

Pricing & Market Access Outlook

2015/2016 Edition



Acknowledgements

Thank you to the following people for their contributions to this report.

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Pricing & Market Access Outlook

2015/2016 Edition

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Dear clients, colleagues and friends,



I am pleased to introduce the 2015/2016 Pricing & Market Access Outlook. As we look forward, it is also helpful to look back over previous editions. In doing this, we noticed how a number of trends seem to have become deprioritized — for example parallel trade into the US. However, many others continued to have an impact and evolve; shaping the industry and the ways in which we make decisions.

Emerging markets, for example, have been a focus for almost ten years. Initially the focus was on entry and partnership and building a business on mature products. With new launches, however, we are seeing emerging markets as somewhat less important as a driver of growth. The focus now in these markets is typically how to expand beyond the wealthy and investing in patent-protected products. Similarly, provider integration and its resulting implications for pharma has been central to our strategies from the days of decentralization in Europe and now is critical in a growing number of therapeutic areas in the US with integrated delivery network penetration and evolving payment models driving convergence between payers and providers.

Despite this ongoing evolution, pricing and budget concerns remain a constant. Pharma and payers are pushing to find a balance between budget management and patient access. Pricing has consistently been a pressure point. This is even more extreme today with the shift to specialty products and treatment of rare diseases. As P&MA becomes central to commercialization, P&MA as a function is crucial to achieving leadership through this challenging environment. However, it is important that we not just identify trends – but as an industry we stay ahead of them and even influence their evolution. P&MA cannot be just a source of expertise within pharma — it needs to be a proactive leader of business results, shaping the future and engaging with stakeholders, and influencing decision-making.

We appreciate the chance to connect with you, our clients, through the Outlook and look forward to having further dialogue about all of the topics in the coming year.

Warm regards,

A handwritten signature in black ink that reads "Marc Benoff". The signature is stylized and includes a long horizontal line extending to the right.

Marc Benoff
Vice President and Global Lead
P&MA, IMS Consulting Group

I Unlocking the globe

Emerging markets have long been considered “the future” across industries due to their accelerated growth relative to more developed markets, and their potential for tapping a hitherto untapped population. However, the promise presented by these markets has yet to be fully realized, with various hurdles hindering entrants. In this section we explore how the environment is changing for pharma, and how the healthcare systems are becoming more accessible and lucrative for those entering.

II Let’s talk about drugs

Negotiations regarding the clinical benefit and substantiating the price of innovative medicines is something pharma faces when launching a new product. Increasingly, these discussions continue post-launch, with growing pressure on manufacturers to continually justify their products’ value to maintain their access and pricing. In this section, we explore the various pre- and post-launch issues that pharma must consider when conversing with payers.

III The price is right, right?

It is perhaps stating the obvious to comment that prices are going up, regardless of which industry you care to examine. However, this is notably true in the pharmaceutical industry, where media speculation and sensationalist articles abound on the seemingly ever-increasing prices of innovative medicines. In this section, we explore pricing trends in an effort to understand how the industry is evolving at a time of heightened price scrutiny.

IV Crystal ball conjectures

The future is never a linear path that can be easily predicted, as things continue to evolve and change — sometimes unexpectedly. The future of the pharma industry is no different, although themes and trends can be predicted, and occasionally paradigm-shifting occurrences happen that forever change the Pricing & Market Access landscape. In this section, we look to the future of the industry to comment on important upcoming changes that are likely to make a sizeable impact.

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How to treat more patients and make money in emerging markets

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Raja Shankar

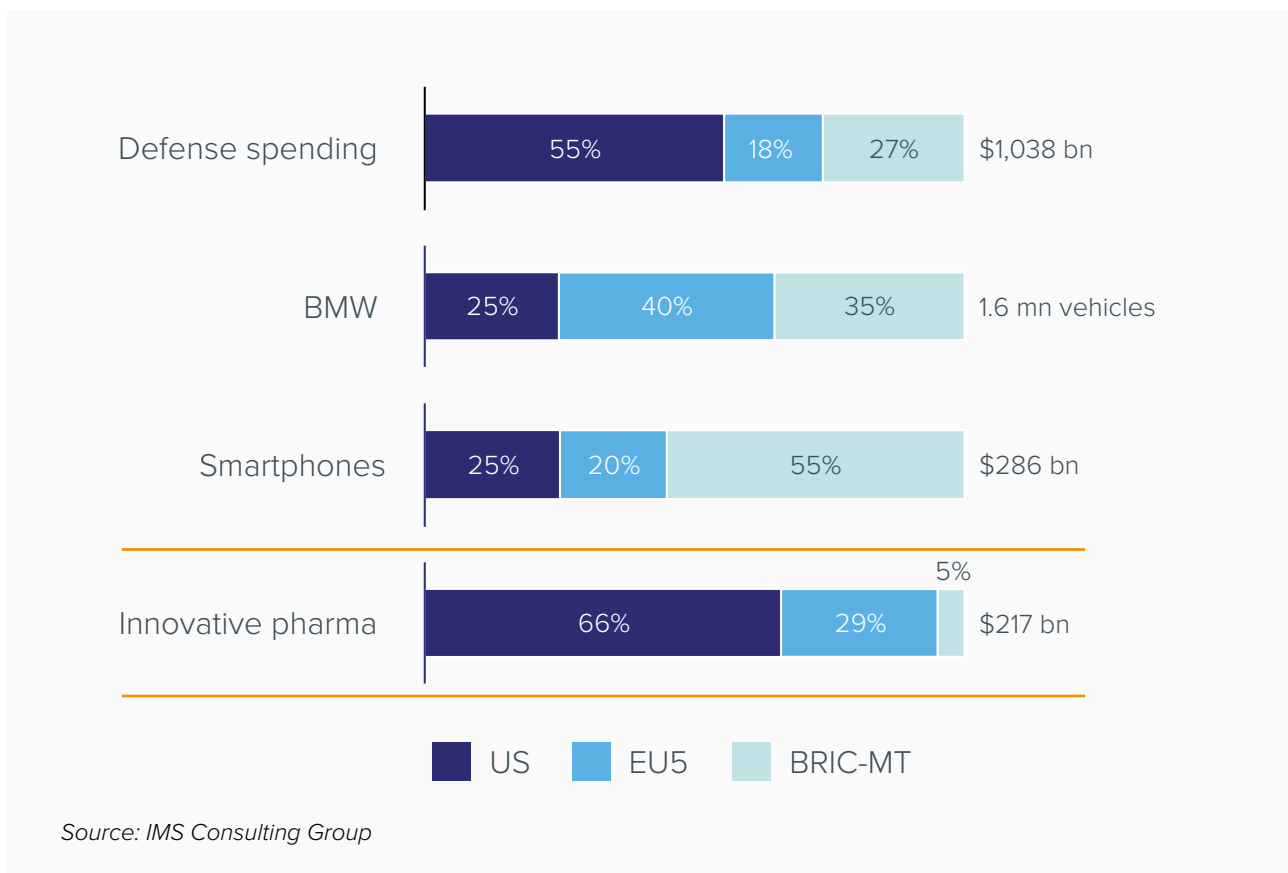
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People buy innovative products in emerging markets. Millions of Brazilians, Russians, Indians, Chinese, Mexicans, Indonesians, South Africans, and Turks text, tweet, google, use Facebook and shop on their smartphones, spending billions of dollars. More than half of all smartphone sales come from emerging markets. If we look at other industries such as cars, and even military equipment, emerging market revenues are more than revenues in the US or Europe. This story holds across industries — people in emerging markets buy expensive high-tech products.

But they do not buy innovative medicines (see Figure 1). Cumulative 1-year and 5-year sales of new molecular entities (NMEs) after launch in each market in Brazil, Russia, India, China, Mexico, and Turkey (BRIC-MT) combined — 3.2 billion population — is lower than that in France — 66 million population! There are twice as many diagnosed breast cancer patients in BRIC countries as in EU5 or the US, but total volume sales of Herceptin are a fraction (<1/6th) of that in US or EU5. The mismatch is even higher if we looked at breast cancer incidence, rather than just diagnosed patients — the gap between potential demand and current supply is more than 50-fold.

Aside from the ethical question of millions of patients not receiving the life-saving or life-enhancing treatments that are available, there is the financial question. Let's take the case of rheumatoid arthritis (RA). There are 25 million potential RA patients in BRIC countries. Smartphone penetration in China is ~50% of the US. If we assume a similar relative share of RA patients receiving biologic treatment in BRIC countries (12.5% in BRIC versus 25% in the US), we would have 3 million RA patients on biologics. Average smartphone price in India is ~25% of that in the US. If the 3 million patients got biologics at 1/4th the list price in the US, there would be 20 billion dollars of additional revenue from these markets. If we halve the penetration and halve the price, we would still see 4 billion dollars of additional sales.

FIGURE 1. MONEY TO SPEND — BUT NOT ON INNOVATIVE MEDICINES



BARRIERS TO TREATMENT

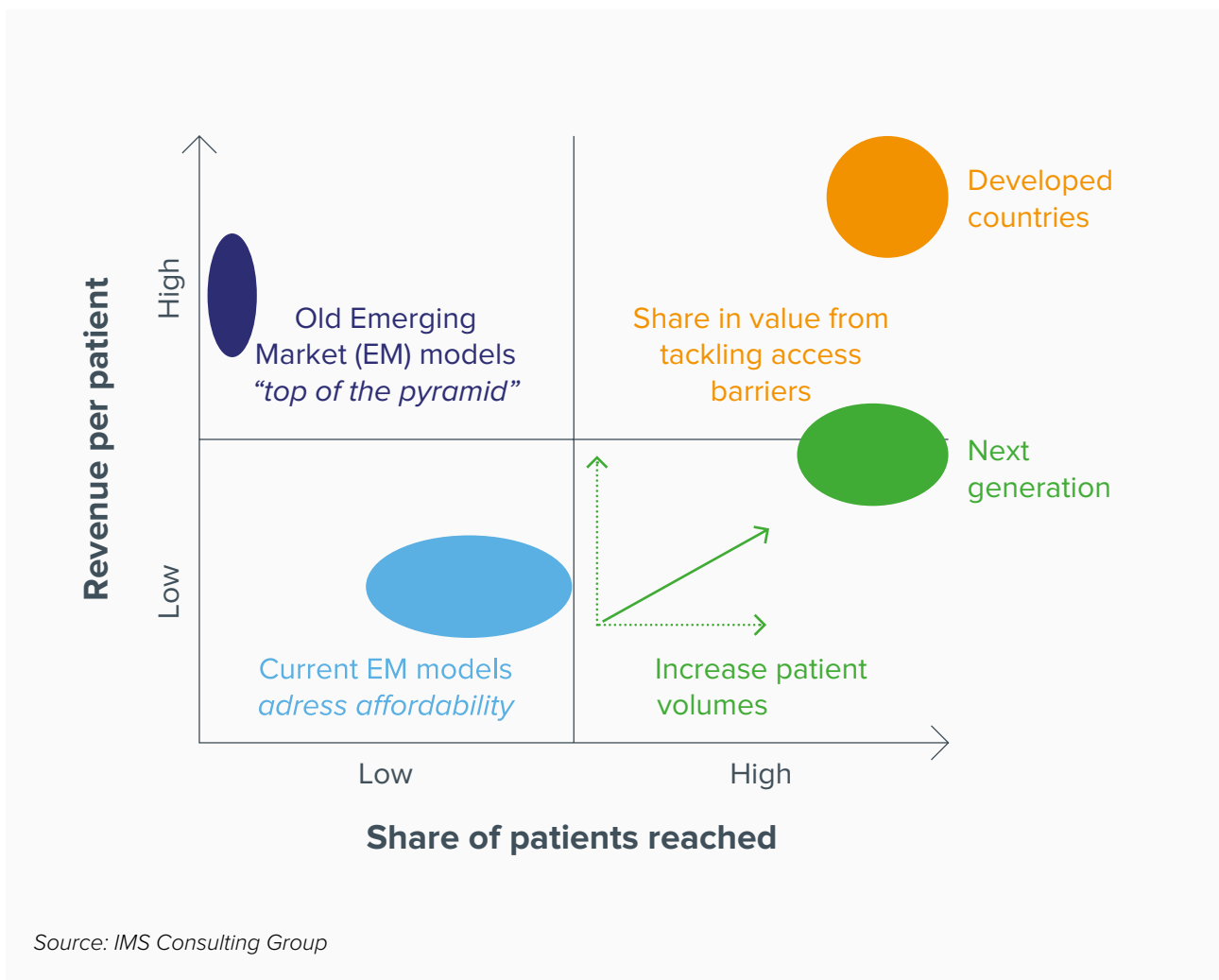
There are five barriers to effective access to medicines across the care pathway from screening and diagnosis to initial treatment (e.g. disease-modifying anti-rheumatic drugs in RA, metformin in diabetes) to innovative treatment and proper patient management. First is low **awareness** of patients and healthcare professionals of the right treatment protocols or the benefits of new medicines. Second is inadequate **accessibility** to care as often there are not enough hospitals, clinics, diagnostic equipment, or trained medical staff to diagnose and treat patients. Third is the lack of **availability** of medicines in local pharmacies or hospitals near the patient. Fourth is **affordability**, not just of the new medicine, but of the interventions across the entire care pathway. Finally, **adherence** to treatment is often poor, so patients do not fully benefit from the innovative treatment, and consequently do not see its full value. Given these barriers, most patients do not get to the point in the care pathway where they are eligible for innovative medicine. For example, many cancer patients are not diagnosed. For those that are diagnosed, many do not get surgery or radiation or chemotherapy that often precedes the use of innovative oncologics. The small proportion that get treated with the innovative medicines are not managed optimally, which means patients do not see the full benefit of high cost innovative treatments, thereby making them less willing to pay for such treatments.

NEXT-GENERATION ACCESS MODELS

Old and current access models have tended to mainly address the **affordability** barrier. The former focused purely on the few patients who could afford to pay premium prices. Today, many pharma companies implement some form of affordability strategy such as differential pricing, patient assistance schemes, and loyalty cards. These have increased volumes, but only in the small share of patients who get to the stage in the care pathway where they are eligible for innovative treatment. Therefore, overall sales gains have been modest.

Next-generation access models must take a two-pronged approach by: (1) reducing the **five barriers to access** along the care pathway to increase volume sales and (2) **sharing in the added value** generated for patients and healthcare systems in that process (see Figure 2).

FIGURE 2. NEW ACCESS MODELS TREAT MORE PATIENTS FOR MONEY



DYSLIPIDEMIA TREATMENT IN THAILAND

Consider how such an access model might operate in the case of innovative dyslipidemia treatment in Thailand. This is a country of 65 million people, making it similar in size to the UK or France. Of these, 15 million have private insurance and 50 million are covered by the National Health Security Office (NHSO), which has a public health mandate to improve cardiovascular (CV) outcomes.

There is much room for improvement. Only 18% of high cholesterol sufferers in Thailand are aware of their condition compared with 62% in the US; only 12% are treated compared with 48% in the US. And of those treated, control is lower than in the US. A next-generation model would have the manufacturer work in partnership with the NHSO, external CV expert organizations, pharmacists, and a technology company to address the five barriers. This model would increase **awareness** of the condition through a proper care protocol, address **accessibility** by training healthcare professionals (especially, local general practitioners and nurses) in the care protocol and its implementation, increase local **availability** of the treatments through addressing supply chain barriers with distributors and pharmacists, improve **affordability** by agreeing to value based integrated care offer with NHSO for reimbursement, and support **adherence** via better management.

This approach will have the ability to increase patient access and, therefore, revenues significantly for a new treatment as Figure 3 shows. Old and current models lead to limited revenues, while the new model can increase revenues manifold amounts compared to focus on the top of the pyramid baseline.

FIGURE 3. RELATIVE REVENUE OPPORTUNITY FROM NEXT-GENERATION MODEL: CASE EXAMPLE

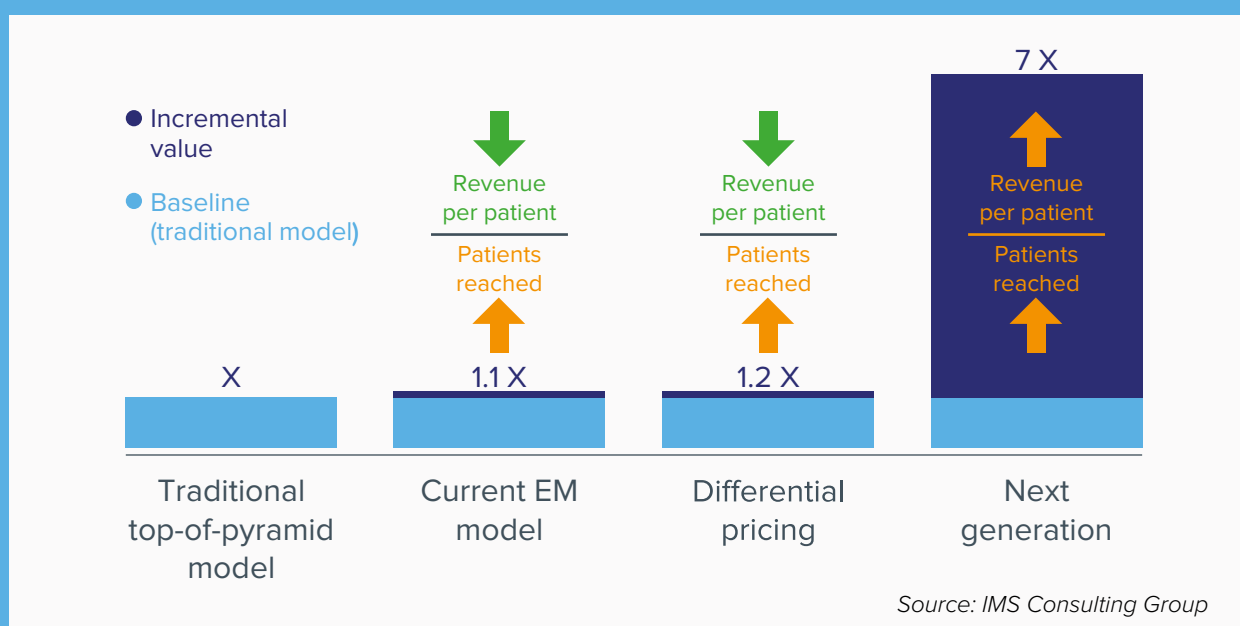
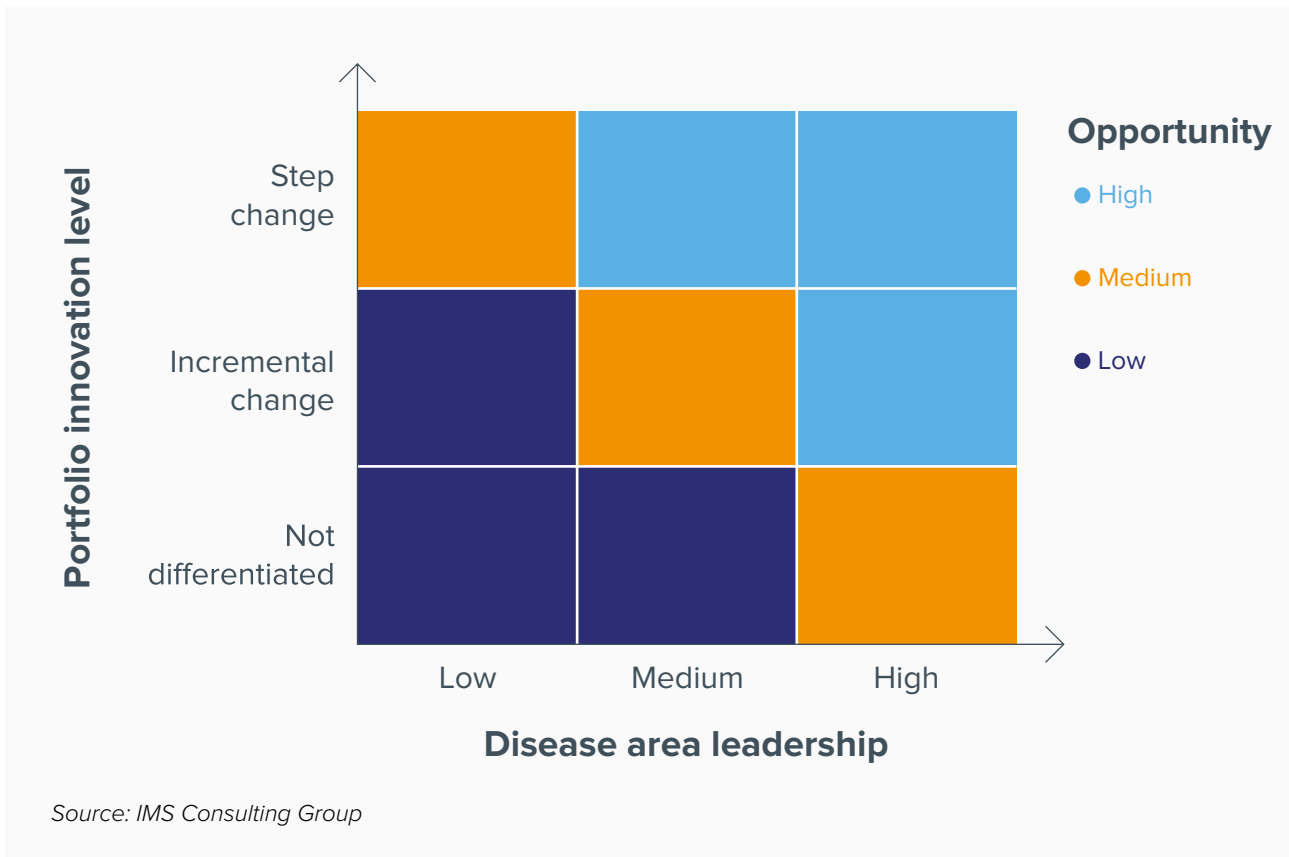


FIGURE 4. LEADERSHIP AND INNOVATION ARE KEY



The commercial attractiveness of next-generation access models depends on many factors, not least the level of a company’s leadership and innovation in a therapeutic area. Figure 4 shows how the greatest opportunities present where these two factors are most pronounced.

Affordability will always be a concern in the emerging markets but collaboration between pharma and healthcare service providers to release new value along the care pathway by addressing the five barriers is a direction more companies, especially those leading in a particular disease area, can be expected to take in the future.

WHY SHOULD THIS MATTER TO YOU?

- Millions of patients remain untreated and billions of dollars in sales from innovative medicines remain unrealized in emerging markets.
- Next-generation access models must remove barriers along the care pathway such as availability of diagnostics, to reach these patients...
- ...and generate revenue from the manifold increase in patients, as well as from sharing in the value generated by addressing these barriers.

Five key trends in the Middle East and Africa



Challenges



Opportunity



Relevant data point(s)

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1



Diverse healthcare funding mechanisms



Heterogeneity of health financing can affect regional uptake of innovative drugs.

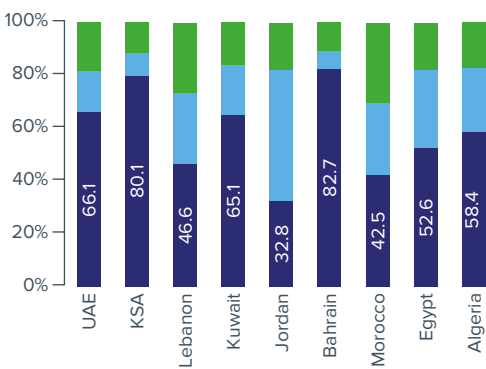


Innovator products occupy >80% of the market share in Kingdom of Saudi Arabia and >66% in the United Arab Emirates.



The more reimbursed markets of The Gulf Cooperation Council (GCC) exhibit a strong tendency to consume more innovative brands and this trend is expected to continue in the foreseeable future.

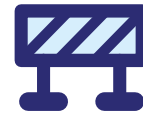
Opportunity - reimbursed GCC markets



The more reimbursed markets of the GCC exhibit a strong tendency to consume more innovative brands and this trend is expected to continue in the foreseeable future

- Innovator prescription
- Generic prescription
- Over the counter (OTC)

2



Tackling regulatory hurdles



Lengthy regulatory timelines render a big opportunity cost



Early access, named patient program, and temporary authorization for use, may be implemented to gain initial traction and to avoid treatment delays



Length of early access programs may vary:

KSA — 24 months (until market authorization or until formulary inclusion)

Egypt — 2–3 years (until market authorization)

Morocco — 2 years (until market authorization)

Market	Global	Africa	Asia Pacific	Central & East Europe	Japan	Latin America & Caribbean	Middle East	North America	Western Europe
Size (US\$)	1,270–1,330 bn	28–38 bn	245–285 bn	65–75 bn	80–90 bn	90–110 bn	22–32 bn	480–520 bn	215–235 bn
CAGR '14-'19*	3–6%	8–11%	7–10%	4–7%	(-1)–2%	5–8%	6–9%	3–6%	1–4%

*Compound annual growth rate 2014-2019



- Qatar
- United Arab Emirates (UAE)
- Lebanon
- Kuwait
- Jordan
- Bahrain
- Iraq
- Saudi Arabia (KSA)
- Iran
- Oman

3 ↑

Pricing effect offset by volume and new brands

- Downwards pressure on drug prices due to price unification and referencing
- Although price changes and withdrawn products had a negative impact on growth, MEA's market growth is driven by volume and new packs
- \$2.04 billion can be attributed to volume whereas \$515 million can be attributed to net price effect

4

Advent of health technology assessment

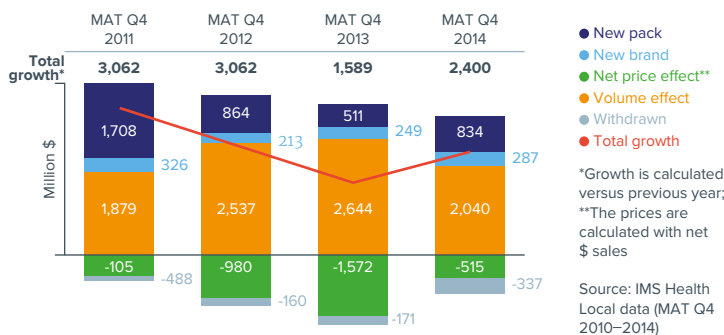
- Authorities constantly enforce measures to curb overall healthcare spending especially the drug budget
- Payers in Egypt (Ministry of Health), KSA (Institutional Hospitals) and UAE (Dubai Health Authority, Health Authority - Abu Dhabi) are looking at incorporating pharmaco-economic studies at various stages of decision-making - pricing, purchasing and reimbursement
- The Egyptian drug authority has already conducted a number of cost-effectiveness analyses including seven on oncology drugs

5

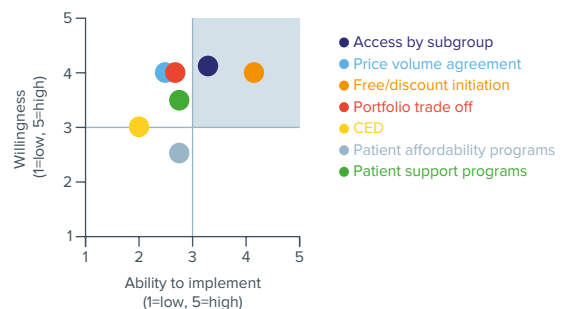
Changing payer purchasing behavior

- Majority of purchasing via molecule specific tendering
- Currently payers find more value in finance-based risk agreement as they are limited in their ability to implement and monitor performance-based agreements. But payers exhibit high willingness to execute such deals.
- Payers preference for agreements — free goods/discounts > sub-group access > pharmacovigilance agreements/portfolio trade off > performance-based agreements

Source of growth analysis, net growth - value, \$m



Payers and physicians reactions to innovative agreements (average rating)



Global negotiation strategy: The 3Ps framework

Developed by IMS Consulting Group and Vantage Partners

AUTHORS

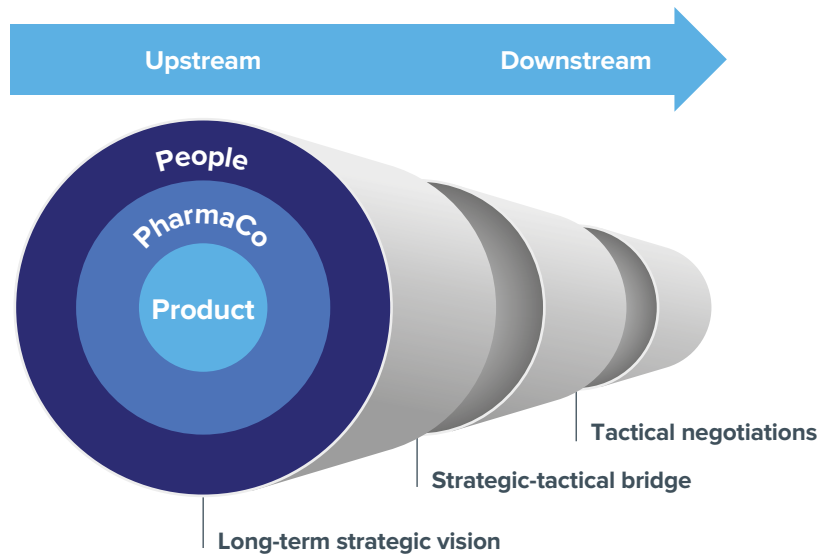
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High-level, strategic decisions have an important impact on the end result of individual product negotiations and common issues faced at the negotiation table could be avoided if global Pricing and Market Access (P&MA) teams were involved earlier in the process.

IMS Consulting Group has joined with Vantage Partners to make a framework applicable to the strategic decisions faced by global P&MA teams.

Our framework looks at how the key questions derived from each of the seven elements apply to the 3Ps (people, pharma company and portfolio/product) across three time points (long-term strategic vision, strategic-tactical bridge, and tactical negotiations).



The 3Ps: people, pharma company, and product/portfolio

The seven elements: relationships, communication, interests, options, legitimacy, alternatives, and commitment

Key Takeaways

1

Make the right strategic decisions early, using the 3P Framework

- HQ strategic decisions (5+ years early) constrain the options and alternatives during tactical negotiations
- P&MA executives should be proactive to ensure awareness of the impact of these decisions and get involved as early as possible to maximize the commercial potential of assets

2

Make the pharma company's options better than the payer's alternatives, and ensure that upstream decisions enable option flexibility at the tactical level

3

Maintain relationships with "People" in the 3Ps

- It is an iterative process that needs constant communication, even in the absence of a product

Create a platform for communicating value

- For both the Pharma company and the portfolio, independent of any product launches

Strategic-Tactical Bridge

How does a company ensure optimal outcomes for all drugs in their portfolio?

Are all the stakeholders being engaged in the right way?

Relationships > Relationships consist of the common understanding shared by a pharma company and external stakeholders. They can take the form of advocacy, formal partnerships, and/or knowledge sharing.

Interests

Each stakeholder has their own set of interests. These interests can be either shared, different or conflicting. Pharma companies must understand the interests of the stakeholders they engage with.

Options

Options relating to products are considered by both the Pharma company and People and must appeal to the interests of both parties.

Alternatives

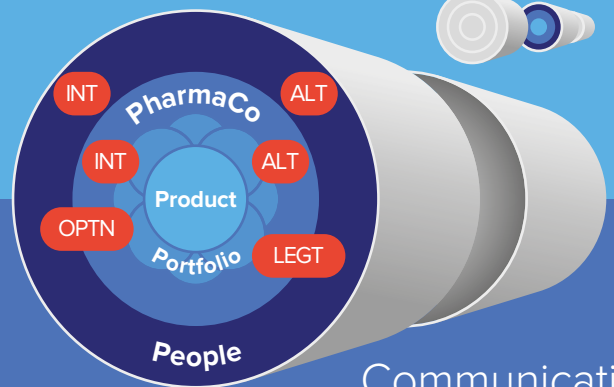
Often choices outside of the traditional reimbursement pathway. Pharma companies need to understand which party has the better/worse alternatives as this influences leverage power.

Legitimacy

A legitimate option or set of options is defined by whether they can be qualified as appropriate by an external, impartial judge. Legitimacy must be shared across the different external and internal stakeholders.

Relationships

Strategic-tactical bridge



INT: Interests OPTN: Options LEGT: Legitimacy ALT: Alternatives

Communication is the continuous link between product teams and external stakeholders. It is also a pharma company's means of persuasion and information circulation. < Communication

Strategic decision points



Elements

Interests



People

How can a pharma company do more to understand the interests of the payers?



Pharma company

How can the global policies dictated by pharma company interests be actioned?



Product/portfolio

How can a portfolio be crafted to cater to all internal and external stakeholders?

Options

Options relating to products are considered by both the pharma company and people and must appeal to the interests of both parties.

What are the options in trial design that lead to the best commercial outcomes?

Alternatives

Does a pharma company have a good understanding of alternatives that payers may have?

Does the pharma company have the right resources to action their alternatives?

What alternatives are available for products in the portfolio of the company?

Legitimacy

Have we explored all of the arguments a payer might use to challenge the legitimacy of options?

Is an option legitimate to the other stakeholders in the company?

How can a pharma company utilize real-world data to provide evidence for their portfolio?

Preparing for battle: Defending value with real-world evidence

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As payers increasingly launch their own studies to understand a drug's real-world performance, the need for robust evidence strategies to support the value of innovative medicines is clear. Pharma must be prepared for more intense questioning about the value of its products not only at launch, but also throughout the lifecycle. This requires thinking through the evidence requirements in early development, preparing well, and collaborating with payers around common objectives to reinforce the value payers are looking for.

It is not unusual for payers to insist that pharma collect post-launch evidence of product performance in the real world. This could be to substantiate a price agreement or to clarify uncertainties about the clinical and/or safety outcomes outlined at registration.

The results of such requests are often in pharma's favor. When Janssen used its 2005 real-world evidence (RWE) study to maintain the price premium in the UK on its long-acting injectable bipolar medication, Risperdal Consta, the study showed reduced hospitalization rates when compared with the oral equivalent.

PAYER-GENERATED EVIDENCE

In recent years, a combination of higher drug prices and the ready availability of robust and integrated real-world data has meant that payers can generate their own evidence at relatively low cost. This constitutes a compelling argument for companies to reconsider their evidence strategies, as without pharma involvement in the generation and interpretation of the data, results could be less likely to be in pharma's favor. This is especially true where a premium price is being sought, where the target population is large, and where cheaper alternatives may satisfy much of the unmet need.

For example, the results of a couple of high profile payer-led head-to-head trials of Avastin versus Lucentis in age-related macular degeneration (AMD) have led to payers in Italy allowing off-label use of the cheaper Avastin. Discussions are ongoing in other EU countries, while in the US, half the scripts in AMD are now for Avastin following the results from the US-based Comparison of AMD Treatments Trials (CATT).

PHARMA'S INFLUENTIAL RWE

If pharma is well prepared, however, it can use payers' enhanced proficiency with RWE to its advantage. Here, the battle is not so much with the payer, but with the competition. This was illustrated in France recently when the Transparency Commission was evaluating the performance of three agents in the novel oral anticoagulant (NOAC) space.

The two main databases in France — one of reimbursed care in the outpatient setting (SNIIRAM) and the other on stays in public and private hospitals (PMSI) — were linked in 2006 and one of the initial studies was to compare the clinical benefit of NOACs versus the older anticoagulants.

In 2014, the Transparency Commission reassessed the NOAC class of drugs and, as a result, changed the important SMR (medical benefit) and ASMR (improvement in medical benefit) ratings, which are critical to the level of reimbursement. Interestingly, the latest entrant to the NOAC market, Pfizer's Eliquis, was the only one to be supported by a package of RWE and the only one to have its rating raised. Bayer's Xarelto maintained its rating, and that on Boehringer Ingelheim's Pradaxa actually went down.

Similarly, Celgene's in-house RWE for Revlimid, which is indicated for multiple myeloma, convinced the UK's National Institute for Health and Care Excellence (NICE) to fund the drug in 2014. This was after a patient access scheme had failed to demonstrate cost-effectiveness because of uncertainty surrounding clinical practice.

FOCUS WHERE PAYERS FOCUS

Detailed analysis of the factors leading to post-launch payer scrutiny suggests that pharma should concentrate its efforts to generate RWE along the criteria outlined in Figure 1 that pertain both to therapy area and to specific drugs.

These have been considered in relation to five new drug classes in the following therapy areas: hepatitis C (anti-HCVs); dyslipidemia (PCSK9 antibodies); oncology (PD-1 inhibitors); heart failure (ARN inhibitors); and asthma (anti-IL5s). They all fulfill enough of the criteria to make it highly or moderately likely that payers will want to follow their performance in the real world with a view to either cutting price or reducing access.

FIGURE 1. LIKELIHOOD OF PAYER SCRUTINY IN FIVE NEW DRUG CLASSES

		Anti-HCV	PCSK9 Abs	PD-1 inhibitors	ARN inhibitors	Anti-IL5s
Therapy area	Large population within indication	✓	✓	✗	✓	~
	Large number of alternative treatments	✓	✓	~	✓	✓
	Established and lower cost standard of care	✗	✓	~	✓	✓
	Low payer-perception of remaining unmet need	✓	✓	✗	~	~
Drug-specific	Chronic treatment	~	✓	~	✓	✓
	Limited/no efficacy and safety differentiation vs. comparators	✓	✗	~	~	~
	High price vs. alternative options	~	✓	✓		✓
	High absolute price	✓	✓	✓	~	✓
	Limited RCT data at launch	~	~	✓	~	✓
Likelihood of scrutiny		High	High	Medium	High	High

✓ Meets criterion
 ~ Partially meets criterion
 ✗ Does not meet criterion

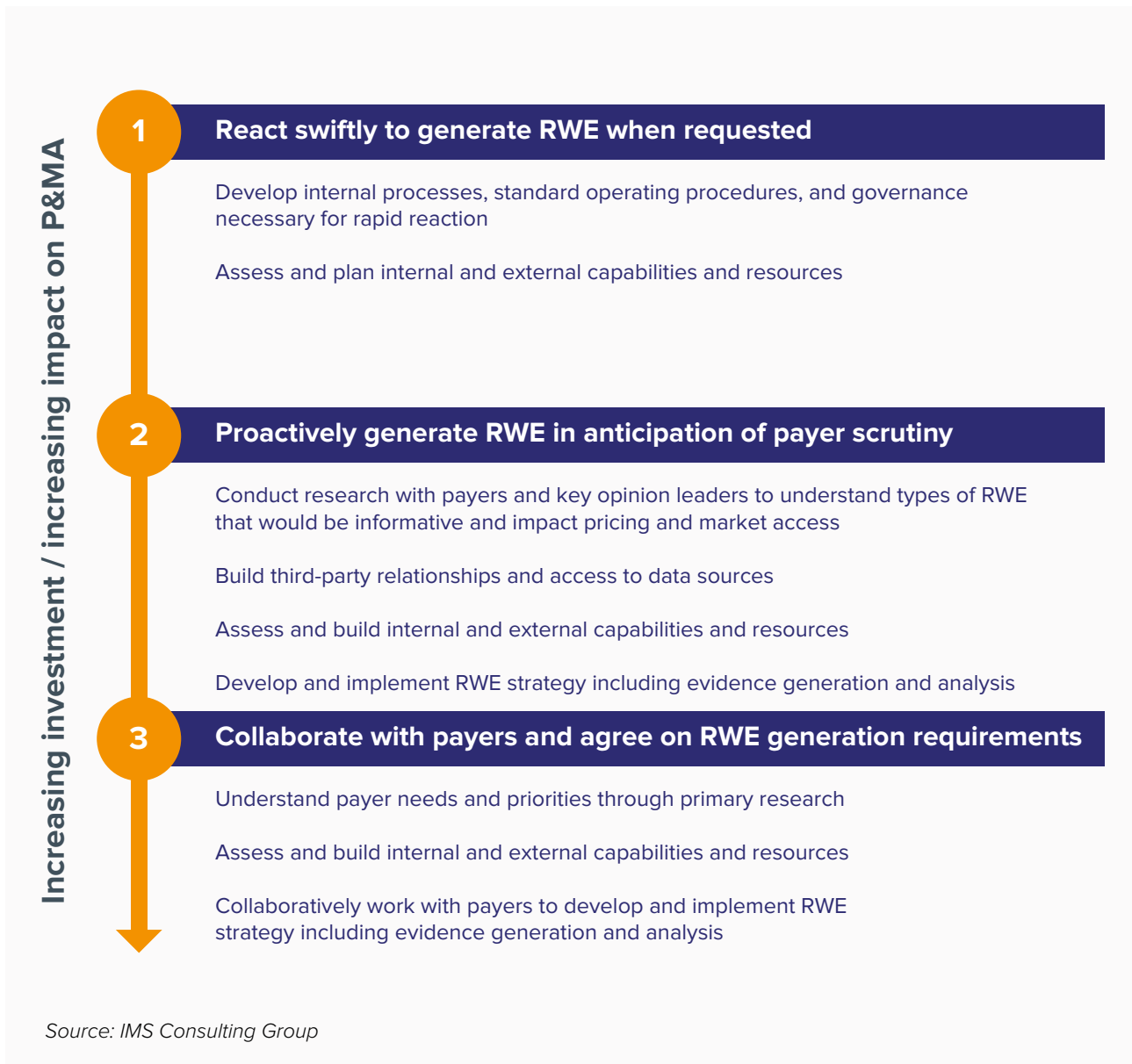
Source: IMS Consulting Group

RWE STRATEGIES

Companies need to consider how best to design compelling RWE strategies to maintain value post launch. The different options are ranked in Figure 2 according to the level of investment and potential impact on payers’ decision-making. The best option will be based on many internal and external factors, particularly the company’s capacity to execute. The criteria in Figure 1, the therapeutic area, the likely evolution of indications, and/or future pipeline will also be important factors to consider when choosing a strategy.

Certainly, as the regular use of RWE becomes more prevalent as part of payer decision-making, movement towards collaborative working with payers is inevitable. To support the value of innovative medicines throughout their lifecycle, it is vital to develop strategies that embed RWE in the clinical development program, the infrastructure that supports R&D and market access, and the way that commercial teams communicate value to clinicians. This is already expected from markets like the UK, France, and Sweden. Markets like Italy, Spain, and the Netherlands are becoming more receptive to this type of evidence and all of these markets could have a formal place for RWE in their assessment processes.

FIGURE 2 RWE STRATEGIES RANKED BY INVESTMENT AND IMPACT POTENTIAL



WHY SHOULD THIS MATTER TO YOU?

- Payers are increasingly conducting their own RWE studies, which can be used to contest pharma evidence and to fill gaps in evidence and understanding.
- Pharma must prepare its RWE strategies early, be proactive, and collaborate as much as possible with payers.
- Pharma should concentrate its RWE efforts on those therapeutic areas where payer scrutiny is most likely.

US payers versus manufacturers

Today, US commercial payers and drug manufacturers are locked in a battle of wits and strategy, competing in a Game of Thrones.

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The government is the judge
Sets and enforces rules and penalties, and should be impartial and fair to both sides



Shareholders are the king
The objective of the game is to protect the king (shareholders). Failure to do so results in loss of the game



Employers are the queen
Most powerful piece in the game; can decide the fate of the king (shareholders) directly or indirectly, and who eventually wins



Exchanges are bishops
Bishops only access half the board like exchanges are only relevant for a small percentage of population, but are influential



Physicians are knights (in shining armor?)
Powerful players that protect the pawns (patients) and support the king (shareholders)



Integrated delivery networks (IDNs) are rooks
Have become more powerful and influential as the game has evolved



Patients are pawns
Relatively weak and numerous; easily manipulated or sacrificed for larger purpose of protecting the king (shareholders)

US payers and manufacturers are facing a draw in the chess match today, but who will win in the future?

Pharma manufacturers win if...

- Co-pay cards can continue to be used
- No government intervention on pricing
- Exclusionary lists will not include innovative drugs
- Consolidated payers are focused more on medical savings than drug savings
- Innovation is rewarded, albeit at slower rates than in the past
- They recognize that winning commercial strategies in 2015+ are more complex and tailored than ever

Payers win if...

- Government intervention will curb high drug prices and/or use of co-pay cards
- Expansion of exclusionary lists includes more new, high-cost drugs
- Increased consolidation leads to greater negotiating power
- Increased use of biosimilars and generics are used to curb costs

Payers and integrated delivery networks (IDNs): A roadmap to US access

Over recent years, pharma has engaged in a hearty debate — do IDNs influence prescribing and brand performance? IMS Health research and client work shows that they do in a number of important therapy areas (TAs) for pharma, but more often at a class level than at the brand level.

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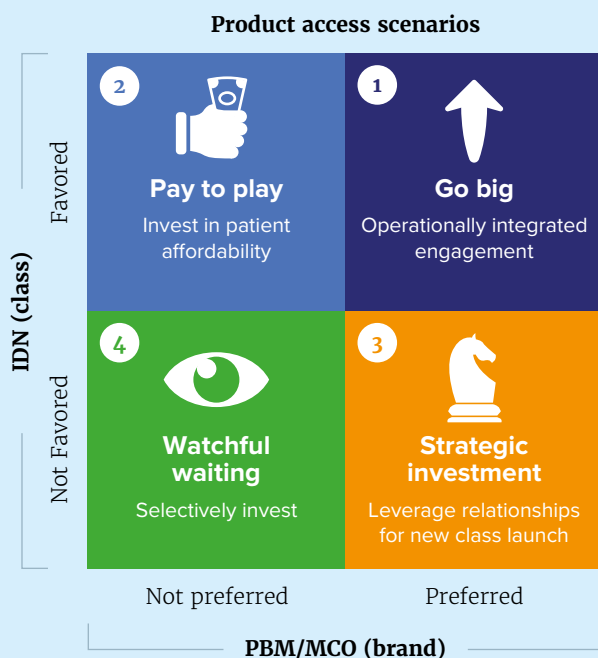
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Payers and some IDNs — in TAs they are focusing on — are arriving at an equilibrium around prescribing. This means that for at least the intermediate term, achieving access in these TAs means addressing both IDNs and payers:

Access with key payers in a given region will continue to form the foundation for commercial success locally

Where IDNs are exerting control, they tend to manage prescribing by class, based on their perceptions of optimal care and the need to accommodate the many payers who cover their patients

This equilibrium provides a roadmap for navigating the US market



- 1 Go big**
Where every pharma company aspires to be! This is where adherence, diagnostics and other collaborative care programs really pay off
- 2 Pay to play**
IDN-affiliated physicians are encouraged to prescribe your class — but you are missing out due to lack of payer access. If the IDNs are large, upping investment in payer access can pay off; for Metropolitan Statistical Areas (MSAs) with smaller IDNs, targeted couponing can make a significant difference
- 3 Strategic investment**
Where the IDN influence is big enough and/or an MSA has high enough volume, collaborative real-world evidence (RWE) is key to shifting the IDN perception of your class — as is making sure that independently minded physicians understand current payer coverage
- 4 Watchful waiting**
Clearly the most challenging environment, this requires assessing the value of rebates to payers in MSAs with high control IDNs and understanding where to invest in RWE to change IDN favorability. Additional opportunity exists in targeting independent physicians and supporting patient affordability

'No regrets' moves — regardless of which quadrant you are in...

Identify ways to generate mutual and sustainable value — which may include above-brand programs if you are the market leader, especially in the “go big” quadrant

Make sure the business value and results timing are clear to all stakeholders — moving a controlling IDN can take much longer than changing payer positioning or physician prescribing

Don't forget about the individual physician — understand what information they need to effectively use your product and how they best want to receive that information

New tendering trends call for action

AUTHOR

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Pharmaceutical tendering is becoming increasingly diverse as countries attempt to contain healthcare costs via different tools. While price remains the main driver, new criteria are being introduced to recognize unique drugs and differences among those within the same therapeutic area or concerning the same molecule. Global pharma operations must work with the affiliates to keep abreast of these changes and approach tendering as a strategy that straddles pricing and commercialization, if only because of its profound impact on brands and portfolios.

Pharmaceutical tendering has vastly increased in scope in recent years as EU payers explore new ways to contain rising healthcare costs. The main trends include countries extending the tendering process through direct individual negotiations; enlarging the range of drugs, particularly recently expired large molecules; ensuring the discounts achieved locally, regionally, or nationally are made public; considering 'net prices' as reference in the internal pricing system; and starting to embrace value considerations other than price.

These factors, coupled with enhanced expertise on the part of the payers informing tenders, mean tendering now has a greater potential impact on global pricing and commercial strategies than ever before. This becomes clear on taking a closer look.

TENDERING TRENDS

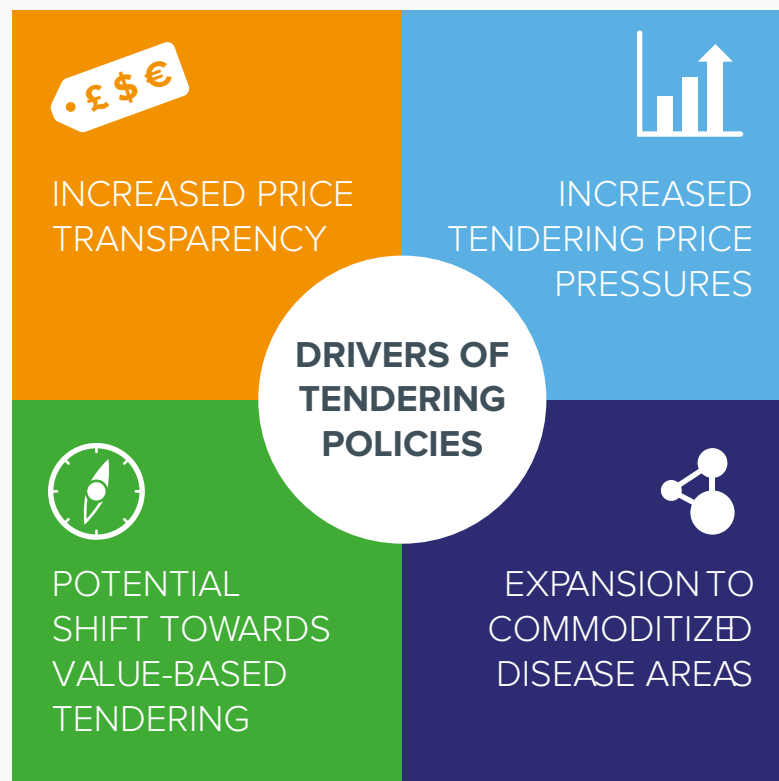
Current tendering trends are broadly illustrated in Figure 1. Expansion into commoditized disease areas brings more drugs into the tendering process. Norway, for example, was able to secure a 72% price discount on the biosimilar infliximab, which is indicated for a range of autoimmune diseases. At least one hospital group in France has since called for a similar tender to secure access to this drug. Other routes of expansion come from

the emergence of tendering by therapy area rather than the traditional molecule level. Denmark, for example, recently put out all drugs in the multiple myeloma space for tender. The first, second, and third treatment recommendation within a line of treatment in the guidelines are all based on the tender results. This is unusual, not just because of the type of tender, but also because it happened in oncology and in an area of largely orphan-designated drugs.

Increased transparency is another key trend. In Italy, for example, discounts are collected at national level to provide all regions/hospitals with an average sub-national discounted price. Information collected is not just related to generics/biosimilars tenders, but also extended to individual sub-national negotiations. This affects pricing levels internally (across regions and across hospitals) in the same way pricing levels in one country affect those in other markets via international reference pricing.

An additional trend, value-based tendering, involves criteria other than price and is being introduced into the tendering process in countries such as the UK, Finland, Norway, and Sweden, where it is also combined with accessible and transparent price information.

FIGURE 1. WHAT IS DRIVING TENDERING POLICIES?



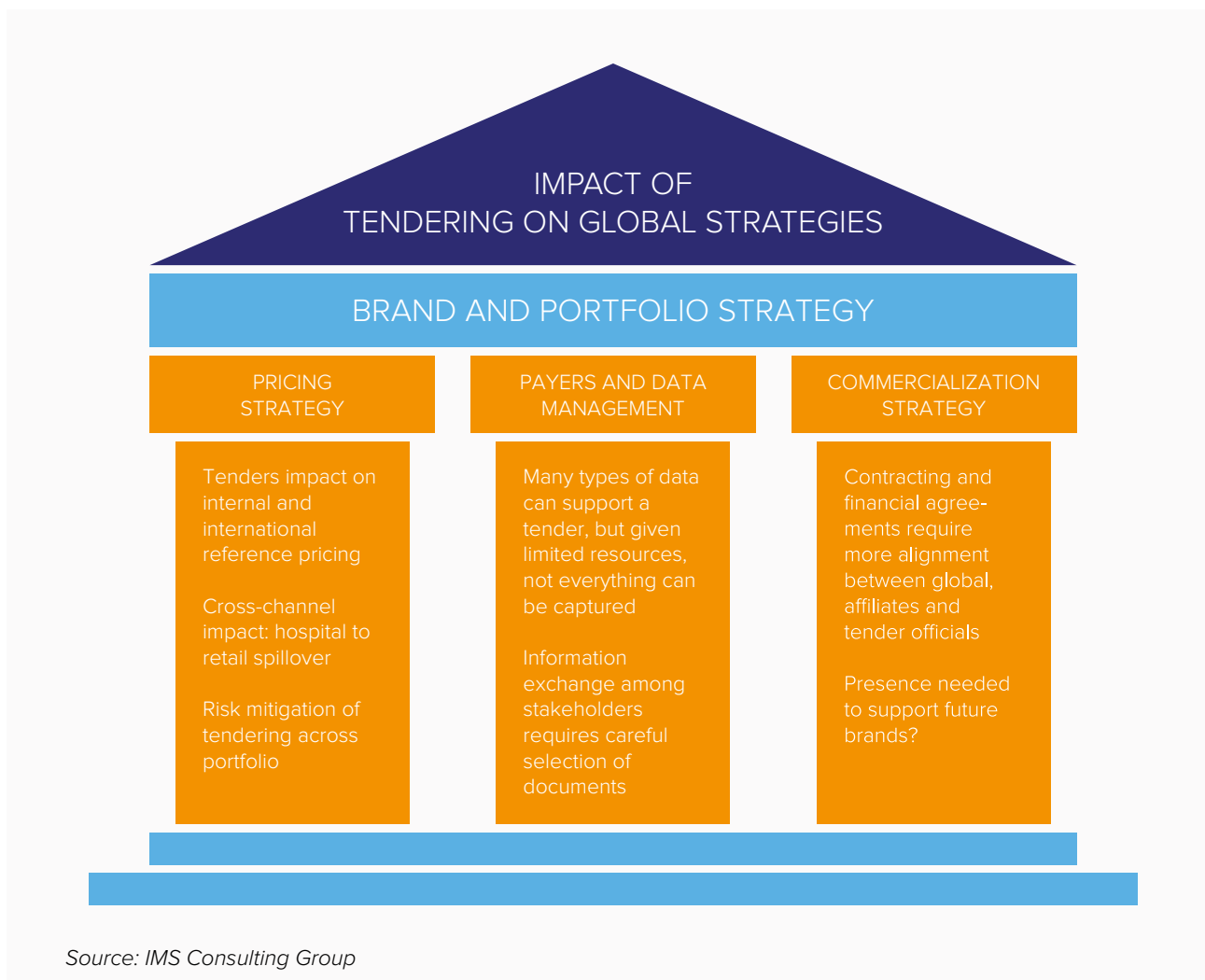
Source: IMS Consulting Group

A GLOBAL PHARMA CONCERN

All these trends have a profound impact on global pricing and commercialization strategies, as shown in Figure 2, making it imperative that tendering is not left to the affiliates alone as has traditionally been the case. Increasingly, tenders require an integrated and coordinated approach to gather net price opportunities and challenges and to select those to answer in light of the likely impact on other countries. Negotiations, launch sequence, and commercial strategies should take into consideration these new issues raised by tendering trends and be informed with an action plan that combines capabilities at global and affiliate levels.

Communication with payers is also critical as in the tendering process it is not always clear how information exchanged between pharma companies and payers will be used and with whom it will be shared. Furthermore, in some cases, interaction with payers is limited because of the web-based tender submission. Engaging with tendering payers and understanding their needs becomes as imperative as fostering a careful document selection.

FIGURE 2. IMPACT OF TENDERING ON GLOBAL STRATEGIES



TAILORING THE BID

The most important thing is to know how payers are managing the tendering process, why they are calling a tender, and, for planning purposes, when tenders are scheduled. Channels opening better global–affiliate communication create the visibility and understanding of how the information in the value dossier submitted is used by payers. Although the information is ideally used to support product value, it can have the opposite effect as a lack of tailoring to payer needs can highlight and bring focus to product weaknesses relative to bid competitors.

It is critical therefore to customize information to respond to specific payer needs. This means developing an understanding of which decision–drivers that payers use in calling a tender and if these vary across therapeutic areas, diseases, and/or settings of care. Such information steers how a bid might be improved with outcomes data, the kind of services and solutions that could be provided to address payers' concerns in managing a disease, such as the need to raise adherence rates.

While there is no generic solution or formula for a successful bid, companies putting together an effective tendering management strategy should consider:

- The key drivers of product value: the data types that can reinforce this value; competitive intelligence in terms of the history of tendered prices; and competitor product value.
- The company reputation and global–affiliate relationships that ensure all tender submissions and outcomes are seen at the global level.
- Past experience: including relationships formed at the affiliate level with tendering authorities as well as learnings from past submissions.

It can be easy at the global level to forget that tenders are the second step of the access process at the sub–national level in most EU countries. As they broaden in scope and payers become more proficient at using them, better global–affiliate communication to create the optimal bid becomes more urgent. And remember that successful bids, are primarily about communicating value.

WHY SHOULD THIS MATTER TO YOU?

- Pharmaceutical tendering is evolving in response to increasingly constrained budgets, the opportunity presented by biosimilars, and enhanced payer expertise.
- Tendering processes are becoming more transparent and the results more accessible.
- These trends impact on global pricing and commercialization strategies and facing them will require a greater coordination between global and local teams in managing tenders.

2014 product launches: Price premiums versus discounts and time to market

AUTHOR

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As healthcare budgets continue to tighten, the list price of pharmaceutical products is subject to ever greater scrutiny. To provide some perspective on the relative value of new brands, an annual relative list price has been produced by analyzing the list price of all new molecular entities (NMEs) launched in the US and EU¹ in 2014 in terms of either the premium or discount achieved versus direct or indirect comparators.

PRICE PREMIUMS VERSUS DISCOUNTS IN 2014

- The number of NMEs approved has doubled in the EU (14 in 2012 to 28 in 2014) and almost tripled in the US (12 in 2012 to 33 in 2014) since 2012 (see Figure 1), putting more pressure on already stretched healthcare budgets.
- Overall, approximately 65% of the NMEs launched in the EU adopted a premium² list price strategy with 35% attaining parity or discount pricing versus comparator (see Figure 2). This ratio is precisely that observed in the US in 2013; in 2014 a further reduction was seen in the US to 43%.
- Of the 33 NMEs launched in the US, 16 were orphan products; 22 were indicated for specialty care; 10 were in oncology; and 11 were biologics (see Figure 3).³ 8 had a direct price comparator at launch.
- Of the 48 NMEs launched in EU8, 18 were orphan products; 37 were indicated for specialty care; 17 were in oncology; and 16 were biologics (see Figure 4).⁴ 14 had a direct price comparator at launch.

¹Germany, Denmark, Spain, France, the Netherlands, Sweden, and the UK.

²Premium is defined as 5% or more above the price of the comparator.

^{3,4}The categories are not mutually exclusive.

FIGURE 1. NME APPROVALS IN EU8 AND US

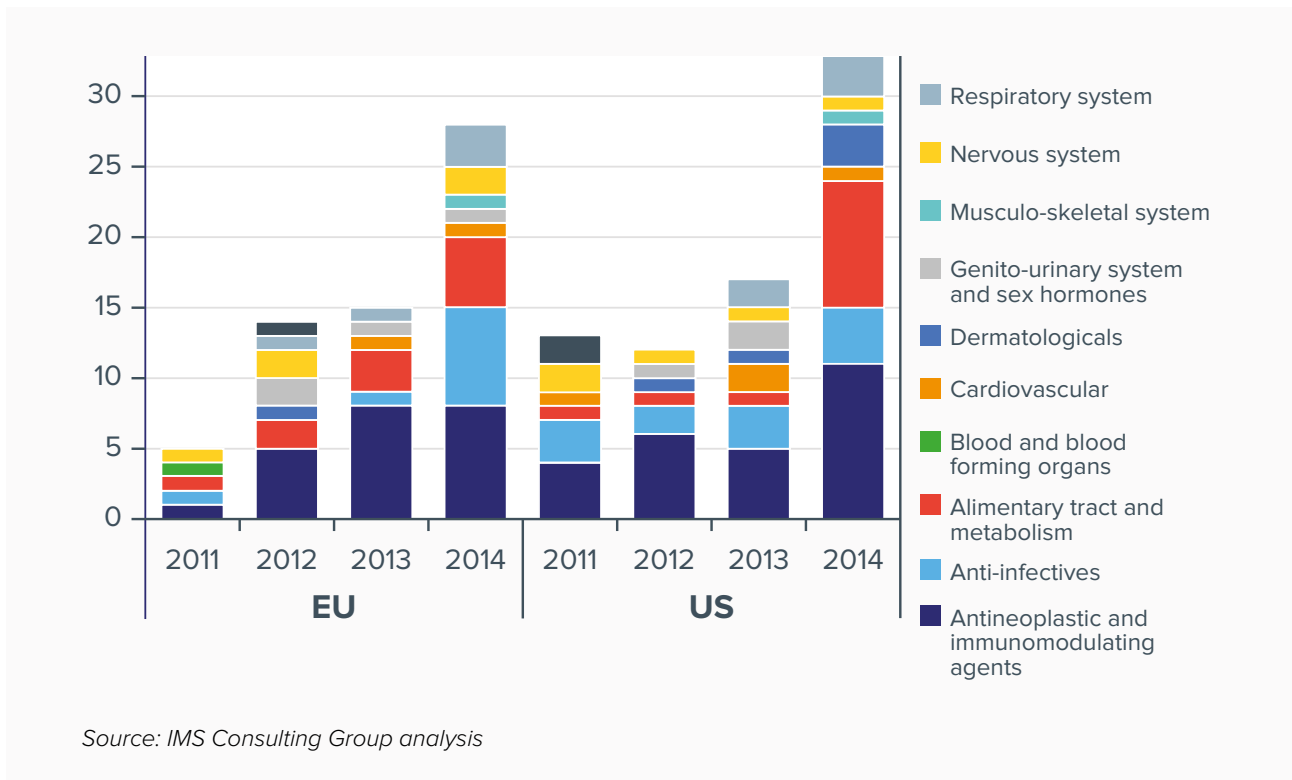
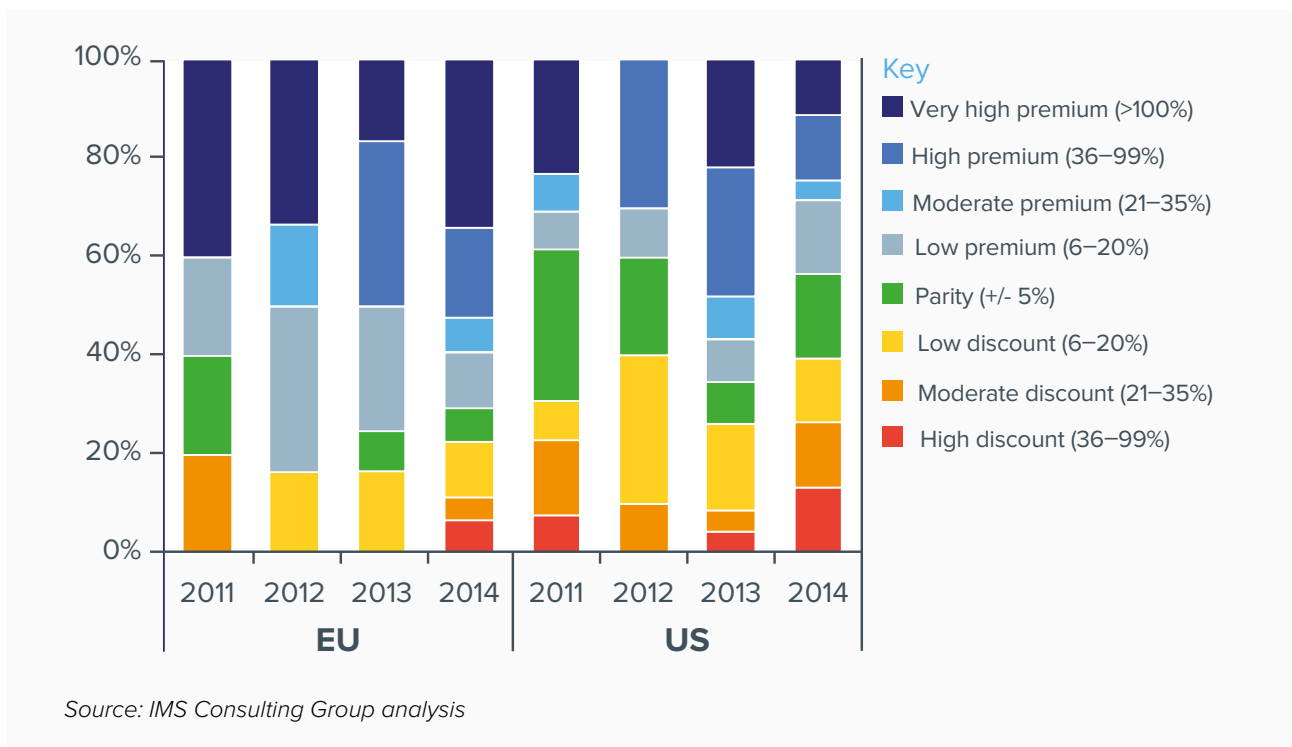


FIGURE 2. COMPARATIVE PRICE OF NEWLY LAUNCHED PRODUCTS











- Only 11 brands launched in the EU were in primary care and all had been launched previously in the US. While comparisons between the markets are problematic, it is worth noting that discounts can be observed for five of these products in the US, whereas in the EU this was only the case for one, in Germany. All the others secured a price premium relative to the comparator.
- The relative list price may be an indication of relative value, but it is becoming increasingly distant from net realized price as real questions of affordability by payers force companies to concede further discounts to secure market access.

TIME TO MARKET

- The 2012 European Commission Transparency Directive 89/105/EEC, which mandates a limit of 120 days (4 months) for national pricing and reimbursement decisions, does not reflect the reality. In 2014, only the UK and Germany met this requirement, and then only in terms of first sales rather than reimbursement, as both have initial free pricing policies while preparing for price and access negotiations.
- The time from regulatory approval to first sales took more than a year in eight EU countries (see Figure 5).
- The significant inter-market variations in average time from regulatory approval to first sales largely disappear when the time taken to make reimbursement decisions is also considered. Figure 6 shows the average time from regulatory approval to full reimbursement access is remarkably consistent. Among the EU5 countries the range was between 14.9 and 18.1 months.
- Wide discrepancies in patient access can be seen from the fact there were 30 new launches in Germany in 2014 but only 7 in the Czech Republic and 13 in Greece. In contrast, 42 new medicines were made available in the US within less than two months of the time of approval.
- Delays in access suggest a direct relationship with increasing levels of scrutiny by Health Technology Assessment (HTA) agencies and other price-setting bodies, as in France and Italy. In some cases, the review and access of new medicines is formally delayed to reduce the economic burden.
- These and other analyses suggest a worrying relationship between list price, time to market, access level, list to net price discounts, and uptake. This reflects the economic climate and the multiple concessions pharma companies are accepting to gain access to markets.

KEY (FIGURES 3 & 4)

 Very high premium (>100%)	 Parity (+/- 5%)
 High premium (36–99%)	 Low discount (6–20%)
 Moderate premium (21–35%)	 Moderate discount (21–35%)
 Low premium (6–20%)	 High discount (36–99%)

DEFINITIONS (FIGURES 3 & 4)

CLL - chronic lymphatic leukemia	IPF - idiopathic pulmonary fibrosis
COPD - chronic obstructive pulmonary disorder	MCL - mantle cell lymphoma
FL - follicular lymphoma	MS - multiple sclerosis
HCV - hepatitis C virus	PsA - psoriatic arthritis

FIGURE 3. NME LAUNCHES IN THE US, 2014

Brand Name (Generic name) Manufacturer	Indication	Product characteristics		Pricing comparator		US
		Orphan	Specialty care	Pricing comparator	Direct	
Sovaldi (Sofosbuvir) <i>Gilead</i>	HCV genotype 1, 2, 3 or 4 infection		✓	Victrelis (Boceprevir)		128%
Harvoni (Ledipasvir & Sofosbuvir) <i>Gilead</i>	HCV genotype 1, 2, 3 or 4 infection		✓	Sovaldi (Sofosbuvir)		13%
Tecfidera (Dimethyl Fumarate) <i>Biogen</i>	Relapsing forms of MS		✓	Copaxone (Glatiramer Acetate)	✓	-15%
Olysio (Simeprevir) <i>Janssen</i>	HCV genotype 1 infection		✓	Victrelis (Boceprevir)		-10%
Tivicay (Dolutegravir) <i>ViiV</i>	HIV-1 infection		✓	Isentress (Raltegravir)		2%
Anoro Ellipta (Umeclidinium Bromide & Vilanterol) <i>GSK</i>	COPD			Spiriva (Tiotropium Bromide)	✓	-11%
Adempas (Riociguat) <i>Bayer</i>	Persistent/recurrent chronic thromboembolic pulmonary hypertension	✓	✓	Tracleer (Bosentan)		401%
Farxiga (Dapagliflozin) <i>AstraZeneca</i>	T2DM			Invokana (Canagliflozin)		0%
Jardiance (Empagliflozin) <i>Boehringer Ingelheim</i>	T2DM			Invokana (Canagliflozin)		-13%
Striverdi Respimat (Olodaterol) <i>Boehringer Ingelheim</i>	COPD			Foradil (Formoterol)	✓	-30%
Incruse Ellipta (Umeclidinium Bromide) <i>GSK</i>	COPD			Spiriva (Tiotropium Bromide)	✓	-25%
Esbriet (Pirfenidone) <i>Genentech</i>	IPF	✓	✓	Vargatef (Nintedanib)		-1%
Vargatef (Nintedanib) <i>Boehringer Ingelheim</i>	IPF		✓	Esbriet (Pirfenidone)		1%
Otezla (Apremilast) <i>Celgene</i>	PsA		✓	Enbrel (Etanercept)	✓	-40%
Viekira Pak (Dasabuvir & Ombitasvir & Ritonavir & Veruprevir) <i>Abbvie</i>	HCV genotype 1 infection		✓	Sovaldi (Sofosbuvir)		-1%
Akynzeo (Netupitant & Palonosetron) <i>Helsinn</i>	Acute and delayed nausea and vomiting associated with chemotherapy		✓	Aloxi (Palonosetron)		16%
Duavee (Bazedoxifene & Estrogenic Substances, Conjugated) <i>Wyeth</i>	Prevention of postmenopausal osteoporosis		✓	Brisdelle (Paroxetine)		-18%
Kerydin (Tavaborole) <i>Anacor</i>	Onychomycosis of the toenails			Jublia (Efinaconazole)		9%

FIGURE 3 continued

Brand Name (Generic name) <i>Manufacturer</i>	Indication	Product characteristics		Pricing comparator		US
		Orphan	Specialty care	Pricing comparator	Direct	
Zydelig (Idelalisib) <i>Gilead</i>	Relapsed CLL in combination with rituximab), relapsed FL and relapsed SLL	✓	✓	Mabthera (Rituximab)	✓	36%
Plegridy (PegInterferon Beta-1A) <i>Biogen</i>	Relapsing forms of MS		✓	Avonex (Interferon beta-1a)		1%
Imbruvica (Ibrutinib) <i>Pharmacyclics</i>	MCL and CLL who have received at least one prior therapy or with p17 depletion	✓	✓	Arzerra (Ofatumumab)	✓	32%
Sylvant (Siltuximab) <i>Janssen</i>	Multicentric Castleman's disease	✓	✓	MabThera (Rituximab)		392%
Tanzeum (Albiglutide) <i>GSK</i>	T2DM			Januvia (Sitagliptin)	✓	5%
Entyvio (Vedolizumab) <i>Takeda</i>	Crohn's disease and ulcerative colitis		✓	Remicade (Infliximab)		64%
Vimizim (Elosulfase Alfa) <i>Biomarin</i>	Mucopolysaccharidosis type IVA	✓	✓	Elaprase (Idursulfase)		79%
Gazyva (Obinutuzumab) <i>Genentech</i>	In combination with chlorambucil, for the treatment of patients with previously untreated CLL	✓	✓	MabThera (Rituximab)	✓	2%
Zykadia (Ceritinib) <i>Novartis</i>	ALK-positive metastatic NSCLC	✓	✓	Xalkori (Crizotinib)		0%
Cyramza (Ramucirumab) <i>Eli Lilly</i>	Gastric or gastro-esophageal cancer and NSCLC	✓	✓	Abraxane (Paclitaxel)		35%
Beleodaq (Belinostat) <i>Spectrum</i>	Relapsed or refractory peripheral T-cell lymphoma	✓	✓	Folotyn (Pralatrexate)		-42%
Sivextro (Tedizolid) <i>Cubist</i>	Acute bacteria skin or skin structure infection			Zyvox (Linezolid)	✓	-28%
Dalbance (Dalbavancin) <i>Durata</i>	Acute bacteria skin or skin structure infection			Zyvox (Linezolid)	✓	82%
Opdivo (Nivolumab) <i>BMS</i>	Unresectable or metastatic melanoma and disease progression following ipilimumab	✓	✓	Keytruda (Pembrolizumab)		-33%
Lynparza (Olaparib) <i>AstraZeneca</i>	Ovarian cancer with BRCA-mutated	✓	✓	Avastin (Bevacizumab)		463%
Keytruda (Pembrolizumab) <i>Merck</i>	Unresectable or metastatic melanoma and disease progression following ipilimumab	✓	✓	Yervoy (Ipilimumab)		-44%
Cerdelga (Eliglustat Tartrate) <i>Genzyme</i>	Gaucher disease type 1	✓	✓	Cerezyme (Imiglucerase)		-29%
Trulicity (Dulaglutide) <i>Eli Lilly</i>	T2DM			Byetta (Exenatide)	✓	9%
Arzerra (Ofatumumab) <i>GSK</i>	Previously untreated patients with CLL and patients with CLL refractory to fludarabine and alemtuzumab	✓	✓	Mabthera (Rituximab)		56%

FIGURE 4. NME LAUNCHES IN THE EU, 2014

Brand Name (Generic name) Manufacturer	Indication	Product characteristics		Pricing comparator		UK	DE	DK	SW	FR	ES	IT	NL
		Orphan	Specialty care	Pricing comparator	Direct								
Sovaldi (Sofosbuvir) <i>Gilead</i>	HCV genotype 1, 2, 3 or 4 infection		✓	Victrelis (Boceprevir)		127%	252%	1720%		462%		187%	147%
Harvoni (Ledipasvir & Sofosbuvir) <i>Gilead</i>	HCV genotype 1, 2, 3 or 4 infection		✓	Sovaldi (Sofosbuvir)		11%	11%	5%	24%		12%		
Tecfidera (Dimethyl Fumarate) <i>Biogen</i>	Relapsing forms of MS		✓	Copaxone (Glatiramer Acetate)	✓	167%	41%	52%	36%				34%
Daklinza (Daclatasvir) <i>BMS</i>	HCV genotype 1, 2, 3 or 4 infection		✓	Sovaldi (Sofosbuvir)		-30%	-33%	-36%	-24%		-29%	-33%	-27%
Olysio (Simeprevir) <i>Janssen</i>	HCV genotype 1 infection		✓	Victrelis (Boceprevir)		-27%	-18%	451%					-27%
Tivicay (Dolutegravir) <i>ViiV</i>	HIV-1 infection		✓	Isentress (Raltegravir)		6%	5%	472%		0%			-16%
Anoro Ellipta (Umeclidinium Bromide & Vilanterol) <i>GSK</i>	COPD			Spiriva (Tiotropium Bromide)	✓	33%	41%		26%				22%
Adempas (Riociguat) <i>Bayer</i>	Persistent/recurrent chronic thromboembolic pulmonary hypertension	✓	✓	Tracleer (Bosentan)		245%	130%	239%	128%				156%
Farxiga (Dapagliflozin) <i>AstraZeneca</i>	T2DM			Invokana (Canagliflozin)		0%	14%		18%				6%
Jardiance (Empagliflozin) <i>Boehringer Ingelheim</i>	T2DM			Invokana (Canagliflozin)		-1%	-23%	3%	12%				20%
Striverdi Respimat (Olodaterol) <i>Boehringer Ingelheim</i>	COPD			Foradil (Formoterol)	✓	46%	58%	42%			48%		35%
Delyba (Delamanid) <i>Otsuka</i>	Multi-drug resistant tuberculosis	✓		Sirturo (bedaquiline)		48%	-9%						
Incruse Ellipta (Umeclidinium Bromide) <i>GSK</i>	COPD			Spiriva (Tiotropium Bromide)	✓	-18%							
Esbriet (Pirfenidone) <i>Genentech</i>	IPF	✓	✓	Vargatef (Nintedanib)		1%	-7%						-8%
Vargatef (Nintedanib) <i>Boehringer Ingelheim</i>	IPF		✓	Esbriet (Pirfenidone)		14%	8%						8%

FIGURE 4. continued

Brand Name (Generic name) Manufacturer	Indication	Product characteristics		Pricing comparator		UK	DE	DK	SW	FR	ES	IT	NL
		Orphan	Specialty care	Pricing comparator	Direct								
Zydelig (Idelalisib) <i>Gilead</i>	Relapsed CLL (in combination with rituximab), relapsed FL and relapsed SLL		✓	Mabthera (Rituximab)		252%	73%	1168%	109%				49%
Plegridy (PegInterferon Beta-1A) <i>Biogen</i>	Relapsing forms of MS		✓	Avonex (Interferon beta-1a)		0%	1%	-1%					34%
Imbruvica (Ibrutinib) <i>Pharmacyclics</i>	MCL and CLL who have received at least one prior therapy or with p17 depletion		✓	Arzerra (Ofatumumab) ✓		20%	33%	1274%					-90%
Sylvant (Siltuximab) <i>Janssen</i>	Multicentric Castleman's disease		✓	MabThera (Rituximab)		917%	825%	6411%					578%
Tanzeum (Albiglutide) <i>GSK</i>	T2DM		✓	Januvia (Sitagliptin)			326%						
Entyvio (Vedolizumab) <i>Takeda</i>	Crohn's disease and ulcerative colitis		✓	Remicade (Infliximab)		55%	46%	53%	56%				-9%
Vimizim (Elosulfase Alfa) <i>Biomarin</i>	Mucopolysaccharidosis type IVA			Elaprase (Idursulfase) ✓			11%	704%					
Cometriq (Cabozantinib) <i>Exelixis</i>	Progressive, metastatic medullary thyroid cancer	✓	✓	Caprelsa (Vandetanib)			-3%						-44%
Gazyva (Obinutuzumab) <i>Genentech</i>	In combination with chlorambucil, for the treatment of patients with previously untreated CLL			MabThera (Rituximab)		329%	148%	118%					3084%
Cyramza (Ramucirumab) <i>Eli Lilly</i>	Gastric or gastro-esophageal cancer and NSCLC			Abraxane (Paclitaxel) ✓			145%	289%					230%
Lynparza (Olaparib) <i>AstraZeneca</i>	Ovarian cancer with BRCA-mutated	✓		Avastin (Bevacizumab)		46%		49%					35%
Trulicity (Dulaglutide) <i>Eli Lilly</i>	T2DM			Byetta (Exenatide) ✓		43%	46%						43%
Arzerra (Ofatumumab) <i>GSK</i>	Previously untreated patients with CLL and patients with CLL refractory to fludarabine and alemtuzumab	✓	✓	Mabthera (Rituximab)		274%	167%	96%	154%			106%	3021%

FIGURE 5. AVERAGE TIME FROM REGULATORY APPROVAL TO FIRST SALES — PRODUCTS WITH FIRST SALES IN 2014

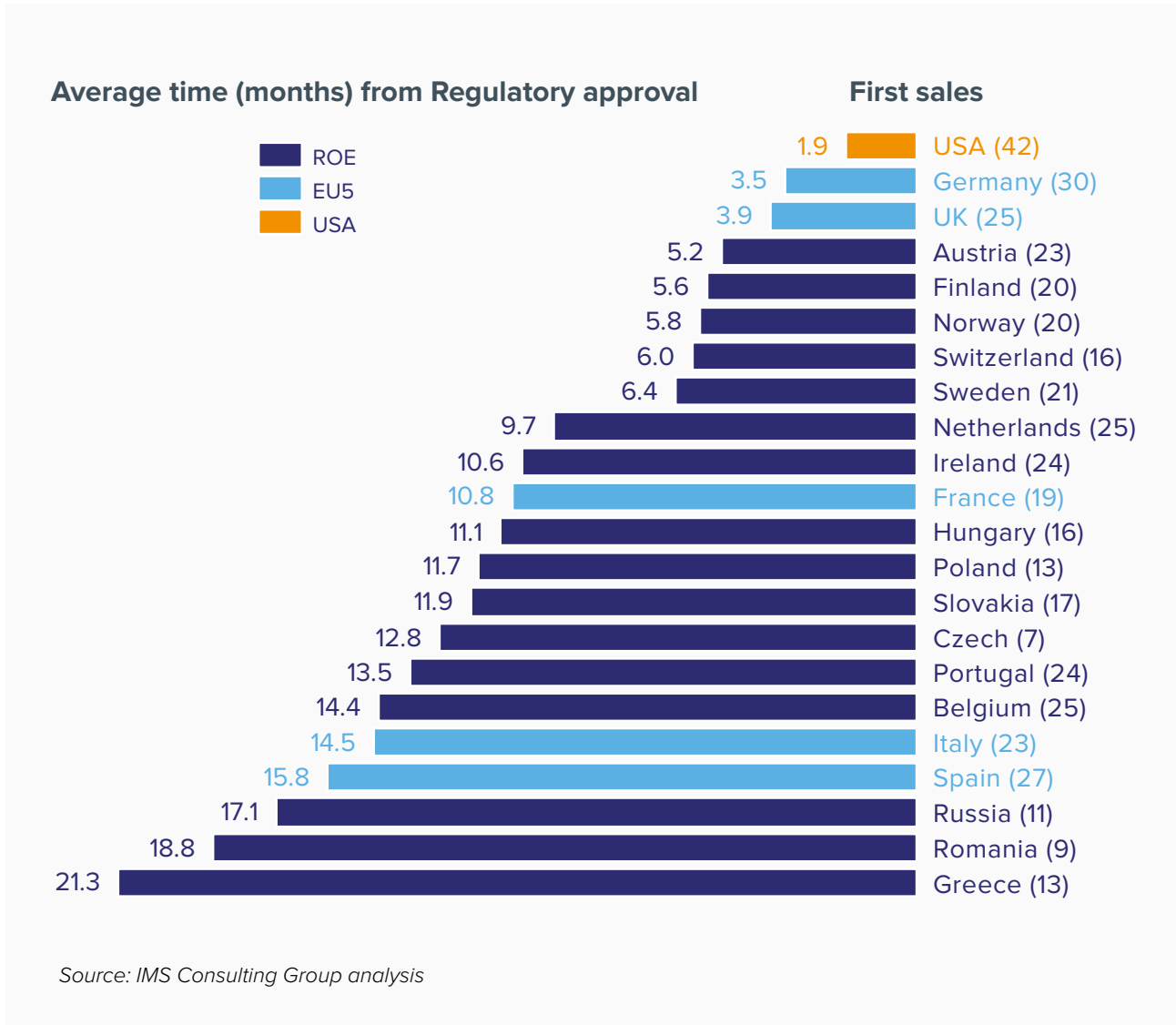
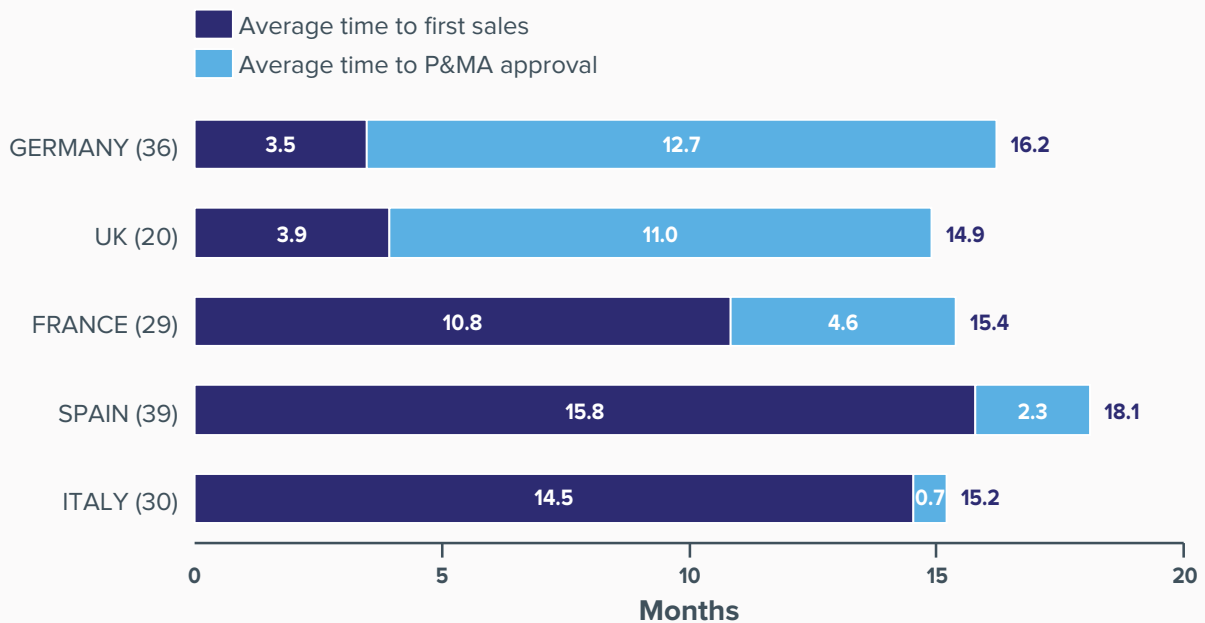


FIGURE 6. AVERAGE TIME FROM REGULATORY APPROVAL TO FIRST SALES AND FROM FIRST SALES TO NATIONAL P&MA APPROVAL IN 2014



Source: IMS Consulting Group analysis

WHY SHOULD THIS MATTER TO YOU?

- As in previous years, EU and US list price premiums in 2014 were strongly driven by launches in specialty care where there is high unmet medical need, when premiums were assessed relative to most appropriate pricing comparators.
- List price discounts were observed in a significant minority of new launches (25% in the EU; 40% in the US), usually in crowded therapy areas.
- Access to market is subject to significant delays in several key EU markets due to national/regional regulatory processes and the budget challenge.

This costs how much? Are you crazy?

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Drug price increases in the US have contributed at least a quarter of industry growth every year since 2004. Coupled with the launch of premium priced brands in specialty therapy areas, the situation has become increasingly difficult for pharma and payers alike. In the EU there has been increasing pressure to contain pharmaceutical expenditure and payers are challenging clinical value for new products often restricting use.

As part of our analysis, we considered the impact on pharma revenues of four potential future scenarios based on different approaches payers could take to curb increasing pharma spending:

- Scenario 1 – Drugs not allowed to take any price increases in the US
- Scenario 2 – US prices are benchmarked to EU prices
- Scenario 3 – Drug prices in the EU are referenced to the lowest price EU country
- Scenario 4 – Price of new drugs in the EU are benchmarked to prices of existing standard of care/comparator

Pharma has become accustomed to achieving ever higher prices. These levels are partly to do with the nature of the products. Two-thirds of products in the pre-clinical stage now are aimed at specialty markets and one-third in all stages of development are biologics. Just ten years ago, the top 10 earning products were all low-cost primary care drugs and none were biologics.

Biologics are not limited to the specialty markets, however. Biologics are now moving into traditional primary care therapy areas. For example, the new dyslipidemia drugs, the PCSK9 inhibitors, would cost up to €27 billion even if use was only in the expected restricted indication and not to replace statins in all patients.¹

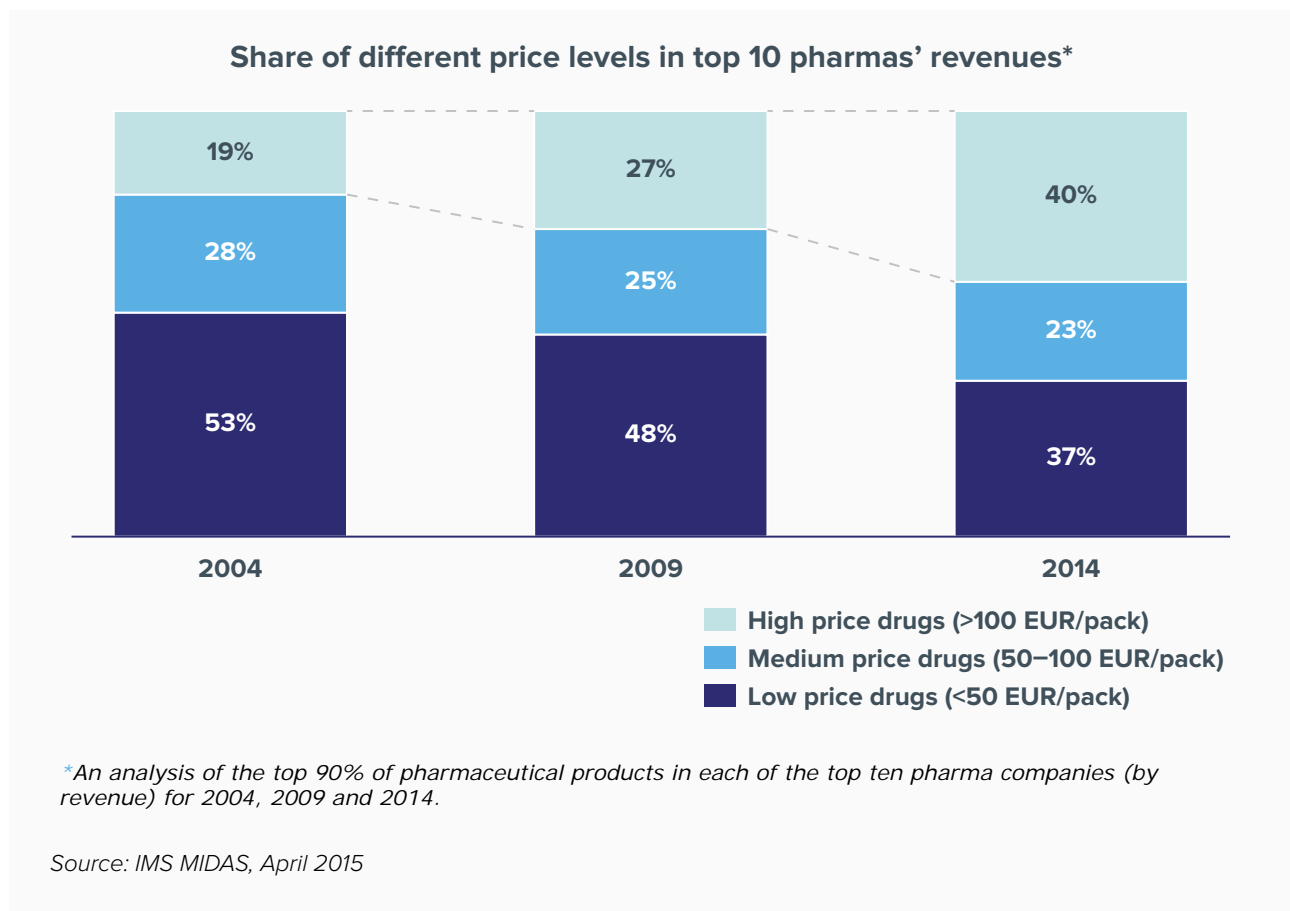
The situation is worrying for pharma and payers alike. For pharma, the concern stems from its growing dependence on specialty brands and therefore premium prices rather than high-volume low priced products. Figure 1 shows that the proportion of revenues from premium priced products (defined as €100,000 or more per pack) rose from 19% in 2004 to 40% in 2014. For payers, it is simply a question of affordability.

THE PUSH BACK

Payers are accelerating their efforts to control drug expenditure, even in the US. For example, Express Scripts, the largest pharmacy benefit manager, famously dropped Gilead's Sovaldi for Abbvie's Viekra Pak in the chronic hepatitis C market after negotiating prices. The CVS Health Research Institute, published a commentary in the *Journal of the American Medical Association*, calling for the American College of Cardiology/American Heart Association guidelines to be adjusted to support utilization management of PCSK9 inhibitors.

Clinical groups are also entering the debate and developing drug calculators and tools to assess the "value" of different therapies. For example, in oncology, there are four initiatives that now include drug costs in the overall "value" assessment:

FIGURE 1. PHARMA'S DEPENDENCE ON HIGH-PRICED PRODUCTS IS GROWING



¹Assuming US annual price 10,000 EUR and EU5 annual price 5,000 EUR for all patients currently on statins

- The American Society of Clinical Oncology is finalizing a drug-assessment scorecard that captures clinical and safety data in a single value score and displays this next to drug costs.
- The National Comprehensive Cancer Network is introducing “evidence blocks” in its guidelines, which will rate products on a scale of 1 to 5 based on affordability.
- Dr. Peter Bach, Memorial Sloan Kettering Cancer Center, has developed the DrugAbacus, an interactive website that compares a product’s price to a “value-based price” based on user weightings of clinical attributes, side effects, novelty, R&D investment, rarity of disease, and population health burden.
- The Institute for Clinical and Economic Review launched a program to produce public reports on new drugs near the time of FDA approval with information on the drug’s comparative effectiveness, cost-effectiveness, potential budget impact and a value-based price benchmark anchored to the “real benefits” the drug brings to patients.

In Europe, the European Society for Medical Oncology introduced the Magnitude of Clinical Benefit Scale as a “tool to assist oncology clinicians in evaluating the most effective anti-cancer medicines” — while this tool does not include cost given the variability in European markets, it is geared to support physician, payer, and policy decision-making.

Such appraisal work has been ongoing in Europe for some time. In the UK, 36% of the oncology approvals in 2014 required Patient Access Schemes (e.g. net pricing deals based on financial and/or clinical metrics) and only 40% of submissions in this area were recommended for approval in the first place. Similar stories can be heard across all the EU5 countries.

HOW BAD CAN IT GET?

Given the importance of price in driving revenues, IMS Health conducted an analysis to understand the revenue impact of four possible scenarios, two in the US and two in the EU.

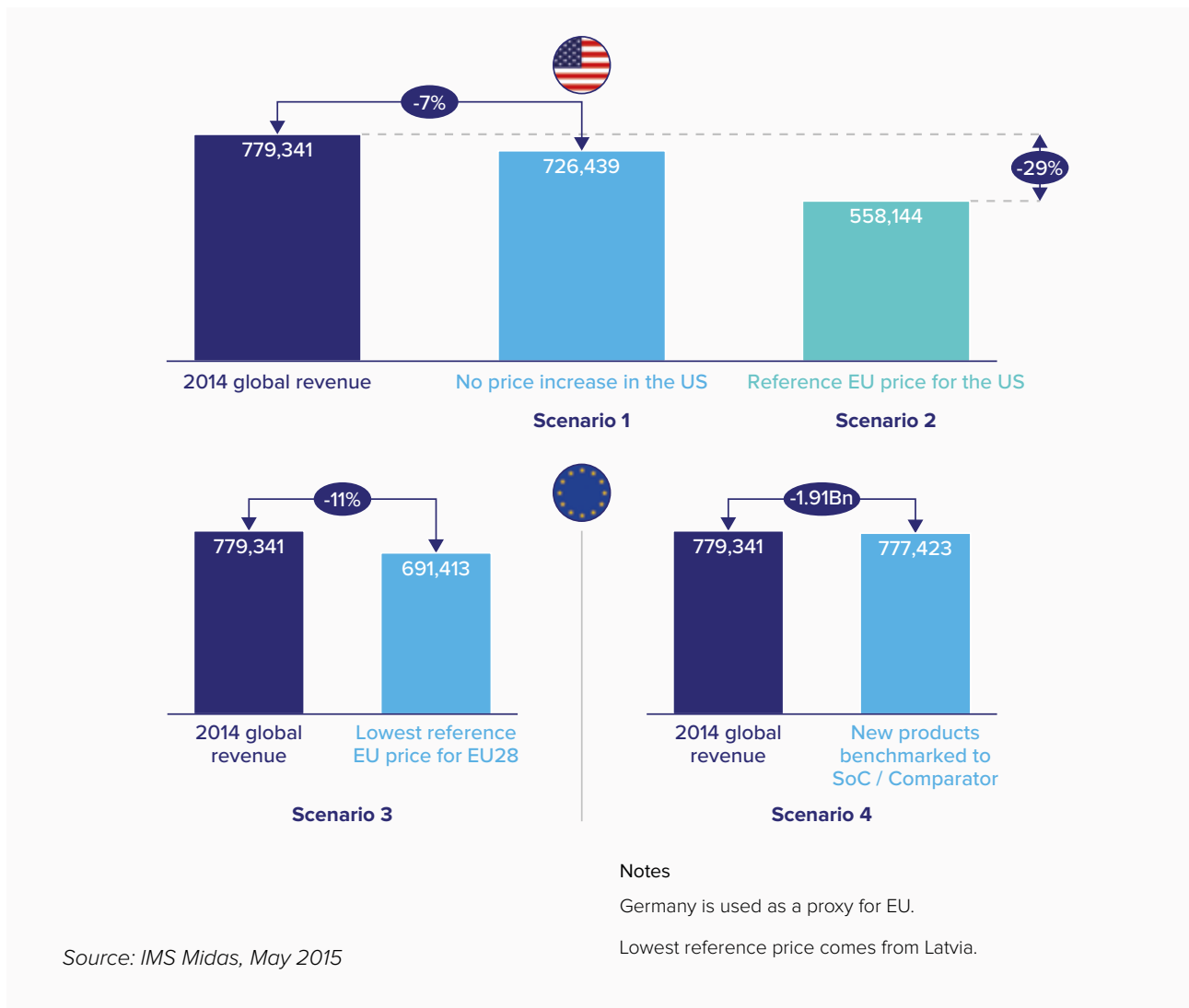
In the US they are:

1. No price increases permitted or possible (the price per unit for US drug sales was benchmarked to 2010 US levels)
2. US prices benchmarked to EU levels (Germany was used as a proxy for the EU applying the 2014 average price per unit to 2014 US volumes)

In the EU they are:

3. Drug prices referenced to the lowest price EU country (Latvian average prices per unit were applied to 2014 EU volume)
4. Price of new products benchmarked to prices of existing standard of care (prices of new EU launches from 2011 to 2014 were replaced with prices of standard of care)

FIGURE 2. IMPACT ON GLOBAL PHARMA REVENUES, EUR MILLION



The results, shown in Figure 2, highlight that the largest budget impact comes from Scenario 2, with a massive 29% of 2014 global revenues wiped out. Scenario 1, while having a much smaller impact, still is modelled to reduce industry value by 7%. While neither scenario is considered likely in the current political environment in the US, they do highlight industry vulnerabilities. Although payer pressures could effectively reduce realized price increases without any formal policy change.

The situation in Europe is more worrisome. Scenario 3, resulting in an 11% drop in 2014 revenues, is a possibility in some form. Countries may not reference the prices in Latvia, but many already use reference pricing and they could easily begin to look at other lower priced markets. Scenario 4, while showing the smallest short-term budget impact in our model, could become more of an issue as the cumulative effect of new product launches builds.

IS PHARMA CRAZY?

Given price levels, many have questioned the logic of the current approach. Pharma finds itself between a rock and a hard place. Whatever it does is subject to increasing scrutiny as money gets tighter, but it is not crazy. As a for-profit industry, pharma is obligated to optimize returns to its shareholders. At the same time, it is fulfilling its ethical obligations in bringing new products to market and working within the guidelines of each country's healthcare system. It is also investing significantly in making its products available to poorer patients via access schemes and similar initiatives. As such, the pharma industry is optimizing its performance given the current rules and market structure it operates within.

While the likelihood of our four scenarios is unclear, it is certain that there will continue to be challenges to the current pharma pricing model. This could result in a bifurcated world, where high value products with smaller target populations continue to maintain a certain degree of pricing flexibility, while less compelling and/or high budget impact products have more difficulty. This implies a more ruthless go/no-go decision-making process in the future, deprioritizing lower value and me-too products. It also may result in two coexisting business models: one operating under tighter price pressures and lower margins, with another looking similar to our historical model but focused on a subset of products offering significant clinical value. No matter what the future holds, it is essential that industry further emphasize demonstrating and communicating value.

WHY SHOULD THIS MATTER TO YOU?

- Over the past decade, pharmaceutical industry dependence on price has increased and has been driven by the shift from primary care brands to specialty brands and rising drug prices in the US.
- However, as the reliance on price to optimize value has grown, pressures on healthcare budgets have increased, which has resulted in greater risk of further cost controls, raising questions on the overall vulnerability of industry value.
- Given these risks, it is important to pressure test the viability of the current pricing model. Is it optimal? What are the risks and what are implications of potential evolutions in the future?

Patients in the US: Do they really matter? Has the era of consumerism in healthcare arrived?

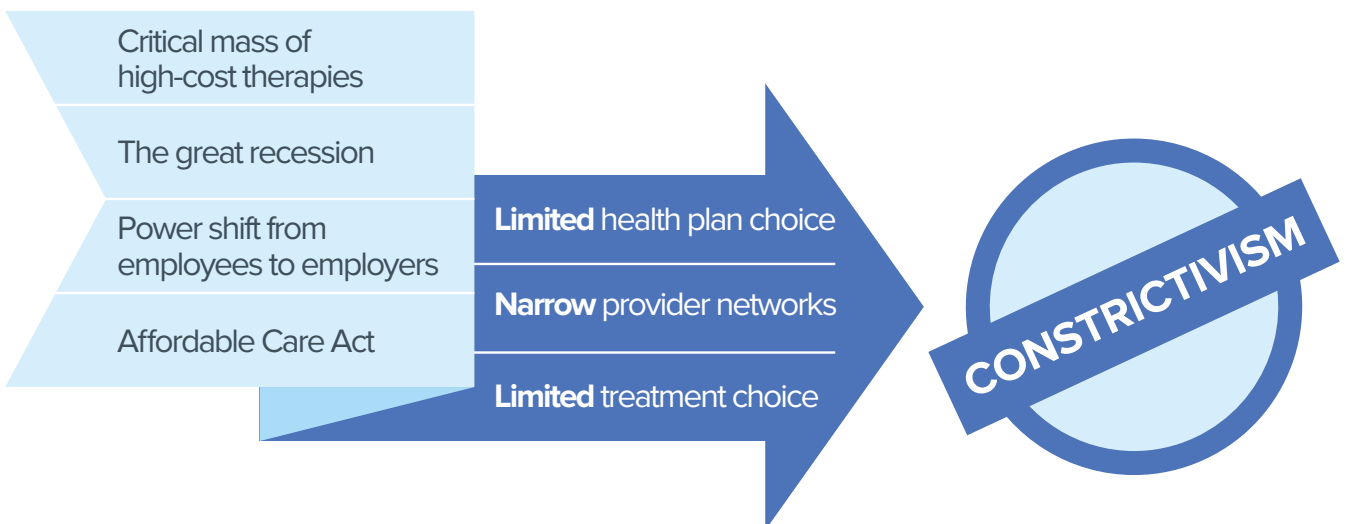
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“Consumerism in healthcare has arrived ... and is here to stay.”
-American Medical Association Op-Ed

“As patients become more sophisticated purchasers of healthcare, they will push competition in healthcare delivery to look increasingly like that in consumer-goods industries.”
- NEJM

We pose that for healthcare, we are in an era of **constrictivism**, not consumerism. So how did we get to where we are today?



During the IMS Consulting Group Market Access Conference on March 12, 2015, we shared data with an experts panel and asked three questions.

Dr. Ira Klein
Former National Medical Director, Office of the CMO
Clinical Thought Leadership

Aetna (Currently Senior Director of Quality, Strategic Customer Group at Janssen)

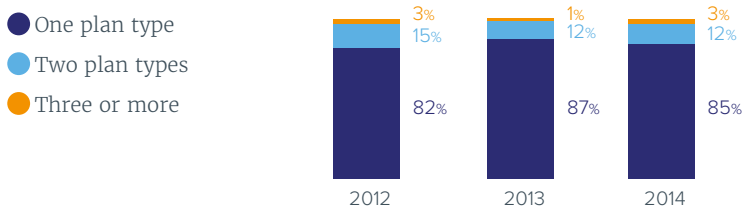
Dr. John Chelico
Chief Medical Information Officer

North Shore University Hospital & Long Island Jewish Medical Center

Larry Lanier
President of State Advocacy & Community Outreach

National Patient Advocate Foundation

Health plan selection:
 Average number of plan types offered to employees



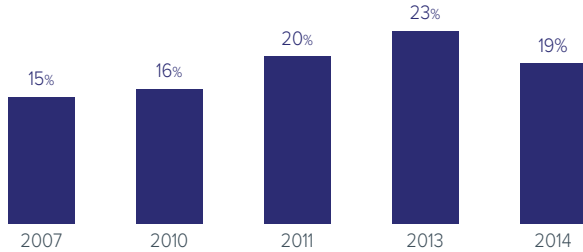
IMS Consulting Group point of view and panel findings

1 Do patients *really* get to choose their health plan?

Healthcare is not a true free market; policy, employers, and payers dictate market dynamics

Employers are more interested in containing costs than maintaining patient choice

Provider selection:
 Use of narrow physician networks in employer plans

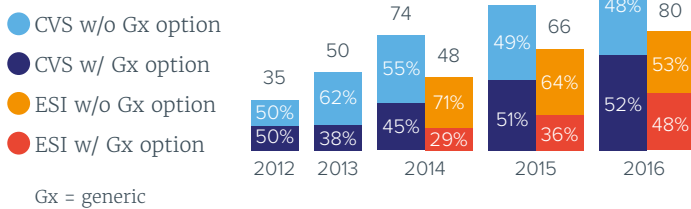


2 Do patients *really* get to choose by whom and where they get treated?

Patients are still important, but payers and healthcare professionals (HCPs) continue to be central, with employers rising in influence

Narrow networks will continue to increase, as payers gain visibility and control over prices

Medication selection:
 CVS and ESI yearly drug exclusions



3 Do patients *really* have more medical and drug treatment options?

CVS and ESI formularies cover ~50M lives

Patients are reactive to the fewer choices available, leading to delayed care and higher barriers for branded treatments with lower-cost alternatives

As such, physicians will have less control over treatment selection

In addition to direct-to-consumer, a stronger connection with patients should be established through HCPs and employers to help patients make smarter choices

Source: Kaiser Survey of Employer-Sponsored Health Benefits (2014), formulary exclusion lists published by CVS and ESI, IMS MIDAS data

Cell and gene therapies: Pushing the envelope of value and access

AUTHOR

Samuel Murphy
Samuel.Murphy@imshc.com

IMS Consulting Group anticipates cell and gene therapies (CGTs) will become important treatment modalities for a variety of diseases in the near future. The entry of CGTs is likely to disrupt treatment landscapes and payment models, with implications for both pharmaceutical companies and payers. New measures will need to be taken as more high-cost, potentially curative, treatments come to market and current healthcare budgets are overburdened. To understand the US access and reimbursement environment for these important new therapies, we sought insights from a panel of experts including three senior medical directors (one national medical director for a major plan, one East Coast regional medical director, and one West Coast regional medical director), collectively representing over 28 million covered lives; an industry representative; and a patient advocate representing a rare and debilitating monogenetic inherited disease. Panelists agreed that accountability for outcomes and high up-front costs require new payment models and collaboration among stakeholders.

MODERATOR: *Let's start with a scenario where CGTs are coming to market at \$1–5 million per treatment, with limited or no long-term supporting clinical data. How would you determine whether to cover each therapy?*

PAYER 1: The first thing I would consider is the current treatment and how the new therapy compares. For example: for a lower back pain treatment, I'd need to see amazing improvements in disability and no more surgeries before I'd be willing to pay that much. If you're talking about something that works to prevent further degeneration, say in multiple sclerosis, even if there's not a huge improvement, that's major; we would end up paying for it.

PAYER 2: If you have two gene therapies for the same disease, then it offers the opportunity for some competitiveness and price lowering. It's not different for gene therapy versus any other

type of therapy. If you look at hepatitis C, it's the first time we've really not done things on the basis of medical necessity, but on the basis purely of cost. We have a cure and we should probably give it to everybody, but because it's a slow disease, we're pushing out the cure because of cost.

MODERATOR: *Hepatitis C is an interesting analogue to consider. The curative therapy is more cost-effective than its effective predecessor, but because of the large number of warehoused patients seeking a cure and the high upfront costs, payer budgets have not been able to handle it; proving that the US is not completely immune to high prices. This price sensitivity is something that will once again be tested with the entrance of CGTs.*

PAYER 3: If the outcomes are the same but one treatment is 100 times more costly than the other, is it our obligation to pay for the more expensive treatment? Who determines what criteria need to be met in order for patients to get these therapies? We need some really strong ethics as part of this process, because these decisions must be science-based and defensible.

PAYER 1: I think as a society we haven't really drawn the line in the sand to say "this incremental benefit is not worth paying for." For example: Is it worth paying for a child to reach his or her first year of life and crawl instead of being bed-bound? We're not necessarily making the gains we all want to see in terms of a cure; just very small incremental gains. The challenge ethically may also be whether we're increasing suffering or really prolonging life in its most meaningful way. What are we willing to pay for as a society? I think the science is probably ahead of the ethics in some of these cases.

PAYER 3: I think that these therapies will need post-market clinical trials to demonstrate medical necessity. Manufacturers should really be thinking about what those trials should look like.

MODERATOR: *Assuming there are no pay-for-performance agreements, what are the implications of covering such a therapy?.*

PAYER 1: If a new gene therapy is replacing a treatment, which is currently costing us ~\$350,000 per patient per year, and the new therapy can show it is efficacious, then the high cost is easy to defend. On the other hand, if a new gene therapy targets a disease for which there is currently no treatment, then it's trickier. We're suddenly seeing a lot of newly treated orphan conditions costing us \$500,000–\$1 million per member overnight. This is an increasingly large problem, especially when you consider that in the US we really don't have a payment methodology to hold manufacturers accountable for outcomes. In our current system, payments will be the same regardless of whether a treatment doesn't work after a few months, or if the patient dies, or if the patient must continue standard therapy at \$300,000–\$400,000 annually.

PAYER 3: We will soon have a gene therapy for retinitis. The question you have to ask is: "What's the cost to the system?" Retinitis patients get vocational training, and they learn how to walk with a cane. We might pay for some assistive devices that will help patients read books, but we certainly don't spend a million dollars on those patients today.

PATIENT ADVOCATE: Patients with currently untreatable diseases are often costing the system a lot more than \$350,000 per year. For example, a child born with a rare disease that requires a long stay in a neonatal intensive care unit. Overall you could say that a million dollars is a

bargain compared to what they're going to cost the system over the next three years with no treatment. However, that argument is difficult to make because we're not a closed system; it's different pockets paying for it so we don't see the whole cost.

For ultra rare diseases, if every single patient was treated tomorrow at a million dollars each, payers wouldn't even notice it. We've been doing these expensive payments for oncology treatments for a while, so let's not shut the door on these horrific neurodegenerative, ultra rare, really debilitating diseases.

PAYER 1: I know that some babies are costing us a couple million dollars today, and obviously even more over their lifetime. But I cringe at the idea that we don't notice million dollar treatments — we are noticing. It's critical that we think about what that incremental cost-effectiveness threshold should be, because sometimes we're really just adding costs.

PAYER 3: For self-funded or administrative services only (ASO), it is not uncommon for that entity, especially if it's small, to have reinsurance both for individual claims and for the aggregate. Obviously the larger your self-funded entity is, the more you can self-insure or the less you may see the need for reinsurance. That being said, we still advise all of our clients to have an informed discussion about reinsurance simply because of cancer treatment costs today.

A child with hemophilia could easily incur costs of \$350,000–\$500,000 per year. This subject is not foreign to purchasers. However, the concept that gene therapy would be provided for an individual who might not necessarily be in your employment or be part of your plan three or five years down the road — that is a problem that we are trying to get our heads around.

PAYER 2: We need better data to understand the value of these therapies—how durable and effective are they in the real world? Companies need to work with us collaboratively to help us mine our data. Then we can say: “What are the actual costs of care for that patient during the lifespan of that therapy?”

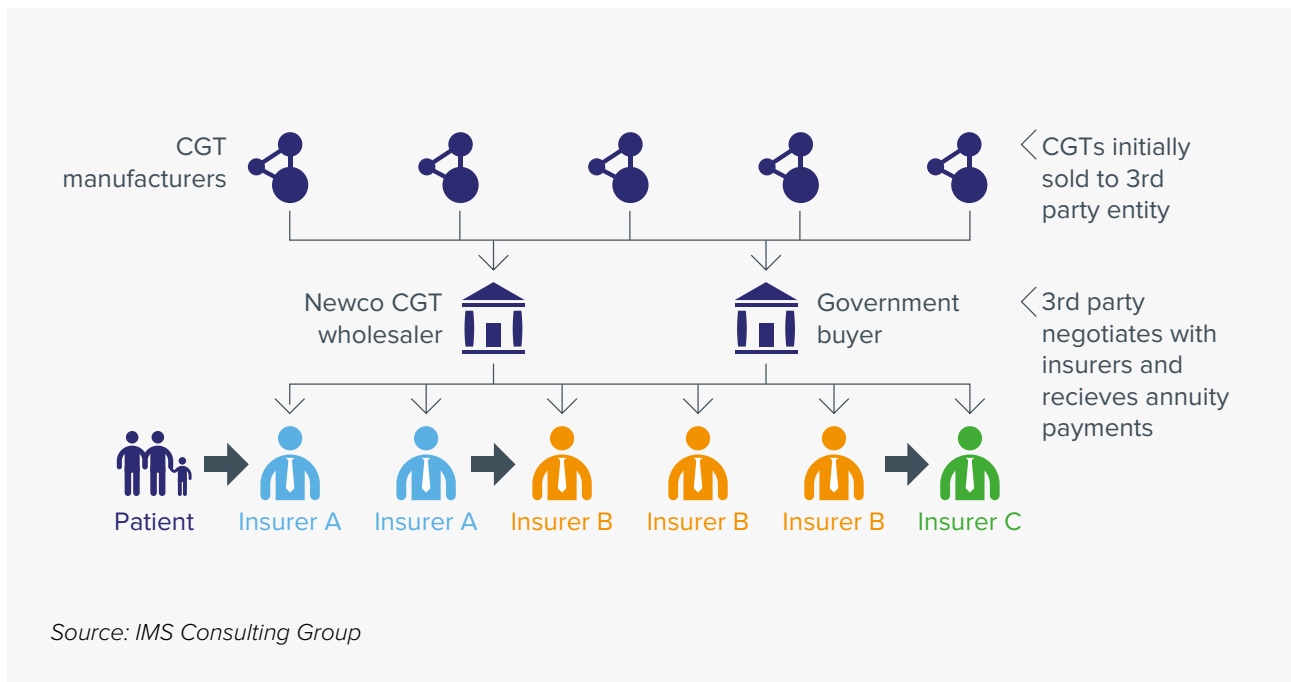
MODERATOR: *Given these concerns, what would present a good solution in the long term?*

INDUSTRY REPRESENTATIVE: The concern I have is if someone says: “I'll give you a tenth now, and another tenth every year that the patient is alive” — if they change plans, I don't think we'll see much of it. The patient is already treated and you can't take it back. Now you're left holding the bag of non-payment. There's got to be some middle man, whether it's government or whether it's another insurer (See Figure 1).

PAYER 1: I'd also like to see that this doesn't just transform into an amortization payment. This should have some bearing on the accountability for outcomes. I think there needs to be a clear outline of what we should expect in the short versus long term. Will a manufacturer or a payer have to support the amortized payment if at year two the therapy is not working and now the patient is using additional treatments?

PATIENT ADVOCATE: Maybe there should be a pilot with payers so that we're not preventing these life-saving or life-altering treatments from getting out there, but it's being done carefully. We need to collect the data and give confirmation that you're paying for something that's making a valuable difference.

FIGURE 1. GOVERNMENT OR PRIVATE INTERMEDIARY MAY BE NEEDED TO CATALYZE ANNUITY-BASED OUTCOMES PRICING



PAYER 2: Frankly, payment for these therapies ought to be nationalized because otherwise there will be huge adverse selection. These treatments provide a benefit to society in the form of prevention of disability and improved quality of life. That's why I would argue in part for making this a national program. At the very least, treatments for orphan and ultra orphan diseases, which are clearly defined, should be paid for through a federal program.

PAYER 3: Agreed. You cannot expect a health plan to eat a million dollar cost this year, especially if that patient is not going to be a member a few years later. We need to think about these companies buying some sort of reinsurance for these high cost treatments. For example: if you have a therapy that's expected to last 10 years and the total cost is a million dollars, then we should be responsible for a tenth of that cost, and not for the full million dollars.

Clearly, we need new models of financing. We have to approach this in a thoughtful and systematic way to avoid a loss for patients, a loss for industry, and a loss to payers. We certainly don't want to see that happen.

CONCLUSION

The emergence of CGTs is likely to trigger significant changes for payers and pharmaceutical companies, as these therapies will disrupt treatment landscapes and challenge existing payment models. Payers must prepare for increased near-term budget impact associated with a high per-patient cost. Shorter-term solutions, such as shifting risk to reinsurance and reducing the number of plan offerings to retain patients over time within the same plan, will likely introduce new stakeholders and lead to fewer

FIGURE 2. KEY TAKEAWAYS AND INDUSTRY IMPERATIVES

Key takeaway		Industry imperative
Payers will challenge medical necessity and ethical implications of therapies	➔	Anticipate needs to conduct post-approval trials to justify cost/payment and to engage in ethics discussions
CGTs are not immune from competitive contracting and formulary exclusion	➔	Ensure preparation for future competitive environment including existing treatments and other CGTs
Reinsurance not uniformly carried by small and mid-size employers	➔	Launch awareness campaign to encourage reinsurance in preparation for CGTs
Long-term solutions are desired by all stakeholders and may require government or 3rd party entity	➔	Lobby government and investors to create future funding vehicles for CGTs
Stakeholders are interested in accountability for outcomes, not just amortization	➔	Collaborate with payers to structure outcomes-based agreements

Source: IMS Consulting Group

choices for employers and patients. Pharmaceutical companies will be faced with the associated market access shifts as they will face increased standards for clinical and real-world evidence. There is a lack of existing infrastructure and legislation for longer-term solutions, which would catalyze annuity-based payment schemes. Given the reactive nature of government and payers, pharmaceutical companies should take the lead now in building support for new third-party entities that would represent a key solution for pharmaceutical companies.

WHY SHOULD THIS MATTER TO YOU?

- CGTs will become important treatment modalities for a variety of diseases in the near future, even as their long-term efficacy remains unknown.
- New policies are needed to reward pharmaceutical innovation, while protecting patients, employers, and payers from extreme costs.
- The emergence of bolus payments for long-term outcomes concerns payers, given the lack of manufacturer accountability and patients' ability to migrate their coverage.
- Reinsurance will play a critical role in coverage of CGTs in the short term while more complex, innovative payment models are developed.
- Manufacturers need to be proactive in establishing innovative payment schemes, and should focus on the creation of public or private entities to mediate recurring payment for durable outcomes of CGT treatment.

Market access in early stage development: It's time to reboot the system

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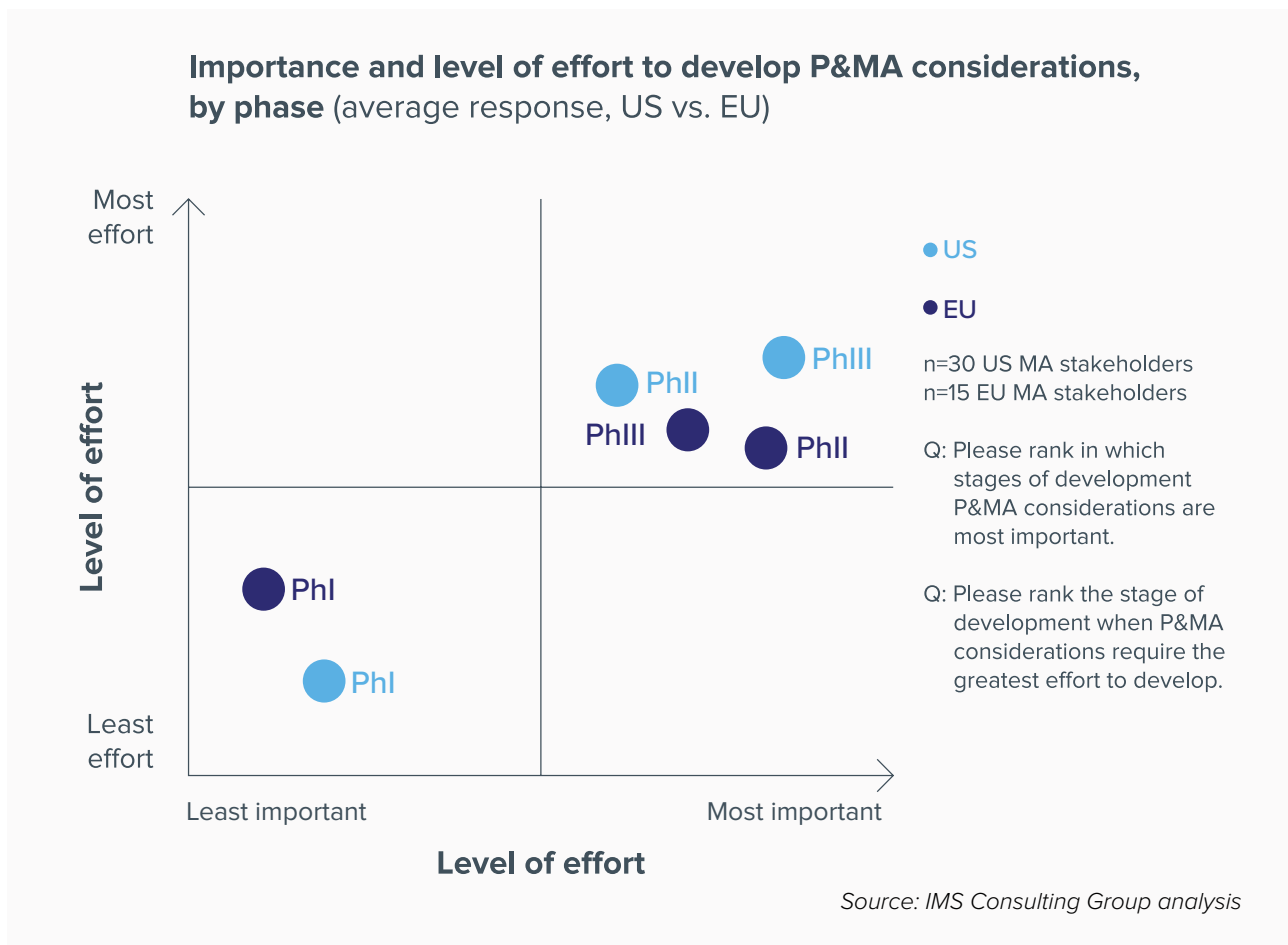
A survey of market access stakeholders from 22 pharma companies reveals that the development of informed pricing and market access (P&MA) assumptions is considered at least as important in Phase II forecasting as in Phase III. However, a majority do not believe they currently capture the nuances to ensure reliable forecasting. As a result, decisions around Phase III study design, go-to-market strategies, and pricing assessments may be compromised. While most companies have begun taking steps to integrate more robust P&MA assumptions in early stage forecasts, those who do not will increasingly struggle to maximize product value.

In today's environment, an increasing number of products fall short of expectations as a result of P&MA stumbling blocks. These case studies raise important questions: How are pharma companies informing pricing and access assumptions in their forecasts, and can something be done to identify — and potentially address — these risks earlier in the development process?

A recent survey of market access personnel reveals that insiders recognize price and access assumptions as equally important, if not more so, in Phase II forecasting compared to Phase III (see Figure 1). This assessment reflects the former's potential to influence key strategic decisions including Phase II to III advancement, resource allocation, and clinical study design, among others.

However, most insiders believe current mechanisms for developing price and access assumptions in Phase II forecasting are inadequate, failing to accurately capture pricing and access risks. In the face of an increasingly challenging access environment, a more tailored approach may now be necessary in cases where standard access assumptions would have previously sufficed. So what are companies doing about it and are their efforts enough?

FIGURE 1. P&MA CONSIDERATIONS ARE SEEN AS EQUALLY IMPORTANT IN PHASES II AND III



The survey, polling 22 pharma companies of all sizes across the US and EU, was designed to understand current approaches towards P&MA assumptions in Phase II forecasting, the perceived adequacy of existing approaches, and potential areas for improvement.

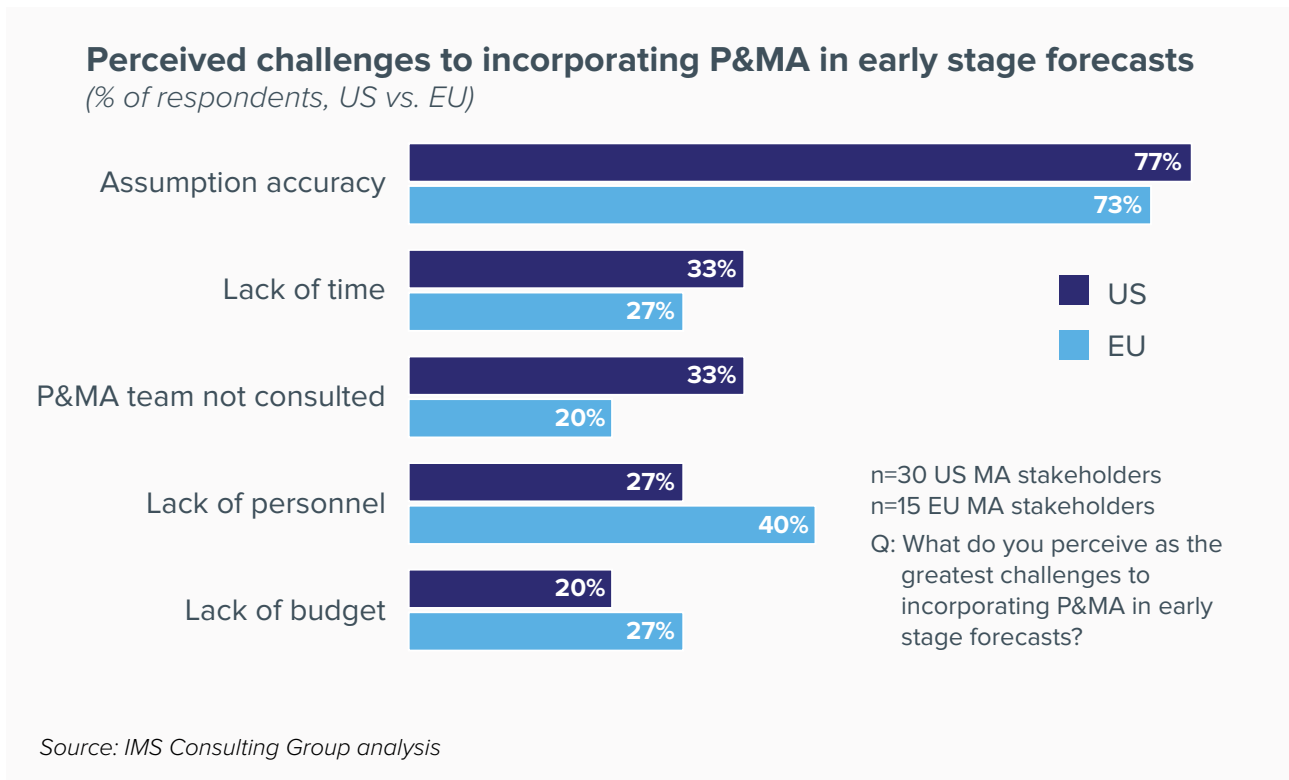
WHAT ARE COMPANIES DOING?

According to surveyed respondents, most of whom are aligned to global market access and strategic pricing, 77% of pharma companies have some formal mechanisms to account for P&MA considerations in their Phase II forecasts.

The survey also revealed that most companies derive pricing and access assumptions from a mix of qualitative primary research, external analogues, past launches, and internal benchmarks.

Within the companies that have strategically invested in developing more robust P&MA assumptions, a tangible impact on decision-making can be seen. While not every product requires significant investment, early comprehensive pricing and access scenario planning is critical for drugs likely to face greater scrutiny from payers or in therapy areas where companies have less experience.

FIGURE 2. DEVELOPING ACCURATE AND APPROPRIATE P&MA ASSUMPTIONS IS THE GREATEST CHALLENGE



In cases where companies have invested in developing more robust P&MA assumptions, stakeholders boast success stories of improved decisions around trial design, go/no-go investments, and choice of trial comparator. Stakeholders also note that these mechanisms generally enable them to develop more realistic, defensible assumptions and to better categorize risk — all of which contribute to a more accurate assessment of a product’s value proposition at an earlier stage.

WHAT COULD COMPANIES DO BETTER?

Despite these clear benefits, more than half of survey respondents believe their current approach does not adequately reflect P&MA risk. Figure 2 reveals that the greatest challenge in developing quality P&MA inputs is the high degree of uncertainty surrounding the clinical profile, competitive environment, and evolution of the market access landscape in early stages of development.

While these uncertainties make it more difficult to develop accurate P&MA assumptions, the task is not impossible. Respondents unsurprisingly noted the lack of devoted resources as another key challenge. Survey findings suggest that the development of P&MA forecast assumptions requires a similar level of effort in Phase II compared to Phase III (See Figure 1); however, many organizations today continue to prioritize their time, money, and human resources on Phase III assets.

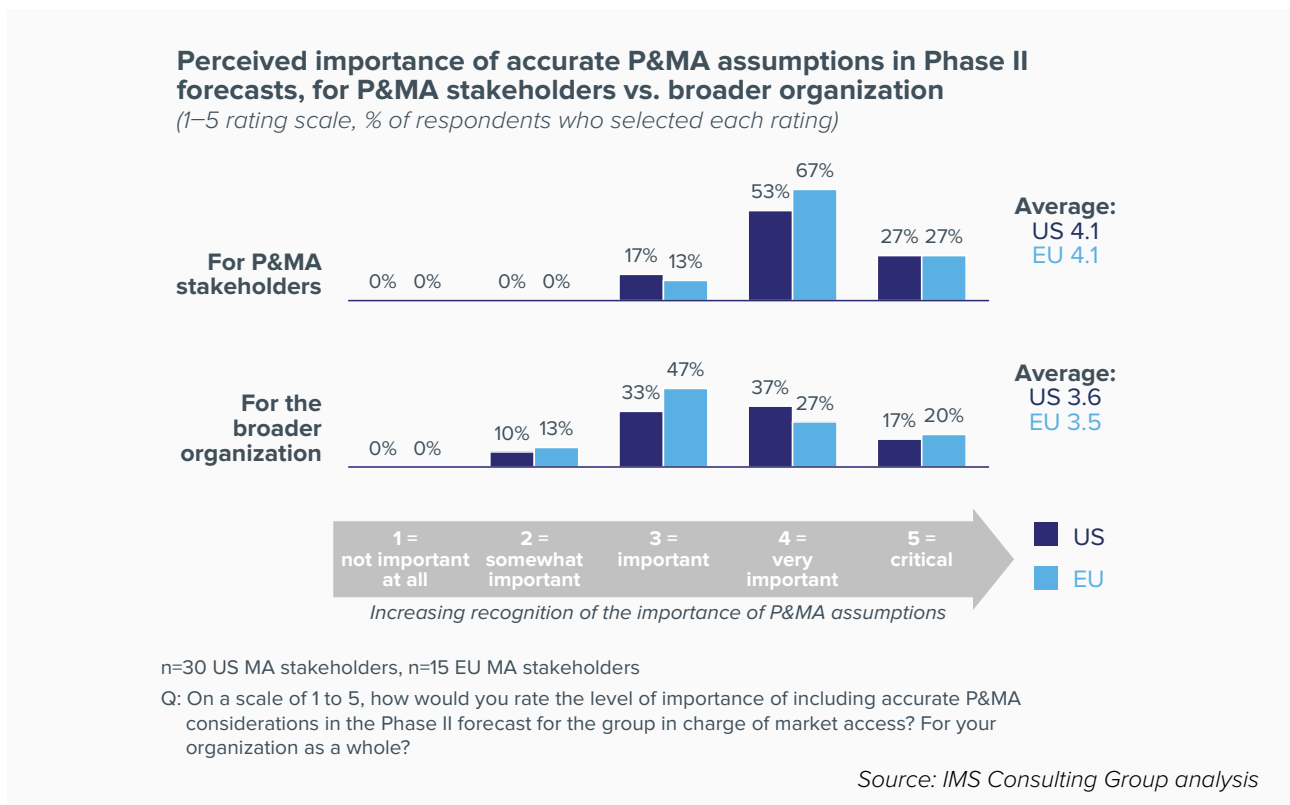
A third potential area of challenge concerns the lack of continuity between the teams working on Phase II forecasting versus those focusing on Phase III. In approximately half the companies surveyed, a different team takes over responsibility for forecasting as the asset progresses from Phase II to III. Through such discontinuity, insights driving the model assumptions can be lost, leading to greater inaccuracies in the forecast as the product moves into later stage development.

Outside of model inputs, and perhaps most significantly, is the challenge of organizational buy-in. Survey respondents, given their areas of responsibility, are aware of the importance of incorporating P&MA considerations in Phase II forecasting. However, as Figure 3 shows, companies as a whole exhibit varying degrees of recognition of the importance of this issue. Those companies who are less advanced are less likely to allocate the necessary resources to identify and address P&MA risks early in the development process.

PHASE II P&MA CONSIDERATIONS: THE FUTURE

As healthcare resources have become increasingly stretched, market forces have already begun to push more companies to begin incorporating P&MA in forecasting sooner and more thoroughly. However, most market access stakeholders still do not believe the existing mechanisms are effective, meaning it may be time to add more rigor to the task of mapping out and planning for more detailed scenarios.

FIGURE 3. COMPANIES SHOW VARYING DEGREES OF RECOGNIZING THE IMPORTANCE OF P&MA ASSUMPTIONS



As in Phase III, the development of accurate P&MA assumptions in Phase II forecasts is likely to face investment trade-offs, with greater accuracy requiring more insights at higher costs. Still, making investments when the market is less understood — particularly for more costly products or in therapy areas where an organization is less experienced — is likely to offer significant long-term returns.

In some cases, a decision framework could be leveraged to determine which assets, therapeutic areas, or countries require a custom analysis as opposed to a standardized approach. In this way, companies could selectively invest in more rigorous assumptions only for products where this is likely to change the course of strategic decision-making in terms of potential clinical endpoints, real-world evidence necessary to ensure sustained access, and resource allocation across later stage assets, or otherwise.

Overall, given the potential for P&MA insights to directly influence early-stage strategic decision-making, companies willing to make the necessary investments — and commitment — to early stage P&MA development stand to gain a tremendous advantage. The importance of developing these capabilities will only increase as pharma continues to navigate a resource-constrained environment with increasingly narrower margins for error, and those not thinking along these lines run the real risk of being left behind.

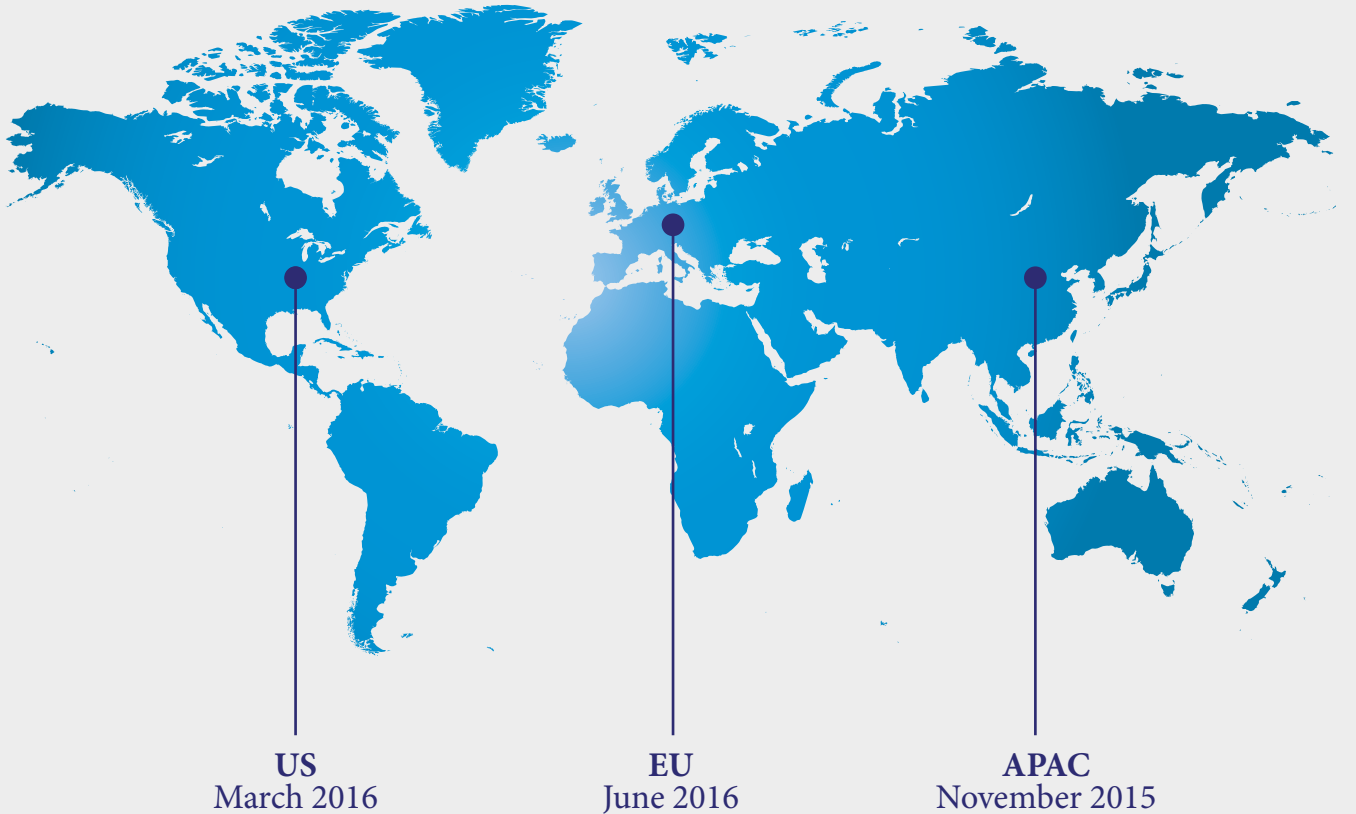
WHY SHOULD THIS MATTER TO YOU?

- In the face of increasingly constrained resources, payers have become more willing to restrict access to drugs where clinical benefit is perceived to be outweighed by cost. Taking the UK as a stark example, 23 oncology treatments were delisted from the Cancer Drugs Fund in September 2015 alone, in an attempt to curb overspending.
- Recognizing these changes in the market access environment, most pharmaceutical companies have already taken steps to integrate more robust P&MA assumptions into the Phase II forecasting process. Companies show varying degrees of advancement in this regard — some have more sophisticated approaches involving decision analytics and relevant analogues, whereas others rely on internal expertise and “access haircuts.”
 - Nonetheless, the majority of market access stakeholders still do not believe their existing mechanisms sufficiently inform Phase II decision-making.
- In light of the potential for Phase II forecasts to influence critical strategic decisions such as clinical trial design and go/no-go investments, it may be time for companies to reassess when a more sophisticated approach to developing P&MA assumptions in early stage decision-making is justified.



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