market access. While Simon-Kucher & Partners was conducting this project for the biotechnology company, the company was in talks with a major pharmaceutical company about being acquired, and at approximately the same time that Simon-Kucher & Partners delivered the final results of the study to the biotechnology company, the major pharmaceutical company acquired the biotechnology company for well over \$1 billion. In fact, Simon-Kucher's pricing and market access assessment proved fundamental to valuing the company's primary asset. In this situation, the underlying decision-making of this M&A decision was similar to a licensing decision for an individual product. Simon-Kucher & Partners was able to accurately inform the value of the asset by assessing its achievable price and market access.

Conclusion

Big pharmaceutical companies keep looking to fill their pipelines by in-licensing assets from smaller pharmaceutical or biotechnology companies. In order for a licensing deal to occur, both sides need to agree on the value of the asset. While healthcare markets are constantly fluctuating, asset valuation continues to be a complex assessment that takes into account many assumptions—most importantly price and volume. Simon-Kucher & Partners can help both the buy-side and sell-side of a licensing deal by accurately assessing an asset's price and corresponding volume.

For correspondence related to this article, please contact Michael Kuehn at Michael.Kuehn@simon-kucher.com.

It's a hard-knock life: Orphan drug launch strategies in the US

By Allison Capone & Brian De

Current environment

Although individual rare diseases, by definition, have low prevalence, there are over 6,800 such diseases, and almost 30 million Americans are affected by one or more¹. Consequently, the life science industry considers the orphan disease area a key frontier with numerous opportunities for the development of novel treatments. As companies work to capitalize on these exciting therapeutic and commercial opportunities, they must be prepared to face the typical challenges of drug development as well as several additional challenges unique to the rare disease space in the United States.

At present, treatment options for many rare diseases are either unsatisfactory or non-existent. Recognition of these unmet needs is widespread, often extending beyond physicians, patients, and their families. The media and the insurance community are also aware of the dearth of treatment options for rare diseases. Because of the lack of effective therapies, there are ample opportunities for drug manufacturers to command large market shares with new treatments for these indications. Beyond high market share, many insurance plans have accepted aggressive pricing for rare disease treatments. For example, the ten most expensive drugs on a per patient basis in the US target rare diseases, and despite their high costs, payers place minimal restrictions on their utilization. Most managed care organizations (MCOs) in the US provide access to these drugs with a simple "prior authorization" form to ensure the patient is diagnosed with the indicated disease. Furthermore, the US government, through measures enacted by the Orphan Drug Act of 1983, incentivizes development of rare disease drugs. This legislation, which defines a rare disease as one which affects under 200,000 US patients, provides pharmaceutical companies seven years of market exclusivity after FDA approval, a 50% tax credit for clinical development, and priority review by the FDA for any drug targeting an orphan indication².

Despite incentives for companies to commercialize orphan drugs, it remains a challenging space. This is especially true for small pharmaceutical/biotech companies that do not have substantial experience in launching new drugs. First, because a rare disease affects so few patients, the manufacturer must capture the majority of the market to ensure a drug's profitability. Additionally, patient cost-sharing for orphan drugs can be extremely burdensome.

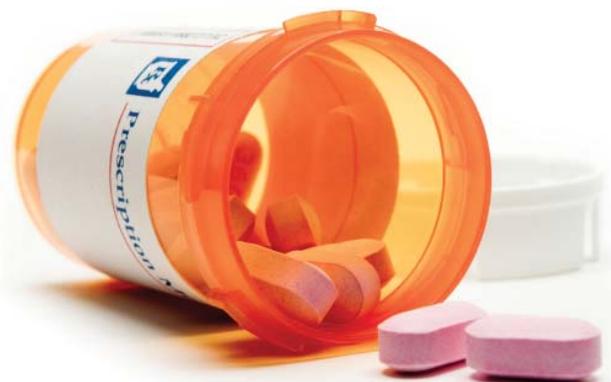
Depending on their insurance coverage, patients can be required to spend over \$10,000 annually on out-of-pocket costs for one drug alone. Given high price tags

and these large patient out-of-pocket costs, drugs treating orphan diseases have become media targets and are often cited in the press as examples of pharmaceutical companies taking advantage of the healthcare system. Thus, drug manufacturers must tread lightly when commercializing an orphan drug to balance profitability to shareholders with public perception.

Addressing physician needs

Physicians are perhaps the most important stakeholders in determining the uptake of a new treatment for an orphan disease. Manufacturers of orphan drugs must understand exactly how current treatment options are perceived by physicians. For instance, while an FDA-approved drug might not be available, the disease could be satisfactorily managed by other medical interventions; because of the lack of therapeutic options, physicians often turn to off-label drugs to treat rare diseases. Furthermore, physicians in the rare disease space differ in their cost-benefit analysis as it relates to safety and efficacy. Physicians, in consultation with patients and patients' families, are more likely to tolerate safety concerns if they are convinced a therapy offers a significant therapeutic improvement over other treatment options.

Beyond the clinical merits of the product, physicians also consider their patients' ability to access the treatment when determining a course of treatment. Patients' insurance coverage and potential out-of-pocket costs may limit their ability to obtain access. Additionally, as evidenced by



1 <http://www.rarediseases.org/rare-disease-information>

2 <http://www.fda.gov/regulatoryinformation/legislation/federalfooddrugandcosmeticactfdacact/significantamendmentstotheact/orphandrugact/default.htm>

examples in oncology, physicians are increasingly aware of the retail price of these treatments and could start publicly pushing back more on cost. For example, several key opinion-leading oncologists published an article in the medical journal “Blood” about the unsustainable prices of drugs in the treatment of chronic myeloid leukemia. This mentality could easily creep into other high-priced indications like orphan diseases (Table 1).

Eliminating insurance hurdles

MCOs currently rely on three major management tools: non-coverage (for closed formularies), utilization restrictions, and patient cost-sharing (e.g., co-pay and co-insurance). Even though most US insurance plans have open formularies and are therefore obligated to cover all FDA-approved medications, there is still a small group of regional plans that have the option not to cover treatments. In cases where there are treatment alternatives, whether medical interventions or drugs used off-label, closed plans may be hesitant to cover the new therapy at especially high prices. However, since most plans are required to cover these therapies, they manage mostly through utilization restrictions such as prior authorizations (PAs). At a minimum, most plans require a PA to the labeled indication to ensure appropriate use. Depending on the insurer’s perception of the orphan drug’s cost-benefit profile and their current management philosophy, the types of restrictions that are imposed can vary substantially. In a recent Simon-Kucher project, it was seen that patients were required to first try the existing standard of care – a non-indicated generic – before they could access the new high-cost treatment.

In addition to controlling access, insurance plans may require patients to pay out-of-pocket costs when receiving an orphan drug. The benefit designs of commercial plans are continuing to move toward having a specialty/

co-insurance tier for high-cost drugs. Where available, coverage for most orphan drugs would default to this specialty tier, resulting in a patient being responsible for 10-25% of the cost of an orphan drug. While most commercial plans mitigate patient cost burden with an annual out-of-pocket cap for drug spending, the number of plans offering this out-of-pocket cap continues to decrease. Medicare Part D patients face similar out-of-pocket cost concerns. Medicare patients pay a co-insurance for treatments that cost over \$600 per month. Given the high cost of orphan drugs, most patients will reach the “doughnut hole” within the first couple of months of therapy and move on to the catastrophic coverage phase, where they are responsible for 5% of the drug cost (Figure 2). As the benefit designs of insurance plans move toward greater cost-sharing, patient willingness-to-pay is becoming an increasingly large barrier for the uptake of a new orphan drug.

In order to successfully navigate potential payer hurdles, the manufacturer will need to investigate the following in detail:

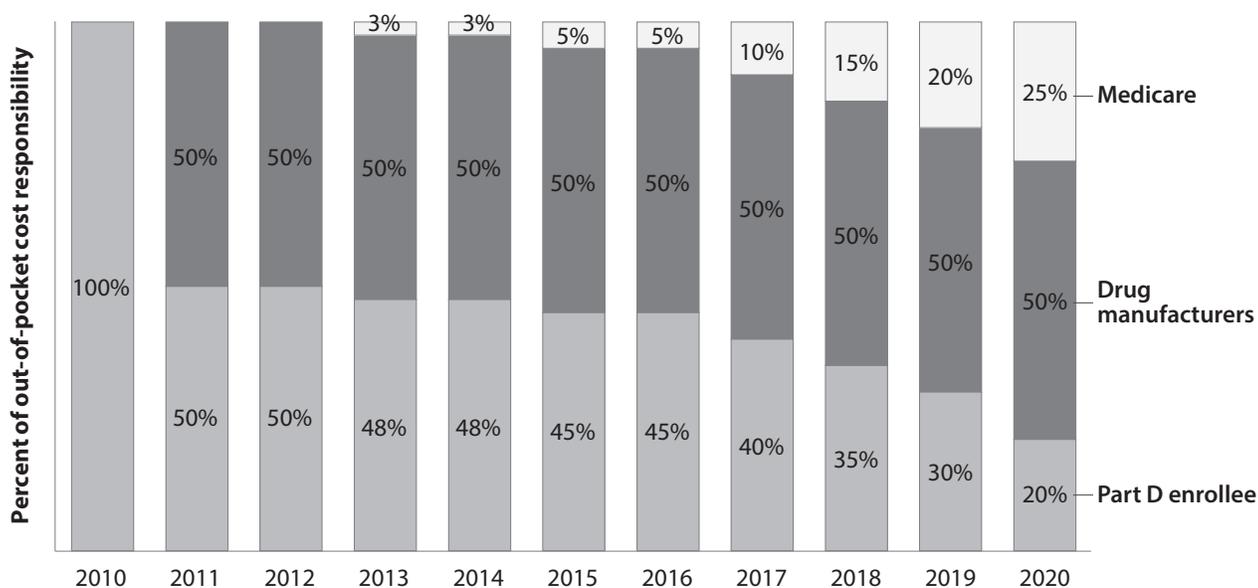
- **Provide reliable epidemiology data:** What is the current market size? How, if at all, will the availability of the drug impact incidence or prevalence of the disease?
- **Determine the impact of dosing on the payer’s budget:** What is the average dose (especially if weight based)? Is there any risk of dose creep?
- **Identify key opinion leaders and treatment centers:** Especially in cases where a treatment option did not previously exist, can treatment centers of excellence be created? If a treatment center exists, can we improve patient access to the center?
- **Increase awareness of the disease:** Is it possible to increase physician awareness and diagnosis rates now that a new treatment option is available?

Table 1: The most expensive drugs in the United States (as of 2010)

Drug	Cost	Indication
Soliris	\$409,500	Paroxysmal nocturnal hemoglobinuria
Elaprase	\$375,000 / year - \$657,000 / year (\$4,125 per vial)	Hunter syndrome
Naglazyme	\$365,000	Maroteaux-Lamy syndrome
Cinryze	\$30,000 / month (6 week treatment)	Hereditary angioedema
Folotyn	\$115,000 / month	T-cell lymphoma
ACTH	\$100,000 / year (children) \$300,000 / year (adults)	Infantile spasms (not FDA approved)
Myozyme	\$250,000	Pompe disease
Arcalyst	\$200,000	Familial Cold Auto-inflammatory Syndrome and Muckle-Wells Syndrome
Ceradase / Cerazyme	\$200,000	Gaucher disease
Fabrazyme	\$200,000	Fabry disease
Aldurazyme	\$200,000	Hurler syndrome

Source: http://www.forbes.com/2010/02/19/expensive-drugs-cost-business-healthcare-rare-diseases_slide_2.html

Figure 1: Out-of-Pocket cost responsibility in the “doughnut hole”, 2010-2020



Managing public perception

In addition to tailoring the commercialization strategy to the typical stakeholders – physicians, patients, and payers – it is important to consider the public’s perspective when launching an orphan drug. The value story associated with the product must be compelling and should be clearly articulated to the media. Furthermore, as part of the overall value story, the manufacturer must be prepared to defend its pricing strategy. Recently, one small biotech company successfully communicated the product’s value in the New York Times by using the patient perspective and also described the rationale of their pricing strategy by referring to price benchmarks within the current treatment environment and other similar indications.

In addition to perception among the general public, advocacy groups for orphan diseases are influential stakeholders that require engagement. Given the tight-knit communities for patients with rare diseases, advocacy groups have access to most patients with the disease and can be an important influencer for both the physician and patient perspective of a product. It is important to engage these groups early in product development through clinical trials and other patient outreach efforts. While there are several methods to work with these groups, including direct funding or other support services, it is essential to understand which route best addresses their objectives and needs.

Communication is just one part of managing public perception of a new orphan drug. Drug companies commonly offer robust assistance programs to patients with commercial insurance. Typically, these types of programs for orphan drugs will cover the entirety of out-of-pocket expenses borne by the patient, thereby mitigating patient affordability issues. In most instances, the addition of the patient assistance program actually increases overall

profit since the cost associated with implementing such a program is heavily offset by an increase in market share. Unfortunately, manufacturers do not have the ability to off-set patient out-of-pocket costs for patients covered by Medicare Part D. However, these patients can often find additional funding through non-profit organizations.

Measures to ensure a successful launch

A successful orphan drug launch will require pharmaceutical / biotech companies to not only engage the typical stakeholders, physicians, and insurers, but also tailor their strategy to the public. Therefore, in order to ensure a successful launch in the orphan drug space, consider:

1. Engaging key opinion leaders, advocacy groups, and patients early in development through clinical trials and peer-reviewed article publications
2. Developing a robust value proposition tailored to all four key stakeholder types: physicians, insurers, patients / advocacy groups, and the media
3. Delivering impeccable customer service, including the creation of treatment centers or other patient services, by understanding the needs of physicians and patients and incorporating them into the commercialization strategy

For correspondence related to this article, please contact Brian De at Brian.De@simon-kucher.com

How to mitigate the risk of price cut in European payer markets

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Price cuts, however, are not unavoidable threats. Because payers might not consider some important value drivers vs. competitors and international prices might be used inappropriately (for example), payers' arguments can sometimes be challenged. This suggests that manufacturers may be able to avoid price cuts under some circumstances. In this context, well thought-out price cut mitigation strategies are the best ways to protect pharmaceutical companies' revenue. The objectives of such a strategy could be to avoid the price cut completely, reduce it, delay it, or deflect it to another product. The following five best practices can help pharmaceutical companies to optimize their chances of success in defending against price cuts.

1. Evaluate payers' expectations and rationale

Before moving forward with a price cut mitigation strategy, the company needs first to understand the drivers of price cuts, such as total healthcare budget decrease, economic crisis, or burdensome expenditures for a specific class of drug or a specific disease. This will help in better defining payers' objectives and assessing acceptable or minimum levels of savings expected by payers. These primary steps will be essential to optimize future negotiations.

Secondly, manufacturers should carefully assess the validity of payers' rationale. Payers present a rationale in order to justify a price cut: a decrease in international prices, launch of new competitors such as branded or generic alternatives, new formulations, indication expansions and their resulting budget impact, or price homogenization in a therapeutic class, for example. Verifying and evaluating payers' arguments is an essential step in any price cut mitigation strategy.

2. Determine whether fighting against a price cut is worthwhile

Manufacturers should balance the pros and cons of moving forward with a price cut mitigation strategy by carefully assessing its potential positive and negative consequences. They should particularly consider the potential impact of the price cut on its global revenue and profit and the upside of a price cut mitigation strategy. Indeed, it might not be worth fighting for a rather limited price cut on a mature product that is already experiencing decreasing sales and contributes little to revenue. However, such a price cut mitigation strategy is bound to be relevant in the case of significant price cuts on strategic products. A price cut mitigation strategy also has substantial downsides. Arguing with payers could, among other negative consequences, weaken the relationship with them. Since

in many countries the same payers are in charge of price negotiations for all products, attempts to defend against price cuts might impact forthcoming negotiations for future product launches. Therefore, it is essential to assess the impact such negotiations could have on the overall product portfolio (current and pipeline) in the short- to mid-term.

3. Develop a pertinent argumentation line

A good argumentation line is the fruit of a thorough analysis of all the potential arguments followed by an accurate distribution of these arguments along a matrix analyzing both their risk and impact. Manufacturers need to develop a comprehensive list of potential arguments from an internal and external perspective, including:

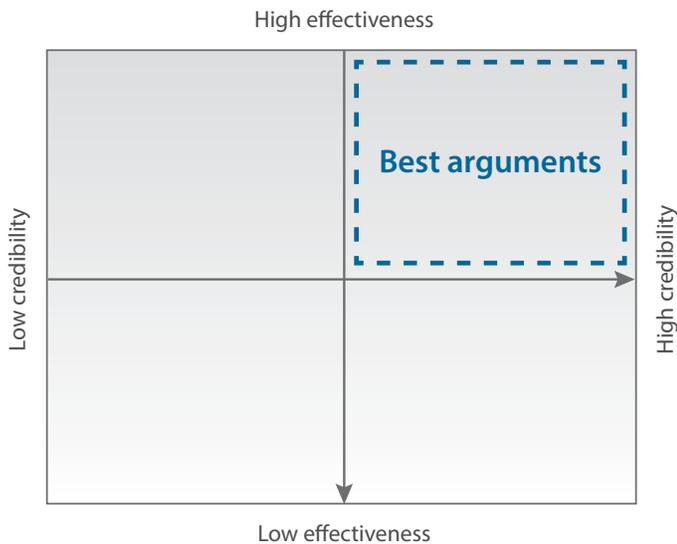
- Payers' perspective: acknowledgment of the economic environment as well as payers' stakes and expectations from the price cuts
- Context and consequences of the price cut for the company: inability to anticipate consequences of the price cut due to short notice and lack of visibility, financial implications (e.g., reduction in investment budgets), need for restructuring, or decreased number of employees
- Market environment: disease prevalence (differences in volume), reimbursement conditions, drug utilization, and position in lifecycle. These factors may explain and justify different prices across Europe
- Product vs. its competitors: clinical advantages, health economic advantages, services, etc.
- European price comparisons: differences in prices, non-relevance of prices in some countries due to different processes, net price argumentation (due to the disparity between the list and net prices)

In addition to this analysis, it is valuable to research any pertinent analog cases: Did competitors face this same problem recently? How did they react?

After defining the potential list of arguments to present to payers, each argument should be evaluated individually along the following two axes and plotted on a matrix:

- Argument's credibility: How credible are these arguments to the payers? Is there sufficient evidence or robust data to support these arguments?

Figure 1: Framework to evaluate potential arguments



- Argument's effectiveness: How convincing and relevant are these arguments to the payers? Are these arguments important, and do they answer payers' concerns? Are the proposed savings (if any) substantial for the payers?

The best arguments will be those in the top right corner of the matrix (highest effectiveness and highest credibility). The pharmaceutical company should then prioritize these arguments in all communications relating to the price cut.

4. Define realistic price cut mitigation strategy objectives with acceptable/unacceptable alternatives and fallback options

Internal stakeholders should discuss the objectives of the price cut mitigation strategy in order to identify alternative options for which to push. Although avoiding the price cut is generally the first priority of a price cut mitigation strategy, alternative options may be suggested to payers in order to limit the damages of a price cut. These include:

- Delay in the price cut by one or several months
- Limited price cut
- Price cut on a different product as part of a portfolio agreement
- Price-volume agreement
- Confidential discount (i.e., price cut on the net price level only, leaving list price unchanged)

The impact of each of these options on both the manufacturer's global turnover and the payers' budget should be quantified. Depending on the threshold above which the financial impact becomes unacceptable for the manufacturer, the non-acceptable options should be eliminated. Then, remaining options should be prioritized to identify which options should be first proposed to the payers. The more options assessed upstream, the better prepared the manufacturer will be to present counter-

price options or explain why some options are not feasible. If objectives are not reached after the initial discussion/negotiation with payers, additional fallback options should also be at the manufacturers' disposal; these include alternative price options less favorable for the company, lobbying options, additional studies on the drug (e.g., observational studies).

Price cut mitigation objectives as well as the alternative and fallback options should be discussed and approved by the global team prior to the negotiation with payers so that they would be in line with the European strategy for the product.

5. Prepare supporting documentation and training for the actual payer negotiation/discussion

Successful negotiations require both supporting documentation and good negotiation skills. The supporting documents should present a consistent and pertinent "story" to serve as the basis for negotiations. They should also have robust fallback slides (slides that detail alternative scenarios). This document will ensure that all internal stakeholders are in line regarding the price cut mitigation strategy.

Negotiation or discussion trainings allow participants to increase their mastery of delivering the value story and then improve their negotiation skills. During negotiations, the company should remain in tune to payers' interests as well as to the current country-specific environment. Such considerations can positively influence the course of the negotiation and ensure a favorable outcome. Future participants in the negotiations can learn how to react to the different options suggested by payers and to practice how and when to present their fallback options (i.e., what to say, what not to say, and when). Trainings also allow the company to test multiple approaches to the argumentation line, to handle objection and fallback options, and then to tailor, fine-tune, and pressure-test the final line of argumentation. A mock negotiation involving the countries affected by the price cut can help the company adapt the negotiation strategies and tactics to each country for the optimal regional product pricing strategy.

The development of successful price cut mitigation strategies can be challenging, particularly given that they may need to be implemented in a limited timeframe and require a regional and global approach. However, well-developed strategies can offer major benefits to a pharmaceutical manufacturer looking to avoid, reduce, or delay a price cut.

For correspondence related to this article, please contact Amelie Scheffler at Amelie.Scheffler@simon-kucher.com

HITting it out of the park in the USA: Succeeding in a digital age

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What does US law say about EMR systems?

With the passage of the economic stimulus package of 2009 and subsequently the Affordable Care Act of 2010, \$19 billion has been allocated to financial incentives for physician practices. Physicians must demonstrate “meaningful use” of an Electronic Medical Record, which is measured by criteria centered on standardized data capture, the ability to share patient information, and eventually their improvement of quality, safety, and efficiency, leading to improved health outcomes (Table 1). While physicians and hospitals must meet “core objectives” to be eligible for bonus incentives up to \$44,000, they can largely do so by implementing systems that are currently available. In accordance with CMS guidelines, these systems track medical histories, current symptoms, diagnoses, and test results, and can interface with each other across physician offices. Physicians and hospitals that do not show meaningful use of EMR systems by 2015 will be penalized with reductions in Medicare reimbursement.

What kind of progress has been made?

With the use of incentives and penalties, the Centers for Medicare & Medicaid Services (CMS) hopes to encourage full adoption in physician practices in the next decade. As of March 2013, CMS reported that over 75% of hospitals are meaningfully using EMR technology¹. Physician practices have been somewhat slower to adopt EMR systems, with 44% of eligible professionals meaningfully using EMR technology – individual physician practices may be less financially capable of training personnel to use such systems. However, adoption by hospitals and physician practices is expected to exceed 80% and 50% by the end of the year. Given that there are over 900 vendors and over 1,700 unique EMR products, the US Department of Health and Human Services (HHS) is also increasing emphasis on interoperability to promote seamless and secure electronic exchange of patient information. Health Information Exchange (HIE) is expected to allow providers to avoid readmissions, decrease duplicate testing, reduce medication errors, and improve diagnoses. In addition to government bodies, health care practices themselves are

Table 1: How meaningful use criteria, objectives, and measures are evolving

Stage 1: 2011-2012 Data capture and sharing	Stage 2: 2014 Advance clinical processes	Stage 3: 2016 Improved outcomes
Meaningful use criteria focus on:		
Electronically capturing health information in a standardized format	More rigorous health information exchange (HIE)	Improving quality, safety, and efficiency, leading to improved health outcomes
Using that information to track key clinical conditions	Increased requirements for e-prescribing and incorporating lab results	Decision support for national high-priority conditions
Communicating that information for care coordination processes	Electronic transmission of patient care summaries across multiple settings	Patient access to self-management tools
Initiating the reporting of clinical quality measures and public health information	More patient-controlled data	Access to comprehensive patient data through patient-centered HIE
Using information to engage patients and their families in their care		Improving population health

Source: <http://www.healthit.gov/providers-professionals/how-to-attain-meaningful-use>

¹ http://www.cms.gov/apps/media/press/factsheet.asp?Counter=4582&intNumPerPage=10&checkDate=&checkKey=&srchType=1&numDays=3500&srchOpt=0&srchData=&keywordType=All&chkNewsType#main_content

also shaping the future of EMR; for instance, hospitals are seeking out systems that seamlessly connect to medical devices in order to automatically make clinical documentation, thereby reducing time investment and potential errors.

How might EMR in the US affect pharmaceutical companies?

The implementation of EMR systems not only offers potential cost and efficiency advantages for physicians and patients but also has substantial implications for pharmaceutical and insurance companies (summarized in Table 2).

For pharmaceutical companies, there are certainly some challenges associated with greater use of Health Information Technology. For instance, there may be greater generic reversion, since some ePrescribing systems default to generic medications when the physician prescribes a medication². In the future, this will require pharmaceutical companies to further strengthen the value proposition of their branded products over alternatives, like generic products. Another potential challenge is the ever-increasing scrutiny of insurance companies, which can have greater enforcement over restrictions before a branded medication can be used. Currently, insurance companies impose a “prior authorization” on a drug requiring certain criteria (e.g., diagnosis confirmation, use of a prior therapy, etc.) to be met before they agree to cover the patient’s use of the drug. With the greater use and sharing of data, insurance companies will be able to create and better enforce objective metrics that

have to be met before a branded drug can be used. Pharmaceutical companies may feel additional pressure to bolster the value proposition of their drugs to avoid formulary restrictions.

There are also tremendous new partnership opportunities for pharmaceutical companies in light of increased EMR use. The average drug development cost is said to range from \$4 billion to \$11 billion³, so any measures to make the drug development process more cost-effective could allow pharmaceutical companies to more efficiently use their resources. A study that looked at over 4,000 clinical trials over 5 years concluded that nearly half of the time spent on a clinical trial involved recruiting patients, sites, and investigators. Further, difficulties in patient recruitment delayed over 80% of all trials from one to six months, which is thought to cost pharmaceutical companies up to \$8 million per day⁴. If pharmaceutical companies are able to partner with hospitals and physician groups, they may be able to more efficiently identify and recruit patients for clinical trials, leading to time- and cost-savings. However, companies must do this while remaining cognizant of patient privacy regulations as put forth by Health Insurance Portability and Accountability Act (HIPAA).

Additionally, one potential opportunity that drug manufacturers could take advantage of is using performance metrics or outcomes data for “innovative” contracting opportunities. While past innovative contracting agreements have not yet depended on physician use of EMR, US managed care payers have commented that future deals could depend on practices’ abilities to track more complex information. With greater tracking of diagnostic information and outcomes in EMR

Table 2: Opportunities and challenges of EMR adoption for pharmaceutical companies

Potential development	Implications for pharmaceutical companies
Challenge: Increased generic reversion when physician prescribes a medication	Drug companies will need to do more to strengthen the value proposition of their products so that clinicians are further convinced of their value over alternatives
Challenge: Insurance companies will have greater scrutiny over how medications are prescribed, leading to greater enforcement of step edits and prior authorizations	More competitive pricing may be needed in already-competitive drug classes, so that undue restrictions (and subsequent enforcement) can be avoided
Opportunity: More efficient identification and recruitment of appropriate patients for clinical trials	Cost-savings and time-savings for pharmaceutical companies, potential to launch products more quickly into the market
Opportunity: Greater pooling of outcomes data by physicians/hospitals, and subsequently insurance companies	Increased innovative contracting opportunities, particularly in areas where new efficacy/safety metrics can be tracked

2 <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3000753/>

3 <http://www.forbes.com/sites/matthewherper/2012/02/10/the-truly-staggering-cost-of-inventing-new-drugs/>

4 <http://healthcare.financialexpress.com/200809/itspecial09.shtml>



systems, insurance companies are optimistic that other such performance-based contract opportunities exist. It remains to be seen whether this approach can be applied to therapeutic areas where selected disease progression metrics are not regularly used in clinical practice. For instance, rheumatoid arthritis is one area where the efficacy metrics used in clinical trials are not regularly recorded by rheumatologists in clinical practice. For example, American College of Rheumatology (ACR) scores, which measure the improvement in tender or swollen joint counts and five other objective parameters, are used in clinical trials. However, rheumatologists commonly record Disease Activity Scores (DAS), which is a measure of disease activity, as opposed to change over time in the activity. While much of medicine is not standardized, use of EMR systems may help to promote uniformity so that the same kinds of measures are tracked across patients in a disease area, which could eventually lead to greater opportunities for outcomes-based contracts.

What's next?

Though the United States health care system is unique in its decentralization, Electronic Medical Records offer one way for patients, providers, insurance companies, and pharmaceutical companies to take advantage of a unified and increasingly standardized resource. EMR systems will allow stakeholders to carefully coordinate patient care, discourage wasteful spending, and leverage tremendous amounts of data to focus on evidence-based medicine. As with other industries, computerization in health care will create additional transparency, which poses both opportunities and challenges for pharmaceutical companies. Despite expected additional scrutiny from payers as a result of more comprehensive efficacy data, pharmaceutical companies can potentially reduce their search costs for clinical trial recruitment and enrollment as well as engage in outcomes-based or performance-based contracts.

Pharmaceutical companies must react to greater use of EMR by increasing partnerships with health care system stakeholders. As EMR systems become more interoperable, stakeholders will have the ability to easily share health-related information; pharmaceutical companies will need to engage providers and Health IT companies to tap into patient data without compromising patient privacy. For performance-based contracting, pharmaceutical companies will also need to collaborate closely with other stakeholders – insurance companies as well as physicians/hospitals. Additionally, in disease areas where disease progression metrics are not regularly recorded, it will be the responsibility of drug manufacturers not only to use clinically-measured endpoints in their trials but also to encourage insurance companies, physicians, and EMR companies to keep track of efficacy and safety metrics beyond those measured today.

Ultimately, greater use of Electronic Medical Records offers all healthcare stakeholders the chance to deliver higher quality, more efficient care to patients. It will be important for pharmaceutical companies to remain more competitive than ever by offering differentiated products at attractive prices and to effectively communicate the value of their drugs.

*For correspondence related to this article, please contact
By Brian De at Brian.De@simon-kucher.com*

FACES & PLACES

News from **SIMON-KUCHER**

Simon-Kucher held successful forums in Philadelphia...



On April 11, 2013, Simon-Kucher & Partners hosted its second Philadelphia Life Sciences Strategy and Marketing forum, which brought together over 50 participants across a broad spectrum of pharmaceutical, biotech, and medtech companies from the mid-Atlantic region. Attendees benefited from a half day of networking opportunities and presentations exploring strategy and marketing challenges facing pharmaceutical and biotech companies in the US and globally. The forum also included medtech-specific presentations providing tactical insights for medical device and diagnostics companies.

Experts from Simon-Kucher & Partners' Life Sciences division presented on a range of topics covering approaches to achieving marketing excellence, insights on global P&R challenges, opportunities for drug diagnostic combinations in oncology, updates on the Affordable Care Act and its impact on the evolving US market, and insights on creating successful market access strategies in emerging markets. In addition, topics specifically geared toward the medtech industry included achieving pricing excellence in medtech, how to successfully engage hospitals, and opportunities, challenges, and trends associated with reimbursement for medical technologies in the US, EU, and the rest of the world. The presentations were well-received, with positive feedback such as "thought-provoking" and "good and insightful analysis". Following the forum, attendees were eager to receive the presentations and discussed with some of the presenters about arranging repeat presentations for their colleagues.

...and in San Diego



At the end of May, the San Francisco Simon-Kucher team hosted the second annual San Diego Life Sciences Strategy and Marketing Forum at the Marriott Marquis & Marina in charming San Diego. 45 participants attended the event, representing a broad spectrum of life sciences companies, including pharmaceuticals, biotech, medtech, and diagnostics. The agenda featured hot P&R topics followed by lively discussions at the networking reception.

Simon-Kucher & Partners sponsors these forums as opportunities for networking among Life Science industry leaders, and to provide a platform for the exchange of knowledge on the ever-changing pharmaceutical, biotechnology, and medical technology world we live in. We are looking forward to many successful forums in the US and around the world in the near future.

Simon-Kucher opens office in São Paulo

Simon-Kucher & Partners will officially open a new office in São Paulo, Brazil in July 2013. The new office opening will support our practice across a broad range of industries, including Life Sciences. Brazil's pharmaceutical market is the 6th largest in the world and continues to enjoy double-digit growth. Partner Manuel Osório will be leading the new office, along with support from Ken Genenz, head of Life Sciences in Latin America, and Rafael Alencar, a Senior Consultant for the LS team in Brazil.



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YOU ARE CORDIALLY INVITED TO ATTEND THE

LIFE SCIENCES EUROPE STRATEGY FORUM IN FRANKFURT

The Life Sciences Europe Strategy Forum will explore the unique pricing and market access challenges facing pharmaceutical companies in Europe and globally. External speakers and experts from Simon-Kucher & Partners will present on a range of relevant topics to help you improve your strategic decision-making.

WHEN

Wednesday, September 25, 2013
11:30am - 6:00pm

WHERE

**Sheraton Frankfurt Airport
Hotel and Conference Center**
Hugo-Eckener-Ring 15
Rhein-Main-Flughafen
60549 Frankfurt am Main

RSVP

Participation is **free**, however space is limited. To reserve your place at the conference or for additional information, please contact us at:

LS-Forum-Frankfurt2013@
simon-kucher.com

PRESENTATIONS INCLUDE

- **Two years of experience with AMNOG in Germany, evaluations of existing products and harmonization of market access in Europe**, Dr. Thomas Muller, Head of department pharmaceuticals, Joint Federal Committee
- **Update on recent changes in the Spanish healthcare system**
- **The role of net price in global pricing strategies**
- **Emerging markets:** “Business as usual” or a paradigm shift for global pricing strategies?
- **Pricing without Borders:** How to manage an international price management system
- **(Commercial) contract management excellence**

ABOUT THE SPONSOR

Simon-Kucher & Partners is a global consulting firm with extensive experience across key sectors of healthcare

PHARMACEUTICALS

Consulted to **24 of the 25**
largest pharmaceutical
companies

BIOTECH

Advised the **5 largest**
biotechnology companies

MEDICAL DEVICES

Worked for **17 of the 20**
leading medical device
and diagnostic companies

GLOBAL PRESENCE

- 26 offices worldwide
- Project experience in 49 countries

YOU ARE CORDIALLY INVITED TO ATTEND THE
**5TH ANNUAL NEW YORK CITY LIFE SCIENCES
MARKETING & STRATEGY FORUM**

Building off the success of the previous four years' events, Simon-Kucher & Partners' 5th Annual NYC Life Sciences Marketing & Strategy Forum will explore the unique global market access challenges pharmaceutical companies are facing today. Simon-Kucher & Partners Life Sciences experts will present a range of relevant topics to help you improve your strategic decision-making at a new Midtown West location.

WHEN

Wednesday, October 10, 2013
10am - 5pm

WHERE

Convene Westside
810 Seventh Avenue
23rd Floor
New York, NY 10019

New venue this year!

RSVP

Please look for a formal invitation to arrive within the next month

PRESENTATIONS INCLUDE

Market access crossfire panel: Successful commercialization of high cost therapies & the role of market access

Multi-disciplinary panel representing **physician, payer, and industry perspectives** on current healthcare system trends

Selected breakout sessions:

- **Oncology in the US:** How to survive the "perfect storm"
- **The evolving US market:** Insurance Exchanges and the state of Accountable Care Organizations
- **Post AMNOG World:** Is price potential dwindling in Germany?
- **Emerging markets and global P&MA strategies:** A closer look at Brazil and Mexico

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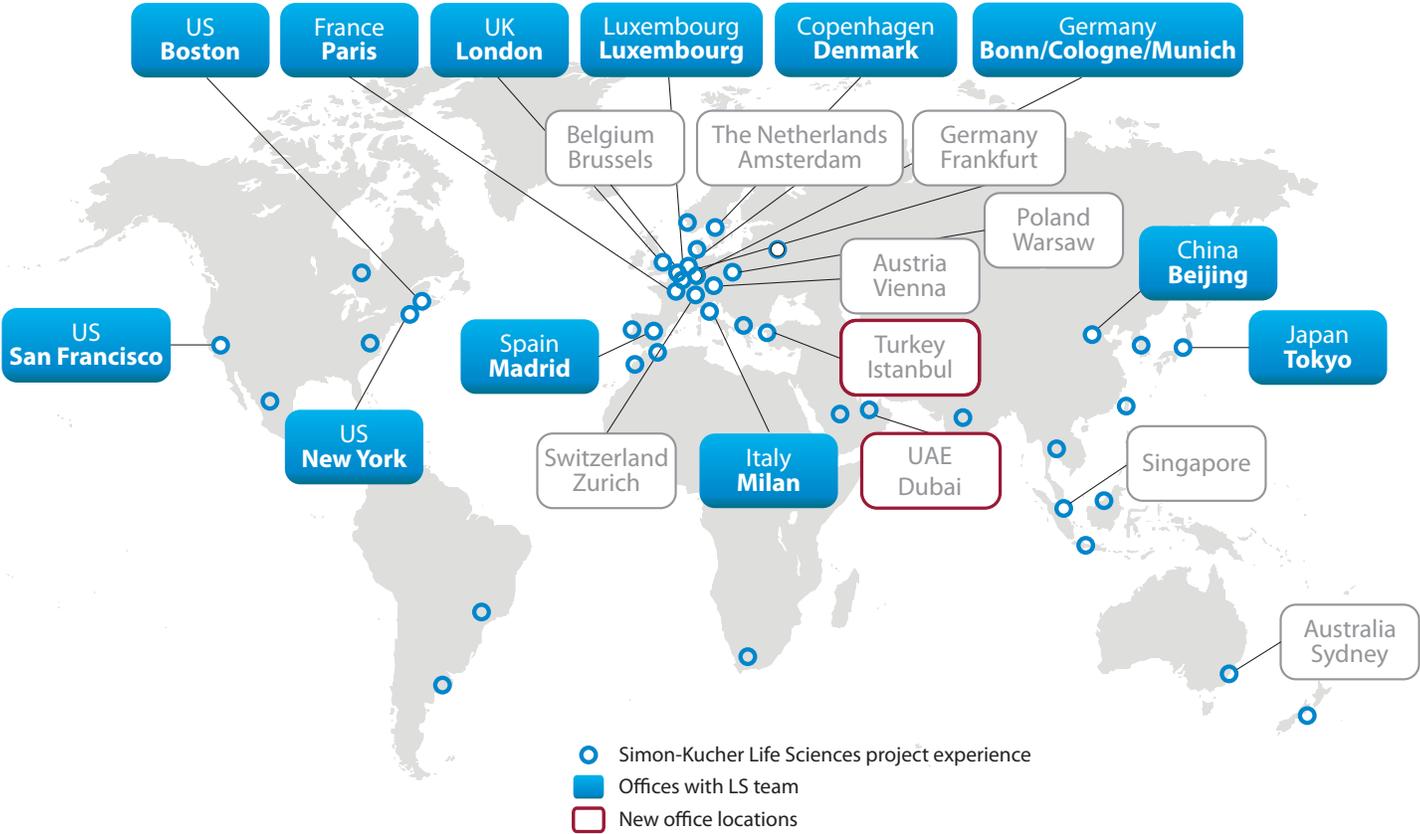
GLOBAL PRESENCE

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About the Life Sciences Practice of Simon-Kucher & Partners

Simon-Kucher & Partners is a leading strategy and marketing consulting company with proven expertise in pricing, market access strategies, product development, and licensing due diligence. Founded in 1985, Simon-Kucher & Partners has over 185 employees dedicated solely to Life Sciences in 14 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 17 of the top 20 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.

**Simon-Kucher’s global Life Sciences presence:
over 185 dedicated professionals in 14 offices worldwide**



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