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POWERFUL INSIGHTS. SMARTER DECISIONS.

# Pricing & Market Access Outlook

## 2014 Edition

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# Pricing & Market Access Outlook
## 2014 Edition

# Dear Clients, Colleagues and Friends

Welcome to the 2014 edition of IMS Consulting Group's Pricing & Market Access Outlook.

Each year, we take great effort to identify and explore important Pricing and Market Access (P&MA) developments in the life sciences industry. After a number of years dominated by patent cliffs and disappointing development results, the near term presents a very different type of challenge as a stream of highly innovative therapies are expected to come to market, building on recent launches in HCV and oncology. The key questions facing both industry and payers is how to value innovation, and how will innovation change the health care system. Will these new products trigger systemic changes to pricing and access models? Or will the ecosystem continue on its current trajectory, using its traditional framework?

In either case, P&MA will play an increasingly central role within commercialization, reacting to the environment, but also preparing for the future. In many ways, P&MA has become a mediator of commercial investment. It is a central gear in a large and connected machine that enables the life sciences industry to continue to move upward. Across many organizations, P&MA has a growing influence in commercial strategy design and execution. Going forward, the function will need to leverage its strategic voice, building and communicating value by linking science to customers, and powering the industry through these challenging times.

With this in mind, IMS Consulting Group is pleased to present the Pricing & Market Access Outlook 2014 Edition. I encourage you to review the articles, which focus on what we consider to be some of the most relevant issues for our industry. The "Outlook" is divided into four themes

**1. Recalibrating the pharma mindset**

New challenges invariably necessitate an organizational rethink and greater cross-functional collaboration across the global enterprise

- Organizational stress test: Is your company fit for payer purpose?
- Integrating patient journeys and funding flows
- Balancing geographic priorities in clinical trial design

### 2. Partnering opportunities

A more integrated healthcare environment creates new opportunities for partnership among a wide range of stakeholders

- Beyond the pill: Two truths and a lie
- Rethinking RWE: Partnering with payers

### 3. Funding challenges

Greater pressure on healthcare budgets and widespread healthcare reform is transforming the global insurance market and creating new rules for successful premium pricing

- Exchanges: Should pharma care?
- Private insurance as an access lever in emerging markets
- List price premiums in US and EU: What are the implications?
- Payment by use: A new value paradigm for oncology

### 4. Shifting sands

The recent focus on specialty drugs may have obscured the gains still to be had from primary care and biosimilars

- Opportunity hidden in plain sight: A return to primary care
- Mind the gap: Expectation versus reality in the EU biosimilar market

These articles represent distinct viewpoints. However, we recognize that there may be other equally valid viewpoints. As such, our goal is for this document to serve as part of a dialogue. I encourage you to engage with your peers, as well as the IMS Consulting Group team. Share your viewpoint on the specific issues covered in the Outlook or others you feel are particularly important to the industry or your organization. Knowledge can only grow by a sharing of facts and perspectives.

We hope that we can be a catalyst, or a gear, for the advancement of P&MA.

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

## I Recalibrating the pharma mindset

New challenges invariably necessitate an organizational rethink and greater cross-functional collaboration across the global enterprise

## II Partnering opportunities

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## III Funding challenges

Greater pressure on healthcare budgets and widespread healthcare reform is transforming the global insurance market and creating new rules for successful premium pricing

## IV Shifting sands

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# Contents

# Organizational stress test: Is your company fit for payer purpose?

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Pricing & Market Access teams, critical to commercial success, have evolved in many organizations to become so highly specialized they can function almost independently of the main fabric of the organization. Companies recognize the value of their input but efforts to integrate them into the commercial operations are typically focused on structural changes, which can easily ignore the more difficult process and behavioral changes needed to achieve full integration.

## EVOLUTION OF P&MA'S ROLE

As payers across the world have become more demanding, the Pricing & Market Access (P&MA) function has evolved in many organizations to be seen as highly technical and specialized which has effectively become isolated from the rest of the commercial organization. P&MA is seen as responsible for negotiating broad access locally and achieving target prices nationally. As such, it tends to develop and execute strategy independently and is not necessarily valued for its input into other key commercial decisions areas such as product development.

As payers continue to become more aligned with clinicians on outcomes and standards that ensure the sustainability of the healthcare system, P&MA needs to become more integrated with the commercial organization by playing a more central part in strategic planning and decision-making from early-stage product development to loss of exclusivity.

## COMMON ISSUES WITH FULLY INTEGRATING P&MA

Based on our client experience, the typical approach to ensuring the integration of P&MA in the commercial organization is to focus on structural changes. However, this ignores equally important aspects of the integration process in four ways.

- **Understanding external P&MA environment**

  Often we find that local P&MA teams have a deep understanding of the payer environment but these insights are not systematically shared or understood by global marketing and medical teams. As such, local payer insights are not fully utilized by the organization to inform strategic decisions.

- **Integrated P&MA function and strategy**

  In many clients, we have seen that annual planning cycles for brand and P&MA strategy are not necessarily aligned. This means that P&MA strategy is often developed separately to brand strategy, reinforcing silo thinking within brand teams.

  Additionally, P&MA in many organizations does not have equal responsibility for product development relative to other functions. This creates a problem as P&MA input into early development decisions is critical for evidence-based market access (see Figure 1).

- **Local P&MA engagement**

  Many organizations struggle to coordinate engagement with payer-influencing stakeholders, as there is typically overlap in ownership with other functions. This can result in insufficient engagement planning and coordination, which can lead to miscommunication of key messages and gaps in stakeholder coverage.

FIGURE 1. CASE STUDY: INTEGRATION OF P&MA INTO PRODUCT DEVELOPMENT

**A COMMON ISSUE WE SEE IN MANY ORGANIZATIONS IS THE NEED TO MAKE BETTER USE OF PAYER INSIGHTS TO INFORM KEY PRODUCT DEVELOPMENT DECISIONS**

### Situation

In one example, a company had almost completed phase III trials when it emerged payers would likely not provide full access / reimbursement at the target price level. The product, in a highly competitive therapy area, had known safety issues; in addition, many EU payers were now expecting head-to-head trials with reduced dosing while the product's phase III design was placebo-controlled with higher dosing than existing products.

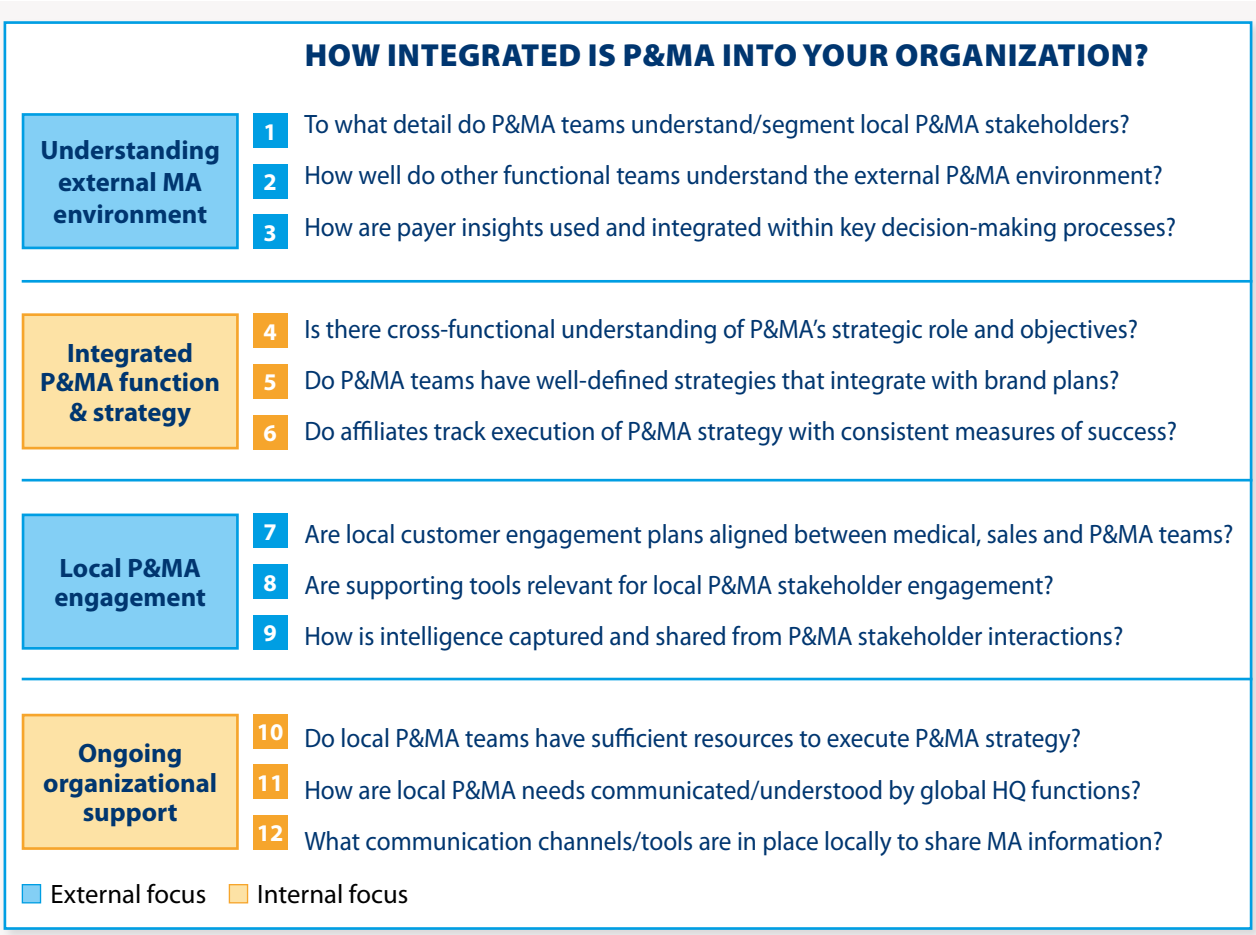
P&MA highlighted this risk based on local research during trial planning; however, P&MA was not a core member of the development team and did not have direct input to the decision. R&D overruled the payer concerns as it believed altering the design would significantly reduce the probability of achieving the target product profile endpoints.

### How could P&MA have been better integrated?

While R&D's concerns were valid, it would have been important to transparently map out the commercial consequences and allow an open discussion. Ultimately, this might have changed the information basis for the investment decision as well as the commercial expectations moving forward. Therefore, it is important to not only gather the relevant information from the markets, but also to ensure it has the right weight and presence when informing important investment decisions.

*Source: IMS Consulting Group*

FIGURE 2: IDENTIFY P&MA'S LEVEL OF ORGANIZATIONAL INTEGRATION




*Source: IMS Consulting Group*

On several occasions, clients reported that in-field market access and medical teams were communicating conflicting clinical / value messages to key opinion leaders who are also members of payer organizations.

- **Ongoing organizational support**

  There is often a need for improved channels that enhance the visibility of local P&MA issues and ensure appropriate resources are allocated. This can be achieved in various ways. In one example, a standard KPI framework was used to align the organization on cross-functional strategic priorities while also creating performance transparency that allowed functions to react in a coordinated fashion to specific P&MA issues as they arose.

## INTEGRATING P&MA INTO THE ORGANIZATION

Achieving full integration is not easy. There are no one-size-fits-all solutions. Rather, it requires a thorough assessment of the current gaps in the integration process and the implementation of customized solutions to address those gaps. P&MA teams need to be fully involved in this process to proactively drive and contribute to any organizational solutions.

The first step is to conduct a diagnostic to identify and secure alignment on the underlying issues. Based on numerous engagements to help companies optimize the involvement of P&MA, we have developed a diagnostic tool structured around 12 key questions that link to the four common issue areas (see Figure 2). These have been designed to assist organizations to understand their integration issues more clearly and therefore enable appropriate action to be taken.

As most companies have achieved some level of integration, this approach is more targeted, highlighting specific areas for improvement which can be segmented into short and long term priorities.

The key to achieving change lies in ensuring broad organizational awareness and alignment on the most critical issues. Therefore, it is necessary that any assessment is not led just by P&MA but includes a broad, cross-functional team which spans global, regional and country levels.

Once the main issues are identified, the same cross-functional team should be responsible for developing unique / customized solutions tailored to the specific needs of the organization. Typically, these solutions involve a combination of simple and complex activities. For example:

- Redesigning key commercial planning processes / activities to ensure the strategic view of P&MA is incorporated (e.g. annual brand planning)
- Redefining key decision-making responsibilities to ensure P&MA is involved from early-stage product development
- Modifying annual performance objectives and implementing standardized KPIs around P&MA objectives
- Developing new communication channels / tools between affiliates and HQ as well as between P&MA and commercial functions.

Overall, the solutions needed to integrate P&MA should go beyond structural changes and seek to elevate the influence of P&MA by addressing behavioral and mindset issues that are a result of P&MA's historic evolution.

## WHY SHOULD THIS MATTER TO YOU?

- As payers exert a growing influence on uptake and access, companies with integrated P&MA teams that are able to play a key role in product development and commercial planning are best positioned to achieve commercial success.
- Many companies have attempted to de-silo and elevate the strategic role of P&MA. However, most fall short of their goals because their efforts are typically focused on structural factors, which can ignore the more difficult process and behavioral changes required.
- Companies need to start by understanding and agreeing on the gaps in their integration efforts to know what steps are needed to achieve full integration of P&MA into the commercial organization.

# Integrating patient journeys and funding flows

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Brand, market research and market access teams often go about the four work streams of understanding patient journeys, stakeholder mapping, funding flows and treatment economics in relative isolation. This can lead to gaps in knowledge, the duplication of tasks and vital missed connections. Integrating these work streams into a single initiative has several key advantages, including the creation of a holistic view of the market, more effective strategies and resource allocation, cost and time savings, and finally improved cross-functional collaboration.

Given the evolving landscape and increasingly connected group of stakeholders pharma needs to engage, ensuring accurate and comprehensive strategies takes on even greater significance. In most situations, properly developing such strategies requires understanding the situation from all angles. However, when examining the pharmaceutical market, one notices glaring omissions to that rule.

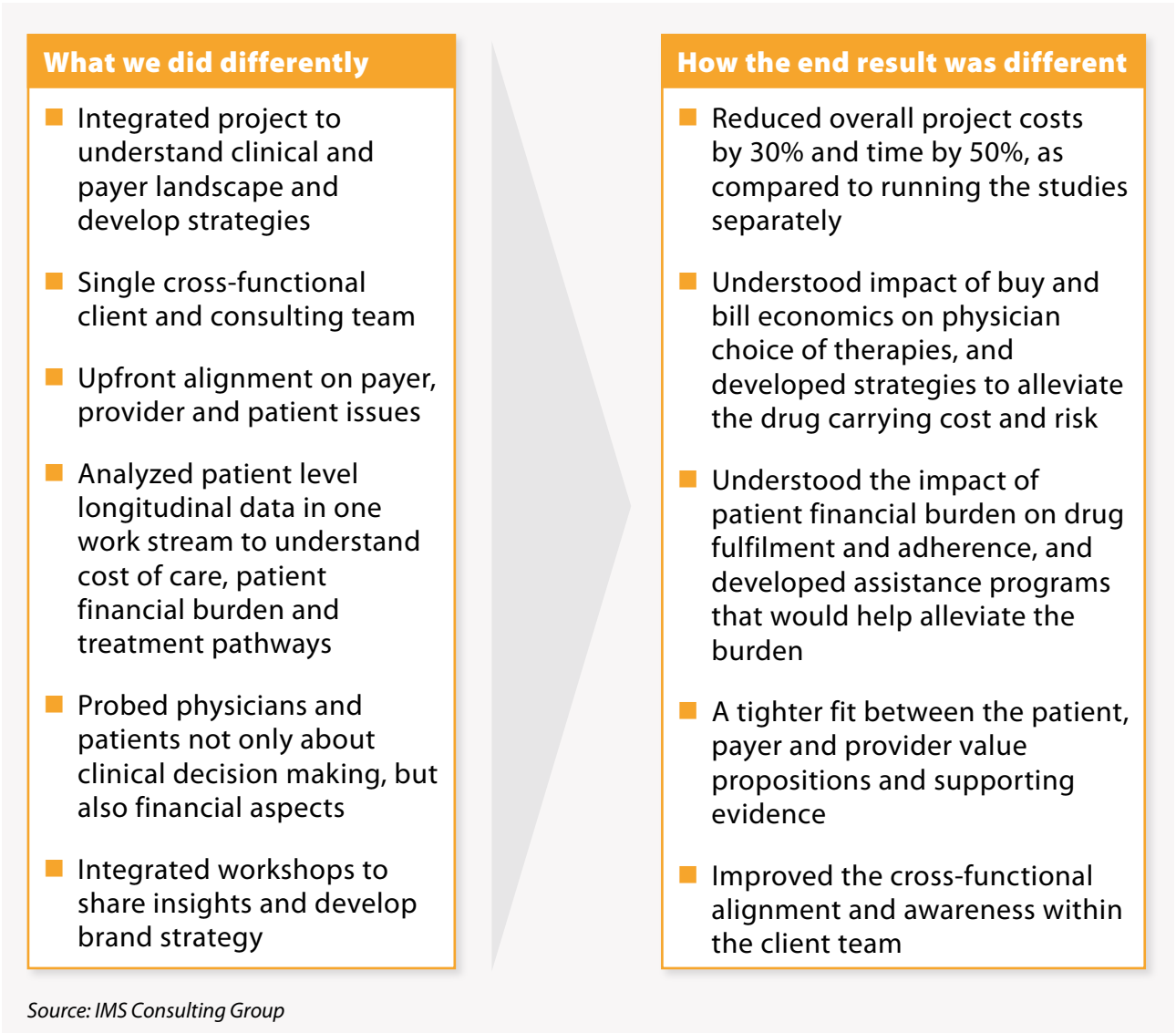
Oftentimes, pharmaceutical companies treat building patient journeys, creating stakeholder maps, and understanding funding flows and treatment economics as individual and separate initiatives to be performed by different teams. Examining these work streams in silos, however, is suboptimal and can potentially lead to a number of issues, including:

- Missed interconnections which can lead to oversight of critical decision nodes
- Incomplete strategic thinking which can lead to ineffective prioritization of resources
- The repetition of work along with extended timelines and costs.

It is crucial to layer the funding flows onto the patient journey as decision-making is synergistic and considers both clinical and economic factors. It is difficult, for example, to assess a patient decision without understanding the consequences regarding their out-of-pocket costs. Similarly, physicians are fundamentally affected by the reimbursement environment, including what is covered and how they are paid for their services.

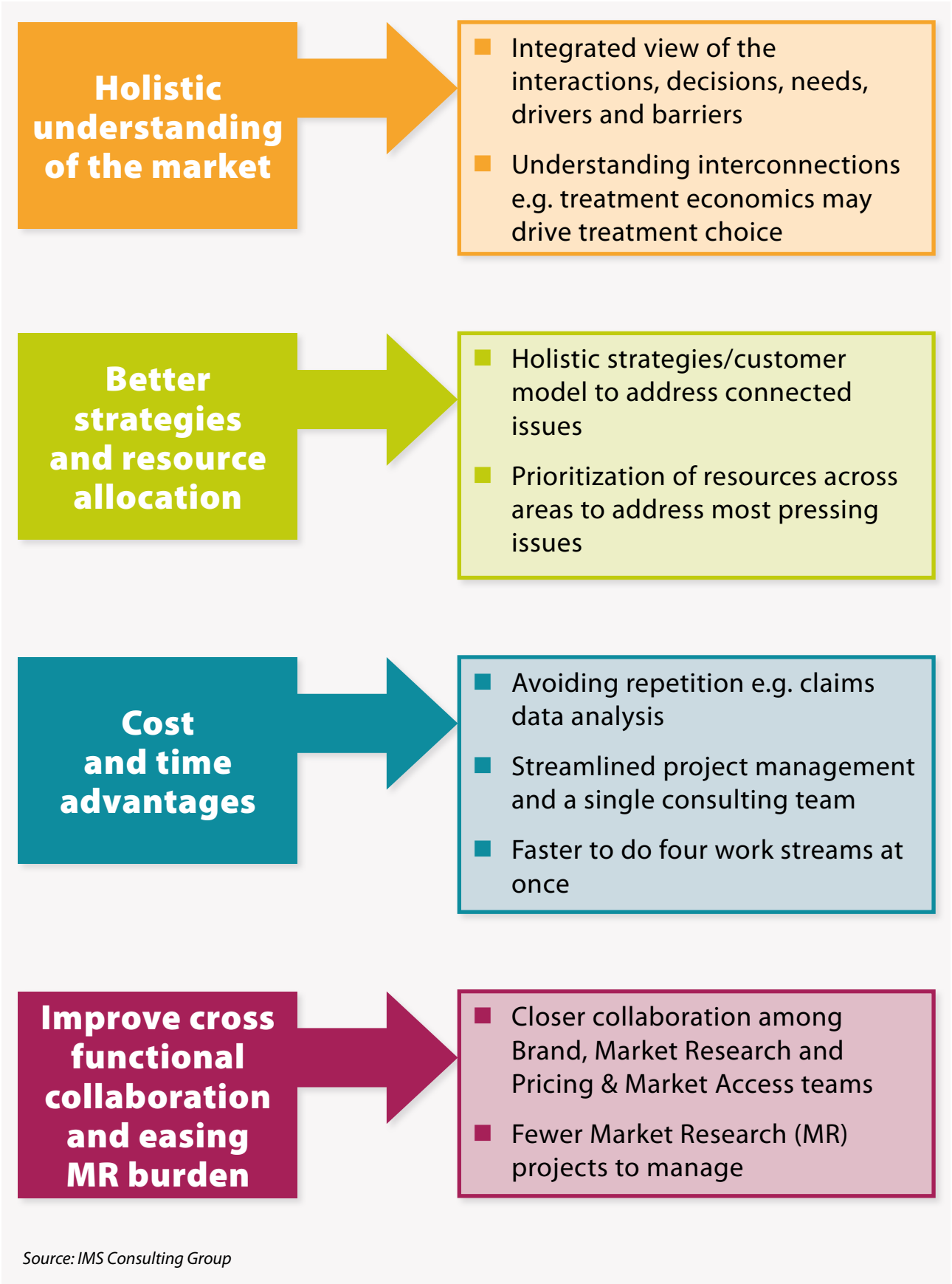
An example of the key advantages behind combining patient journeys and funding flows can be seen from a recent engagement we completed with a large, multinational pharmaceutical company. We were independently engaged by both its brand and market access teams to better understand the flow of patients and payments for the management of cancer. Our suggestion was to combine the two initiatives and deliver a full view of both by analyzing them as one work stream instead of two. Ultimately, this unique approach led to an all-inclusive deliverable with meaningful and actionable insights for the clients (see Figure 1).

FIGURE 1. IMS CONSULTING GROUP'S INNOVATIVE APPROACH HAS LED TO VALUABLE RESULTS




*Source: IMS Consulting Group*

FIGURE 2. A SINGLE VIEW OF THE LANDSCAPE HAS SEVERAL KEY ADVANTAGES




*Source: IMS Consulting Group*

The more generic benefits are shown in Figure 2, illustrating the benefits of a combined approach to patient journeys and funding flows.

Most importantly, however, companies can now add value that is pertinent to patients, payers and providers in a seamless manner. Given the competitive pharmaceutical marketplace, these benefits can provide organizations with the advantages and efficiencies they strive for.

## WHY SHOULD THIS MATTER TO YOU?

- An integrated approach to patient journeys and funding provides a robust, analytic framework that offers a more comprehensive view of the market.
- A holistic perspective enables companies to more effectively build strategies and allocate resources via integrated plans and customer models that address complex connected issues.
- Working across pharma disciplines improves cross-functional collaboration that eases the overall workload as brand, market research and market access teams all use the same single initiative.

# Balancing geographic priorities in clinical trial design

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In an increasingly restrictive European market access environment for assets with clear comparators, pharma faces a complicated decision when investing in phase III clinical trials. How should the potential access gains in Europe from a successful head-to-head trial be weighed against the potential loss in US value from a failed head-to-head trial? To optimize decision-making, quantitative decision analytics for clinical development strategy must incorporate more specific and nuanced Pricing & Market Access inputs.

Traditionally, Pricing & Market Access (P&MA) implications in the decision analysis for Phase III clinical development decisions have played a limited role. Two options are typically considered:

1. **Avoid risks associated with a head-to-head trial:** While this decision sacrifices value in France and Germany, it preserves a potentially large US opportunity, where head-to-head data are not always an access requirement.

2. **Pursue head-to-head trials:** Successful trials allow pharma to unlock full global value, but a failed head-to-head trial may limit the commercial opportunity in major markets and lead to a no-go launch decision globally.

In order to better understand this decision, IMS Consulting Group set out to explore the impacts of different options on a hypothetical product by varying three key decisions: whether to have head-to-head data, when to have it, and where to have it (see Figure 1). Three strategic options for comparative trial planning were defined and evaluated using a high level Net Present Value (NPV) analysis: "Go for Global (A)", "Preserve US (B)", and "Stagger (C)" (see Figure 2).

In the "Go for Global" strategy, the potential for unlocking full commercial value in both the US and EU is offset by the high technical risk and upfront R&D costs. The more risk-averse "Preserve US" strategy limits sales upside but also mitigates downside risk and overall R&D costs. In the "Stagger" approach, the manufacturer was assumed to pursue head-to-head trials after US launch in EU patients only. This strategy aims to balance both technical and

FIGURE 1. DESCRIPTION OF ILLUSTRATIVE PRODUCT AND STRATEGIC OPTIONS EVALUATED

**Product Overview**

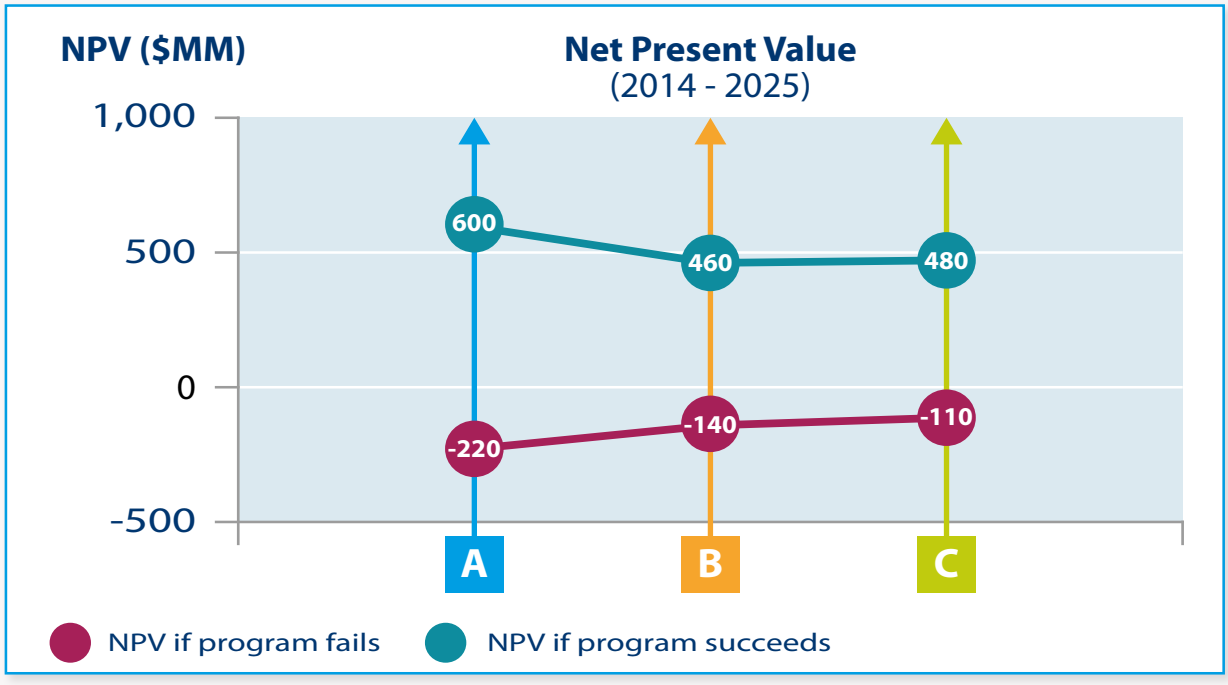
- Development phase – phase II completed
- Expected US+EU peak sales – $750MM
- Expected value split across geographies – US/EU: 60%/40%
- Comparator available for trials – Yes

**Strategic Options: Comparator Data Decisions**

| | Whether to have | When to have | Where to have |
|---|---|---|---|
| A Go for Global | Yes | Before US launch | US and EU |
| B Preserve US | No | – | – |
| C Stagger | Yes | after US launch | EU |

*Source: IMS Consulting Group*

FIGURE 2. NET PRESENT VALUE (2014-2025) RANGE OF ILLUSTRATIVE PRODUCT ACROSS STRATEGIC OPTIONS

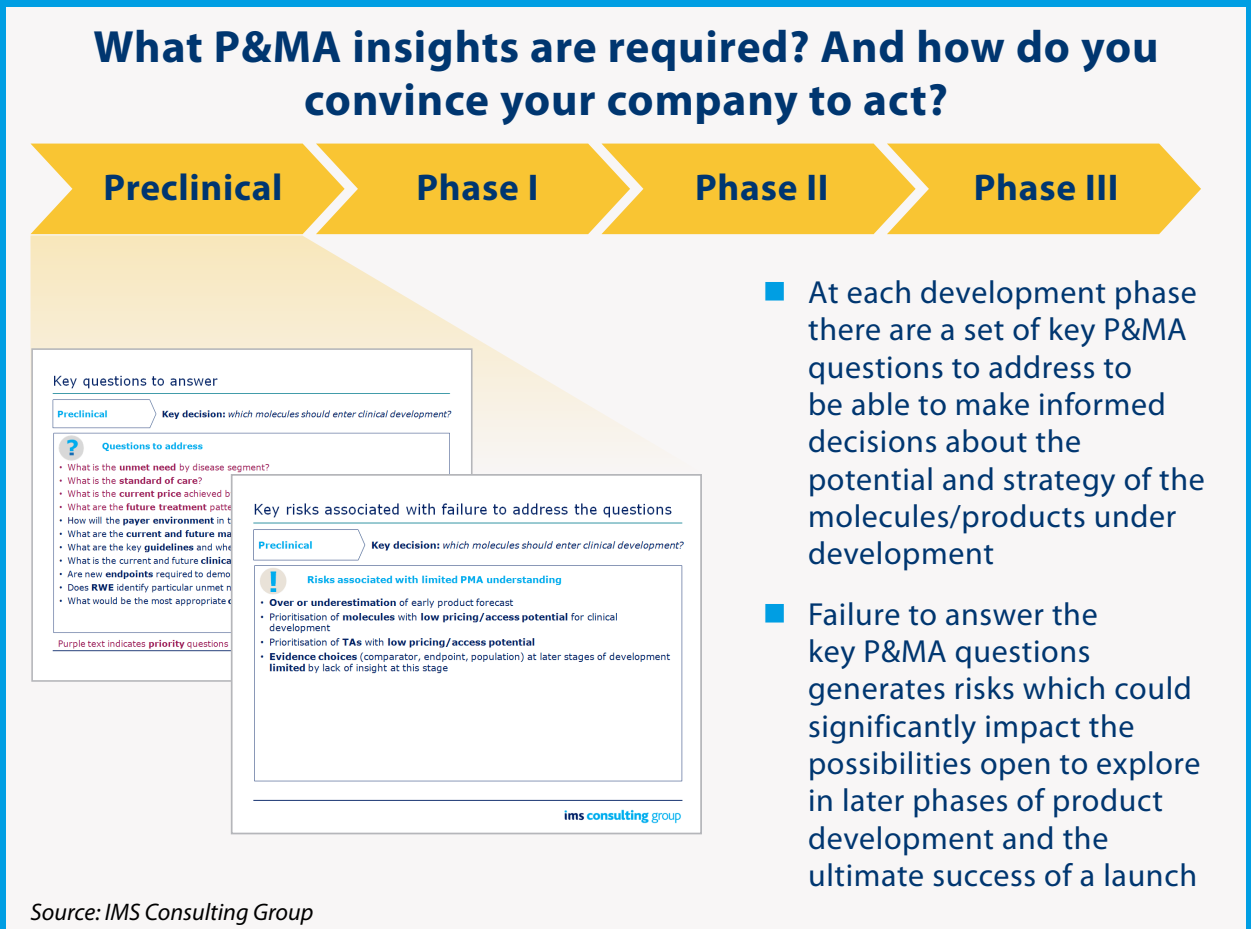



*Source: IMS Consulting Group*

## P&MA INSIGHTS THROUGHOUT DEVELOPMENT

Drug development from identification to launch is by nature inefficient, with only approximately 11% of Phase I drugs in development reaching the market. While Phase III is associated with highest R&D expenditure, earlier phases carry a significant cost as well. In addition, decisions on patient populations, comparators and endpoints made early in development directly influence possibilities for Phase III clinical trials, ultimately affecting launch price and access opportunity. Although this might seem obvious, IMS Consulting Group analysis suggests the role of P&MA in early R&D decisions varies greatly. Barriers to successful integration of P&MA strategy in early clinical development decision-making include misaligned objectives across the product team; limited resources; lack of organizational memory and no standardized process. To achieve the required P&MA understanding for a given development phase, companies should assess whether they should pursue "Foundational" or "Excellent" criteria for any given products in development based on an understanding of the company's pipeline; level of existing therapy area knowledge; product potential; anticipated level of competition and overall payer risk. IMS Consulting Group has developed a roadmap (see Figure 3) with diagnostic questions to enable identification of the critical payer issues to be considered.

FIGURE 3. ROADMAP TO IDENTIFY KEY PAYER ISSUES




*Source: IMS Consulting Group*

commercial risks, but goes directly against trends in clinical development pushing for simultaneous global development programs.

Rigorous quantitative analysis of P&MA implications at key decision-making points strengthens strategy development. Many factors should be considered, including the probability of success, development costs, potential EU launch delay, outcomes of a head-to-head study, and impact of a head-to-head failure in the US.

Depending on the therapy area, comparator, development asset's profile, and risk level of the overall program, the optimal development strategy will vary. For example, the "Stagger" approach is dependent on the assumptions of what happens to product sales in the US market if the post-launch head-to-head trial fails. This is a controversial assumption as there are few precedents. Inherent in the "Stagger" approach is that sales will not completely dissipate following a post-launch trial failure. This assumption will influence the final decision and ultimately depend on the therapeutic area and the competitive dynamics within it.

Additionally, product type can affect clinical development strategy selection: protecting the US is critical for primary care products that have significantly higher US value potential compared with Europe. Therefore, conservative strategies may remain optimal for primary care products, while specialty products may be better suited to alternate approaches as they typically generate a significantly greater percent of their global revenue from Europe compared to primary care products.

In conclusion, the decision analysis that goes into performing head-to-head trials in competitive areas must weigh complex P&MA implications to inform the optimal risk and reward of such programs.

## WHY SHOULD THIS MATTER TO YOU?

- The evolving P&MA landscape is pushing pharma to take on riskier development programs: achieving successful P&MA in France and Germany is challenging without comparator data when a clear comparator exists, but failed head-to-head trials significantly compromise value in the US.
- Pharma should integrate more sophisticated modelling of P&MA considerations when evaluating the financial trade-offs between pursuing and not pursuing head-to-head trials.
- IMS Consulting Group can combine P&MA expertise with sophisticated valuation exercises to support crucial clinical-development decisions.

# Beyond the pill: Two truths and a lie

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There are varied reasons pharma companies consider developing value-added services (VAS) programs, including optimizing pricing and market access, building payer, provider and patient relationships, collecting real-world evidence or providing a competitive value proposition. However, this article focuses on the VAS strategy itself as payers become more discerning about the programs they support. Our research with US and EU5 payers shows that if payer engagement is an objective of a pharma VAS program, the program should also involve provider partners, be based on robust evidence and be able to continually track patient outcomes, while also targeting specialty conditions.

## BUILDING A 'BEYOND THE PILL' STRATEGY - TWO TRUTHS AND A LIE

'Beyond the pill' discussions have played a growing role in dominating product strategy planning over the past 10-15 years. Despite pharma's intent to differentiate through value-added services (VAS), few stakeholders (e.g., payers, providers or patients) experience VAS as making a significant difference in the course of care. Program success is varied and often assessed subjectively but some VAS have proven themselves as worthwhile opportunities to bring greater value to the market. IMS Consulting Group research shows, however, that while these opportunities have evolved with the advent of mobile apps and new technologies, many of the hurdles remain the same. An effective VAS initiative should be able to demonstrate its own value – if not, it will likely be unsustainable. As a result, while there may be opportunities, pharma should look carefully before jumping in.

## TRUTH 1: NEW GAME, SAME RULES

Pharma's attempts to date at providing VAS programs have led to higher expectations and an increased focus on speciality areas. Programs tailored to common conditions, such as diabetes, asthma and chronic obstructive pulmonary disease can still succeed if structured appropriately, but pharma should realize the benchmarks are high and perhaps consider targeting these initiatives at speciality therapeutic areas.

Our research with US and EU5 payers shows that the programs that have risen to the top tend to have three things in common:

- **Focused in specialty areas**: Payers are still working to improve adherence, but their thinking has shifted away from primary care to specialty areas. This is where their spending has increased, where their core gaps exist and where they want to see innovative programs and technology to address the gaps. But these are also more complex areas involving more stakeholders and therefore more effort from pharma, which must be factored into the decision-making process.
- **Backed by evidence**: A sense of faith in programs that had the right intent has given way to stakeholders insisting on data before making a commitment. Best practice programs are now backed by clinical or peer-reviewed evidence as payers want a feedback loop to validate that the program is making a difference. This means any program a pharma company is thinking of setting up must be structured to collect and track outcomes. More sophisticated payers are interested in approaches that use this data to then tangibly and directly impact outcomes. Many payers would like to see evidence of VAS program effectiveness prior to partnering or investment.
- **Involve partners who have skin in the game**: Successful programs have some type of partner (payers, providers or any other third-party stakeholder) commitment, either financial, resources committed or both. The challenge is often that the hurdle is too high to secure this. Based on an assessment of previous successful programs, rather than a partner being merely 'nice to have', it could become a deal-breaker.

## TRUTH 2: PROVIDERS ARE THE ENTRY POINT

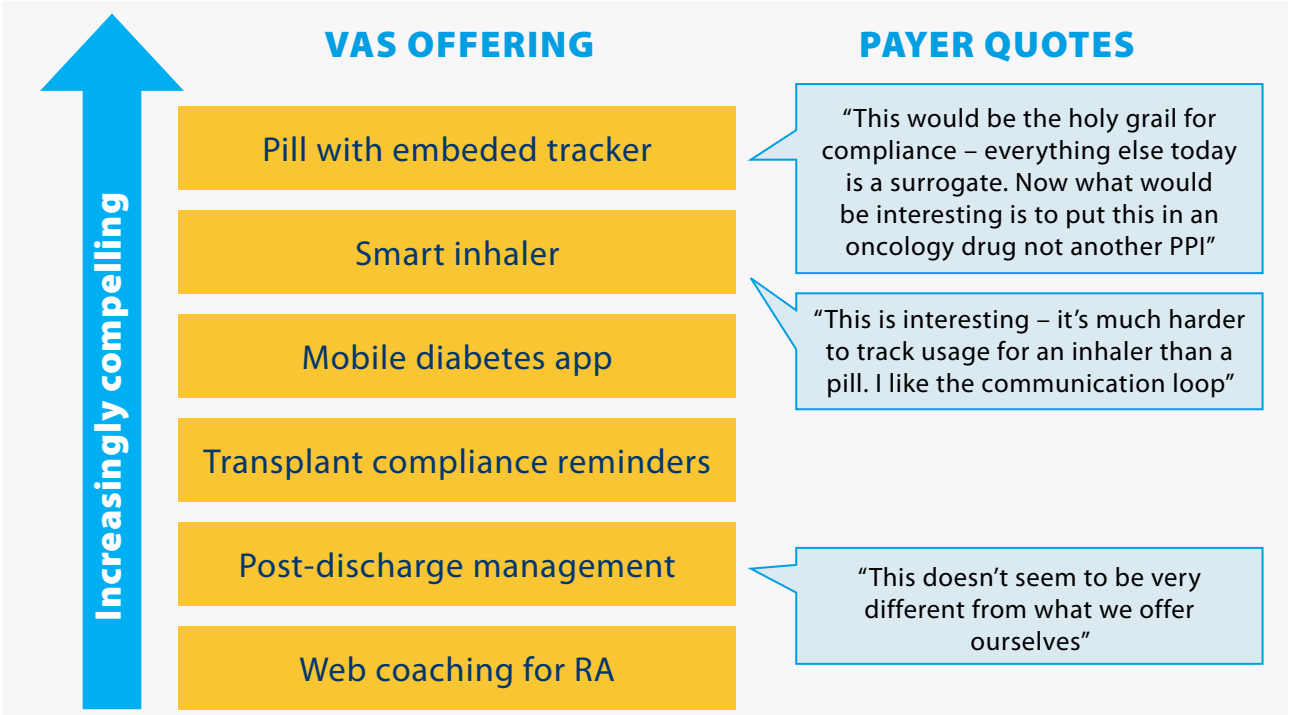
Since providers are the ones delivering care, making treatment choices and driving patient conversations, they need to be brought on board. Also any concerns about a marketing or profit motive need to be resolved early on, or at least aligned with the pros of pharma involvement. In some EU markets, such as Germany, pharma skepticism is so strong that even providing a product-agnostic service may not be accepted if there is pharma involvement.

If success is defined by longevity and payer acceptance, the IMS Consulting Group database of VAS programs highlights that provider-driven programs are the winners across all markets but particularly so in the US since implementation of the Accountable Care Act. Among other things, this has prompted new partnering arrangements, such as provider organizations collaborating with pharma around real-world evidence programs and studies to support protocol / guideline development.

## LIE: PAYERS WILL NOT PAY

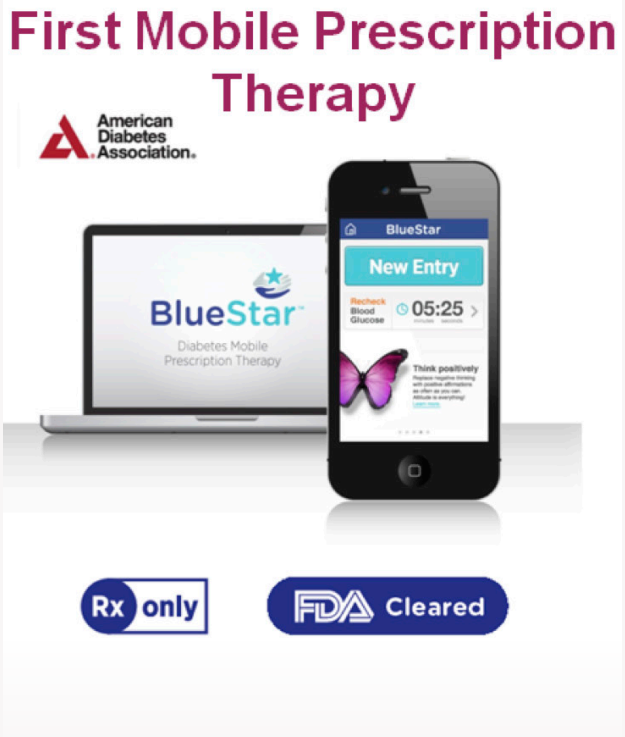
Payers may be more discerning about VAS programs but that does not mean they will never be interested in them. To understand what they value most, IMS Consulting Group conducted research to gauge US and EU5 payer reactions to six hypothetical value-added services: smart inhalers; diabetes apps; transplant compliance reminders; web coaching for rheumatoid arthritis injections; smart pills; and post-discharge management.

FIGURE 1. PAYERS SEE GREATEST VALUE IN TECHNOLOGY THEY CANNOT IMPLEMENT ALONE




*Source: IMS Consulting Group*

FIGURE 2. WELLDOC REPRESENTS A SUCCESSFUL PROGRAM WITH LEARNINGS FOR PHARMA VAS INITIATIVES




*Source: IMS Consulting Group, WellDoc*

**TRUTH: New game, same rules**

- Tied to evidenced based guidelines
- Proven effective in published RCTs, data published in *Diabetes Care*
- Founded in diabetes but expanding to specialty areas such as oncology

**TRUTH: Providers are the entry point**

- Physician detail sales force
- Provides clinical decision support for therapy optimization and quality measures
- Tailored to patient treatment plan
- Integrated with EMRs (Electronic Medical Records)

**LIE: Payers will not pay**

- Dispensed by pharmacies
- Coded via a unique National Drug Code (NDC)
- Reimbursed by PBMs, HealthPlans, Employers, and Integrated Health Systems: Examples include OptumRx, RiteAid, Johns Hopkins Priority Partners

While payers will not pay more for generics fitted with the latest gadgetry, the research found payers appreciated evidence-based technology that they are unable to implement alone (see Figure 1), particularly for specialty drugs. Smart pills embedded with a compliance tracker scored highly. Indeed, anything that provides a communication loop was seen as important. Payers rated smart inhalers and mobile diabetes apps as moderately compelling because of this feedback potential.

Disease management services, despite their potential impact on compliance, were seen as less useful perhaps because payers believe they can provide these themselves or deploy third parties to do so. Pharma might consider partnering with such parties provided other plus points are in place. Even then, reimbursement is not guaranteed.

WellDoc's BlueStar, although not directly involving pharma, is an example of best practice in this area. It is a mobile prescription therapy backed by evidence from trials demonstrating how it can realize improvements in diabetes care. It has since expanded its Expert System platform to specialty areas such as oncology, and it also partners with physicians to deliver real-time information to help them make the best treatment decisions for their patients. It is currently covered by leading pharmacy benefit managers, employers, health plans, and integrated delivery networks, although has not seen universal coverage yet (see Figure 2).

In terms of implementation, our research also shows payers want VAS programs that work across multiple disease areas and demographics, and are also not tied to a specific brand or company. This brings new complexities in terms of investment and approach, as well as challenges in assessing return on investment.

Before jumping in to develop a VAS program, pharma must carefully define its goal. The success of a VAS program by the degree to which these goals align with those with payer goals and sources of value.

## WHY SHOULD THIS MATTER TO YOU?

- Value-added services that move 'beyond the pill' may be fashionable but the bar is constantly rising on what defines value. Payers, having come to expect such support for free, are not always willing to pay unless they can see clear, differentiated benefits.
- If payer partnership is a core goal of a planned VAS initiative, pharma companies should structure VAS programs to address payer needs bearing in mind the evidence required, the stakeholders that should be involved and the areas on which they should focus.
- Discussions with payer stakeholders in EU and US, combined with analysis of an IMS Consulting Group database of VAS programs, provides evidence-based understanding of what payers 'value' in such initiatives.

# Rethinking RWE: Partnering with payers

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Working with real-world data (RWD) is challenging, not least because the market for data is immature and, for Pricing & Market Access (P&MA) purposes, often insufficient. Creating partnerships within the healthcare system offers advantages in terms of access, data availability and analyses. But anticipating the real-world evidence (RWE) required to maintain and defend access is critical. Translating a RWD strategy into a plan of action requires organizational alignment, investment and, above all, adequate lead time.

## IMMATURE MARKET FOR REAL-WORLD DATA

The current imperative for working with RWD highlights, among other things, the complexity of modern healthcare. While all stakeholders are on the same learning curve, a limiting factor for everyone is that the market for RWD is still immature. This means that access to valuable data sources can be slow, governance models are varied and there is not yet an efficient model of matching data owners with those wanting access to their data. In addition, data is rarely linked across providers and off the shelf datasets have limitations for P&MA-related uses. Furthermore, medical protocols and cost structures differ so greatly between healthcare systems that real familiarity is required to analyze the data and broad, multi-country analyses are usually not accepted at local payer level.

Consider, for example, the data sources required to build a real-world picture of patient pathways within type 2 diabetes, where the typical patient per year:

- Spends 1.2 days in hospital, more than 40% of which are for complication-related conditions such as heart or renal disease but more than 50% are not
- Has 4.6 days in other residential care, which may be served by different HCPs
- Makes 3.9 visits to their general practitioner, more than 65% of which are not directly related to their diabetes
- Has 1.5 home health visits, 0.35 outpatient appointments, and 0.33 emergency care visits.

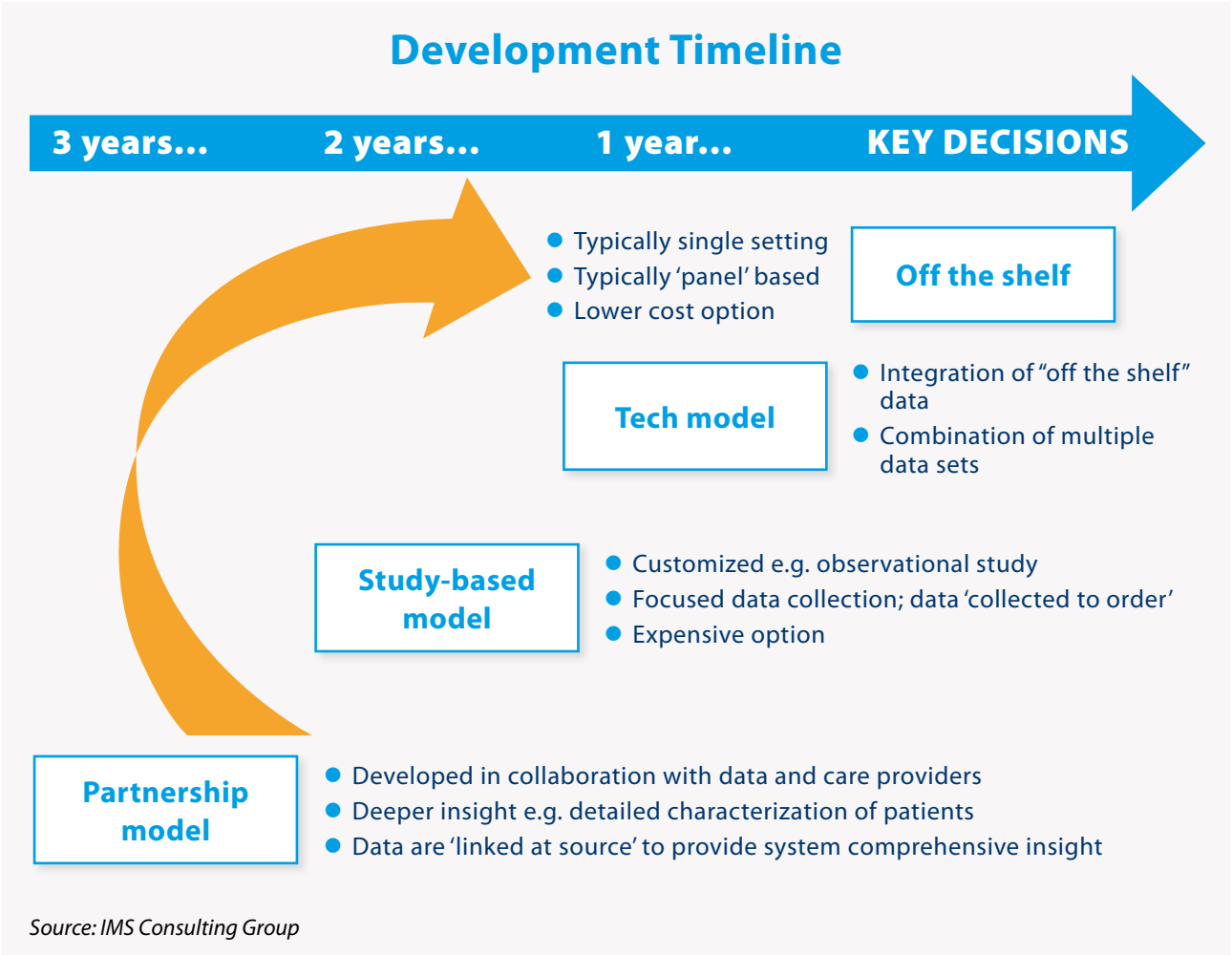
The need to collate data across disparate settings means we regularly observe gaps between pharma goals and what is currently feasible, underlining the need for clarity on:

- Goals of RWD projects: Is the focus a product or patients? Are we interested in characterizing the market, clinical practice, or the disease? Is this realistic?
- Data needed: Is it available off the shelf or must it be created? Is a partnership-access model required?
- How to access it: Is there a framework to access the necessary data? What are the governance considerations?

## PARTNERING WITH PAYERS: PHARMA PERSPECTIVE

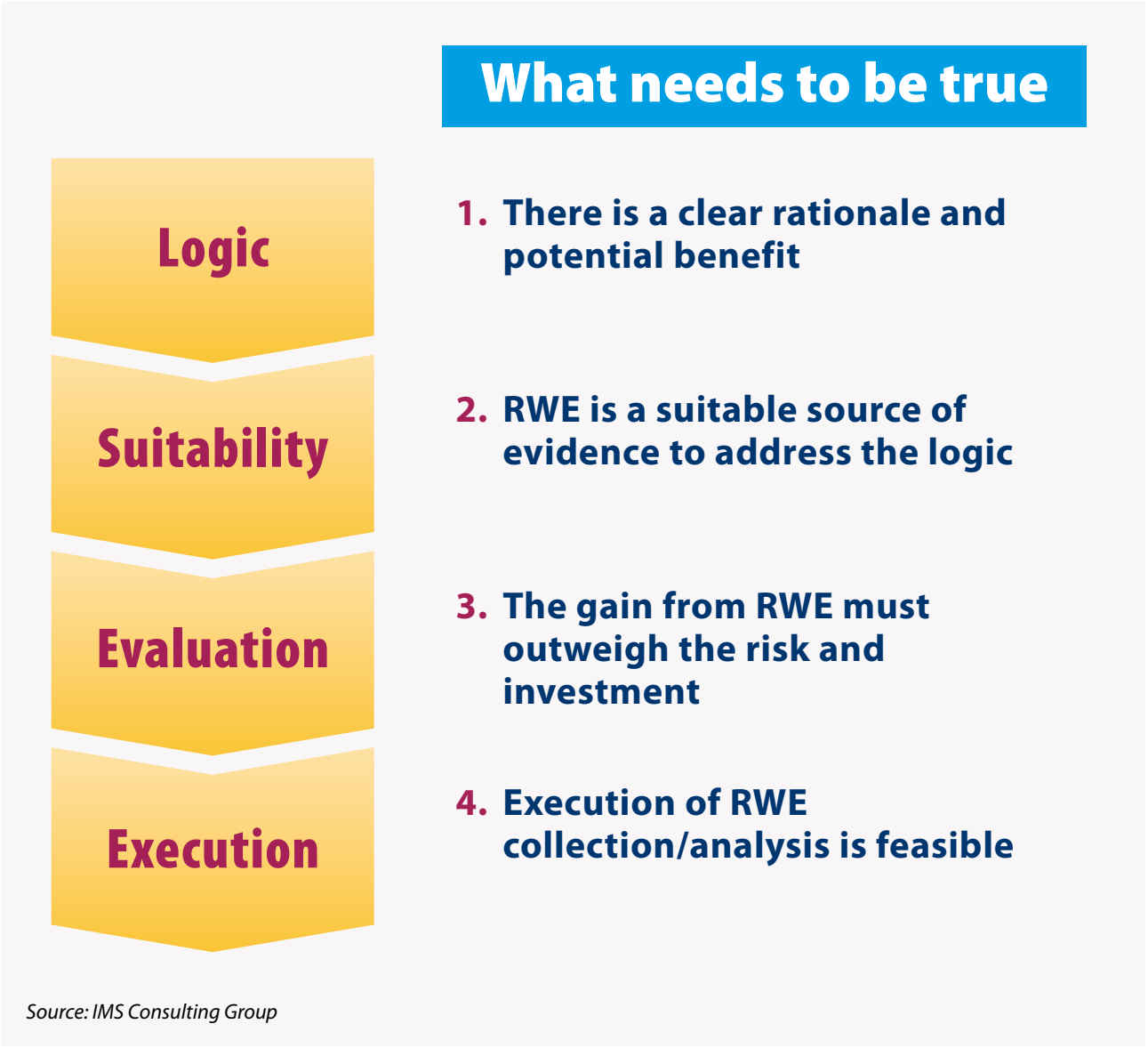
Partnering with payers in disease-related RWD may be a viable option to collect RWD more efficiently, analyze it and ultimately create a body of RWD to support P&MA decisions. Payer partnerships can also improve payer understanding of the disease area, which would otherwise limit P&MA potential; provide the opportunity to establish the manufacturer as a leader in the field; and improve the ability to develop drugs that are clinically and economically viable.

FIGURE 1. CREATING 'LINKED AT SOURCE' DATA VIA PAYER PARTNERSHIPS




*Source: IMS Consulting Group*

FIGURE 2. CHECKLIST BEFORE PROCEEDING WITH A PAYER PARTNERSHIP




*Source: IMS Consulting Group*

It is also pertinent from a pharma-resourcing perspective that payers have different needs for global versus local data. Real-life clinical aspects of existing treatments tend to involve similar patient populations across markets and lend themselves to global acquisition and analysis. However, the economic aspects of existing treatments and pathways vary both within and between countries, putting a premium on more local data sources. Pharma companies should focus on helping with global data as this requires less resourcing, and move towards local data as countries' intrinsic data sources improve.

Before aiming to move forward in partnership, pharma companies must consider the logic, suitability, evaluation of risk versus return and execution of RWE (see Figure 2). Addressing these helps ensure that the basic success factors are in place before a commitment is made. Effort should be invested to ensure these needs are definitely met, rather than taking a compromise approach that is likely to limit the benefit of such an initiative.

## PARTNERING WITH PHARMA: PAYER PERSPECTIVE

The value of pharma to payers in disease-related RWD depends on the sophistication of payers healthcare technology assessment capabilities. The main roles for companies, once a basic infrastructure has been established, are in the collection and analysis of aggregated data and in the distribution of the resulting RWE. To avoid the potential for bias, trusted third party data organizations may be required for the more complex data analytics and to communicate the evidence.

Pharma should also bear in mind that partnering with payers is just one solution to meet the evolving need for RWE. In the longer term, we are aiming to move from a fragmented data market to a one-stop-shop where rich, cross-setting, linked-at-source data is available on demand and at lower cost. The goal of such a scenario is shared by all stakeholders and efforts are ongoing at various levels to make it a reality. Broader collaboration is required between the full range of players, including pan-pharma collaborations and closer interaction between data providers, buyers and sellers.

### WHY SHOULD THIS MATTER TO YOU?

- RWE is increasingly being used by payers to inform P&MA decisions despite the fact that the market for data is still immature, thwarting prompt access to required data sources.
- Pharma companies must anticipate their real-world data needs. Answering the more strategic questions using RWD requires access to rich sources of information, which can typically only be accessed through partnership arrangements.
- Partnering with payers is just one solution to meet the evolving need for RWE.

# Exchanges: Should pharma care?

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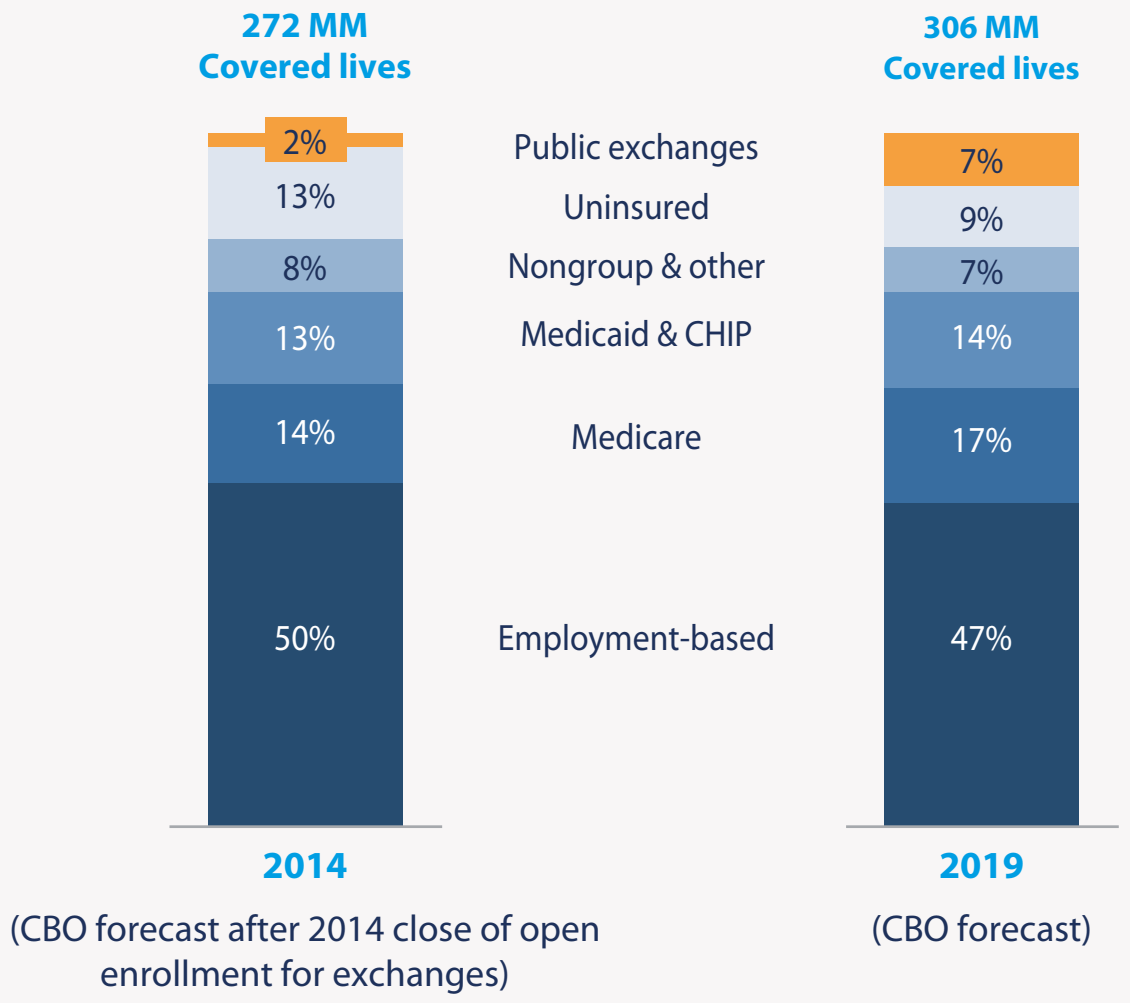
Payers are already using new formulary designs and cost-sharing dynamics in public exchanges and anticipate public exchange plans will accelerate trends for greater cost-shifting and formulary restrictions. For payers that are creating new formularies, there is an opportunity to improve access for products disadvantaged by incumbents with established market share. In the longer term pharma must be alert to signposts that the narrower formularies of exchange plans are gaining traction in traditional health plans.

The launch of public healthcare exchanges has been followed with interest across the United States. With data available for the first complete open enrollment period, IMS Consulting Group initiated research to understand the benefit design and formulary management of these new plans and determine any Pricing & Market Access (P&MA) impact they could have on the pharmaceutical industry. This research looked at public exchange plans, supported by eight one-on-one discussions and a 26-respondent payer survey representing more than 150 million covered lives. In particular, the research focused on the most common exchange tier, the Silver Plans, which pay, on average, 70% of a subscriber's healthcare expenses.

Despite initial technological setbacks that hindered enrollment, the government exceeded its target number of enrollees for the first complete open enrollment period with more than 8 million people and appears on track to eventually cover 24 million lives by 2019. This is, however, just 7% of the total market and roughly half the number covered by Medicaid and Complete Health Improvement Program (CHIP) (see Figure 1).

FIGURE 1. US HEALTH INSURANCE COVERAGE, BY BOOK OF BUSINESS




*Source: DHHS Health Insurance Marketplace Enrollment, Congressional Budget Office, Kaiser Family Foundation*

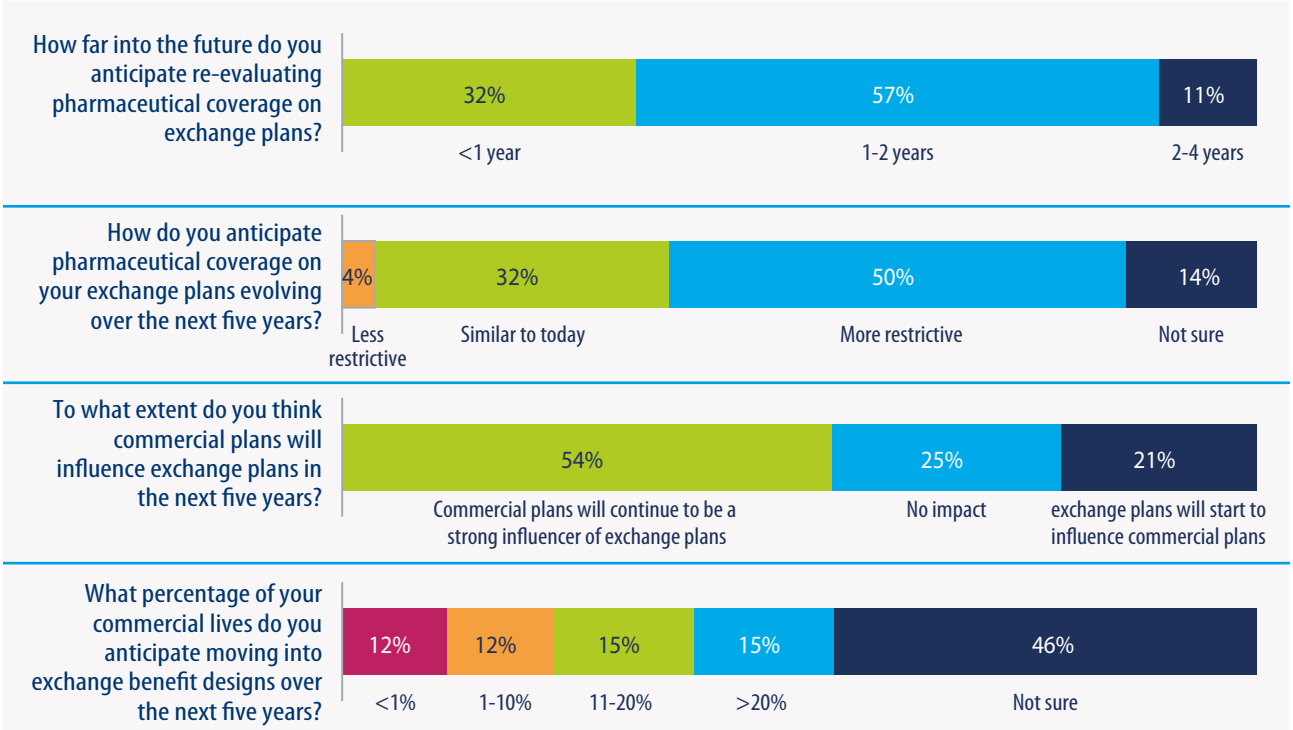
## THREE TYPES OF EXCHANGE PLANS

Our analysis reveals three archetypes of payer in the public exchange market based on shifts from previous practices. The plans of each of these differ based on the degree of cost sharing in both the pharmacy benefit and the formulary design. They are[1]:

- Rebuilders: Comprising 40% of covered lives in the sample, mostly national managed care organizations (MCOs). Their offerings include more aggressive formulary management and increased cost-sharing compared to their commercial plans. The plans have not only shifted more cost to patients but also significantly reorganized the formularies. Some, for example, have shifted certain anti-TNFs to tier four while providing no coverage for others. On cost-sharing, these plans have high co-pays of up to $50 and $100 at tiers two and three respectively, as well as high co-insurance rates of 50% at tiers three and four.

1 *Note: The sample proportions were chosen so as to be reflective of the ratios one would expect for the whole market.*

FIGURE 2. ANTICIPATED FUTURE CHANGES IN EXCHANGE MANAGEMENT




*Source: Payer Survey (n=26)*

- Cost-shifters: Comprising 54% of covered lives in the sample, primarily regional MCOs or pharmacy benefit managers (PBMs). Cost-shifter plans tend to have higher deductibles, co-pays and co-insurance than their commercial offerings. Formulary design tends to remain in line with their commercial plans. This moderate approach aligns with actuarial values required by the Accountable Care Act (ACA), while being designed to temper utilization and adverse selection risks during enrollment. This results in slightly higher co-pays at tier two (capped at $40) and approximately 25% co-insurance at tiers three and four.
- Carry-overs: Comprising 6% of covered lives in the sample, mostly including small, regional MCOs. MCOs of this type offer plans that are almost identical to their commercial ones. They generally cap tier two and three co-pays at $35 and $70 respectively, with the use of co-insurance at tier four. Their general philosophy is one of wait and see, reflecting the high degree of uncertainty about how the exchange marketplace will evolve.

## FUTURE CHANGES IN EXCHANGE MANAGEMENT

While we identified certain payer archetypes in the exchange marketplace, we uncovered a near-term shifting landscape for exchange plans (see Figure 2). A third of payers surveyed anticipated re-evaluating pharmaceutical coverage for exchange plans within a year while another 57% said they will re-evaluate within two years. Furthermore, half the respondents said they believed coverage on their exchange plans would become more restrictive over the next five years, while only 4% said less.

While these findings pertain only to the lives covered by public exchange plans, the most telling finding from our research is that 54% of payers believe such plans will start to influence the design of commercial policies. Further, payers anticipate significant portions of their commercial customers moving into exchange plans over the next five years. Specifically, 15% of payers indicate they expect more than 20% to move over.

Payers agree that exchange plans confirm greater market acceptance of more restrictive plans. And while they admit commercial plans have been heading in this direction, the timeline has certainly been accelerated.

## IMPLICATIONS FOR P&MA STRATEGIES

Given its limited size compared to other streams of business, the public exchange market will have only a limited impact on P&MA opportunities. The more lasting implication, however, may be that a more restrictive management environment is likely to spill over to commercial plans. If enrollment gathers pace and exchange plans become more restrictive, there may be a greater need for detailed account planning and contracting in each state. Furthermore, optimizing exchange access could have direct implications on commercial accounts, driving greater need for synergy and more aggressive contracting to overcome access hurdles in both books of business.

Pharma should take advantage of targeted upsides, such as the chance to gain favorable access in the 'rebuilder' exchange accounts through contracting. These may be unique opportunities for products with traditionally low market share to win greater access. This opportunity is likely to grow as payers re-evaluate their pharmaceutical coverage.

### WHY SHOULD THIS MATTER TO YOU?

- The launch of public exchanges met enrollment targets and, with continued growth, is expected to accelerate general insurance trends toward greater cost shifting and more limited formularies.
- As many as 94% of exchange plans have significantly changed their formulary designs, which pharma can utilize to gain preferential product placement.
- The impact of exchanges does not end with covered lives under their own plans as payers indicate exchange plans will have a growing impact on the design of plans in the larger commercial market.

# Private insurance: An access lever in emerging markets

**AUTHOR**

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Private health insurance (PHI) is an important payer for novel treatments in emerging markets. It is growing rapidly due to economic growth, increased demand and gaps in public coverage. Given these limitations in public funding, governments are encouraging PHI as another source of healthcare financing. Pharma can tap into and expand the PHI opportunity via innovative partnerships, financial agreements and helping develop disease or market-specific PHI products.

## A GROWING SOURCE OF HEALTH SPEND

Private health insurance (PHI) represents an important third source of healthcare spend in emerging markets, alongside public and out-of-pocket spending. Across the key emerging markets, South Africa has the highest proportion of healthcare spend on private insurance, at 45%. In markets such as China, Brazil, Argentina and India, PHI accounts for between 10% and 25% of total healthcare spend (see Figure 1).

PHI is poised to grow with increased healthcare demand, economic growth and inadequate public systems. Looking at Brazil, China, South Africa, India and Mexico, PHI spending is set to increase to $167 billion by 2017. A key reason for such growth is that PHI addresses gaps in public health coverage, such as a lack of quality care and limited benefits.

## DIVERSITY IN TYPES OF PHI

PHI options reflect the type of coverage existing in emerging markets:

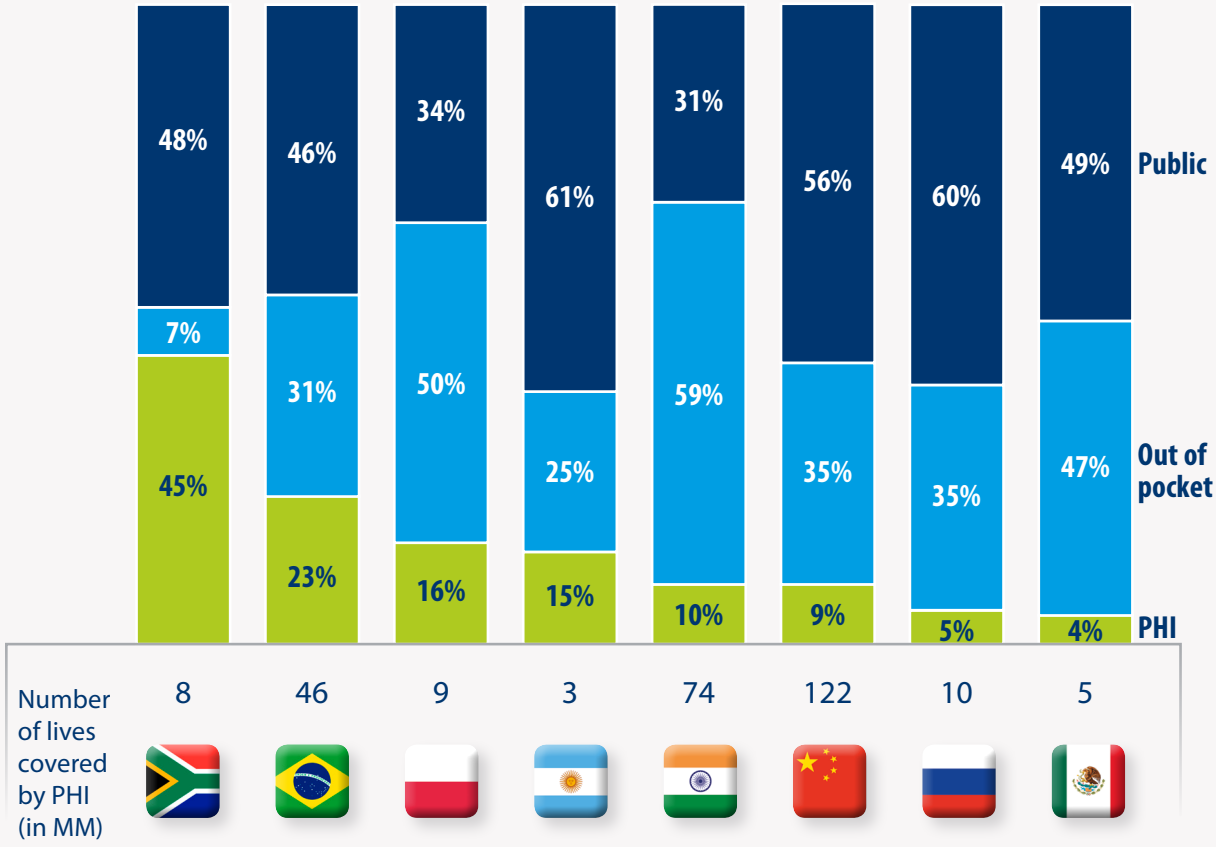
- Primary, covering medical services as a patient's sole insurer (e.g. India)
- Duplicate, providing the same coverage / services offered under the public system (e.g. Brazil)
- Complementary, covering costs beyond those reimbursed by the public system (e.g. China)
- Supplementary, covering treatments not covered by the public system (e.g. South Africa).

Insurance benefit design also varies from fee-for-service reimbursement (Brazil, Mexico, and South Africa) to capped benefits or lump-sum payments (India, China).

## PREMIUM COVERAGE

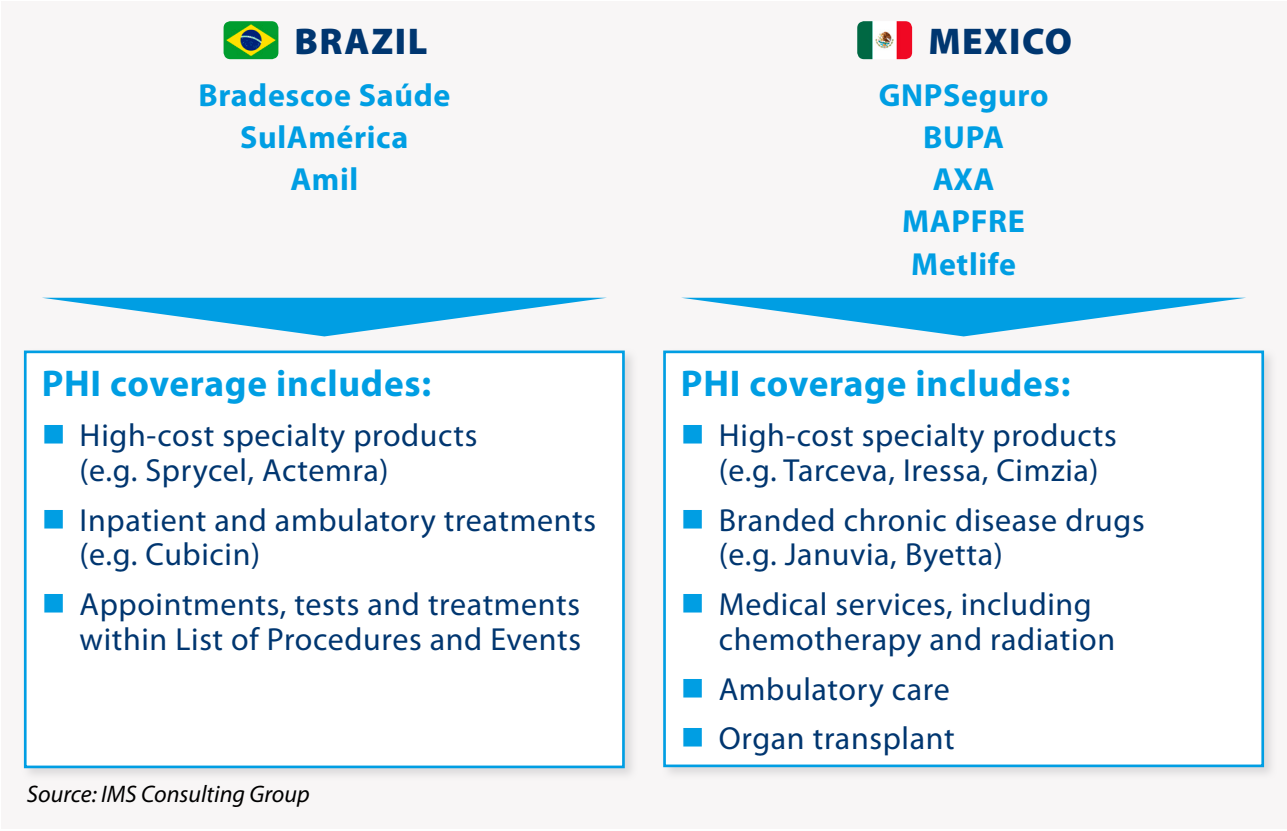
PHI is more likely than other sources of funding to cover premium products. For example, in Mexico and South Africa, PHI includes premium priced specialty products and branded chronic disease drugs not covered by the public systems. Similarly in Brazil, PHI provides shorter waiting times and more comprehensive coverage for some high-cost products (see Figure 2). In China, patients also use PHI to cover the cost of expensive treatments.

FIGURE 1. IMPORTANCE OF PHI IN EMERGING MARKETS




*Source: World Bank*

FIGURE 2. EXAMPLE OF PHI HEALTHCARE COVERAGE IN MEXICO AND BRAZIL




*Source: IMS Consulting Group*

## SEVERAL REMAINING CHALLENGES

Despite the benefits of PHI, several challenges remain. Payers may limit their expenditure by only covering in-patient treatments and/or capping what they spend per patient or treatment. Due to poor or unavailable utilization data, there may be inadequately designed insurance products with insurers either pricing them too high, thereby limiting patient access, or too low, thereby preventing sustainability. Inadequate regulation to address issues of moral hazard, adverse selection as well as lack of coverage of pre-existing conditions can also limit PHI growth. Foreign Direct Investment (FDI) restrictions present another barrier to growth in markets such as China and India.

## GOVERNMENTS ADDRESS CHALLENGES

As governments recognize PHI as an important source of finance, they are instituting reforms to address some of the challenges. For example, in Brazil the government mandated PHI coverage of oral oncology products as well as biologics for some auto-immune diseases such as rheumatoid arthritis. The Chinese government has explicitly stated interest in expanding PHI and putting in place policies to promote it. Some provinces are even partnering with private insurers to help them manage their public coverage. The UAE has mandated coverage of pre-existing conditions along with insurance portability. India is planning to increase the FDI cap on investment in insurance to 49% from 26%. With these reforms, the role of PHI is likely to grow.

## CREATING WIN-WIN SOLUTIONS

The pharmaceutical industry can help address other challenges, especially in terms of understanding utilization and budget impact, to achieve mutually beneficial outcomes. Collaboration with PHI can lead to better designed plan premiums and benefits. For example in China, Roche worked with local insurer CPIC and reinsurer Swiss Re to gather local data and analyze treatment costs. This has enabled Roche to help several major insurers refine insurance product pricing and develop targeted oncology insurance products, setting the example for a new PHI model. Roche has also created awareness and educated different stakeholders of the need for oncology coverage. In addition, it has helped develop programs to provide people with oncology coverage with faster access to care. This has helped grow the number of people seeking oncology insurance, with 20 million oncology insurance policies sold in 2013.

In India, PHI companies work with Third Party Administrators (TPAs) to design caps to control spending. Pharma can help TPAs set the right caps, provide co-pay assistance and also create financial risk shares to limit costs by patient or by the total annual payouts for the drug.

Manufacturers can also partner with private insurers to develop more appropriate insurance products by providing better data. In addition, they can help convince potential subscribers of the value of having PHI. For example, access to premium vaccines may make a policy attractive to families with young children. Similarly, diabetes-specific insurance which provides access to discounted medicines can be attractive to employer groups. On a more general note, pharma can partner to simply create awareness of health risk management, thus increasing the general demand.

Finally, pharma can also partner with insurers and employers to facilitate the creation of employer-sponsored supplemental insurance, especially for high-end employers, as it may help them recruit and retain skilled staff.

In summary, by collaborating with PHI, manufacturers can tap into an additional funding source for their premium products, thereby improving patient access and overall health outcomes in emerging markets.

### WHY SHOULD THIS MATTER TO YOU?

- Private health insurance (PHI) is growing rapidly within emerging markets due to economic growth, increased demand and the public system's inability to meet this growing demand.
- PHI is likely to cover more expensive treatments as lower cost options already affordable or covered are either affordable out of pocket or covered by the public system.
- Pharma should consider new approaches to engage with private health insurers, both expanding coverage for their innovative products and improving the overall health system.

# List price premiums in the US and EU: What are the implications?

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Manufacturers of 2013 launches seem to have succeeded in aligning US and European list prices, achieving more consistent premiums in Europe than in past years (see previous Outlook editions). In large part this is likely due to launches being predominantly in specialty care with high unmet needs and sufficient evidence to back claims. But while EU payers are apparently respecting list price, they are also increasing pressure on the net level. All the while, the public seems to be becoming increasingly aware, and critical, of list price premiums.

## NEW PRODUCT LAUNCHES

Our analysis uncovers an encouraging number of new product launches in 2013, with 24 in the US and 9 in Europe (compared to 10 and 7, respectively, for 2012). This suggests that industry's investment in R&D is paying off. The gap in the number of launches between the US and Europe is likely a result of the continued administrative delays for agreeing prices in Europe, though this is occasionally compensated for by early-access schemes.

## LIST PRICE CONSISTENCY IN SPECIALTY CARE

The historical schism in list price between the US and European markets, at least in specialty areas, appears to be narrowing. In 2013, 19 of 24 launches in the US and 7 of 8 in the EU were in specialty care including oncology, hematology, hepatitis C, HIV and pulmonary arterial hypertension. List premiums pursued in the US were also achieved in the EU. In 2012, in contrast, new launches achieved parity or even discounts in the EU compared to clinical benchmarks.

This apparent list price success in Europe could reflect that the launches were in areas of unmet need and had sufficiently strong value propositions to satisfy EU payer requirements. However, the story is likely to be drastically different at the net level.

FIGURE 1. NME LAUNCHES IN THE EU, 2013

| Brand Name (Generic name) *MNF* | Indication | Therapeutic alternative for same population and line of therapy | Product characteristics: Orphan | Product characteristics: Specialty care | Pricing comparator: Pricing comparator | FR | DK | DE | IT | NL | ES | SE | UK |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Giotrif (Afatinib) *Boehringer Ingel.* | Metastatic non-small cell lung cancer | ✓ | | ✓ | Tarceva (Erlotinib) | | | | | | | | |
| Iclusig (Ponatinib) *Ariad Pharma* | Chronic myeloid leukemia, Philadelphia chromosome positive acute lymphoblastic leukemia | | ✓ | ✓ | Tasigna (Nilotinib) | | | | | | | | |
| Lonequex (Lipegfilgrastim) *Teva* | Neutropenia in patients treated with cytotoxic chemotherapy for malignancy | ✓ | | ✓ | Neulasta (Pegfilgrastim) | | | | | | | | |
| Lyxumia (Lixisenatide) *Sanofi/EurimPharm (DE)* | Type 2 Diabetes Mellitus | ✓ | | | Victoza (Liraglutide) | | | | | | | | |
| Imnovid (Pomalidomide) *Celgene* | Multiple myeloma where disease progressed after other treatments including Velcade and lenalidomide | | ✓ | ✓ | Revlimid (lenalidomide) | | | | | | | | |
| Stivarga (Regorafenib) *Bayer / Baxter (FR)* | Metastatic colorectal cancer for patients who have had or were not candidates for other treatments | | | ✓ | Avastin (Bevacizumab) | | | | | | | | |
| Stribild (Elvitegravir, cobicistat, emtricitabine, tenofovir disoproxil fumarate) *Gilead* | HIV-1 Infection (in combination with other drugs) in antiretroviral treatment-naïve | ✓ | | ✓ | Atripla (Efavirenz, emtricitabine, tenofovir disoproxil fumarate | | | | | | | | |
| Tafinlar (Dabrafenib) *GSK* | Unresectable or metastatic melanoma with BRAF V600E mutation | ✓ | | ✓ | Zelboraf (Vemurafenib) | | | | | | | | |
| Tresiba (Insulin Degludec) *Novo Nordisk* | Diabetes Mellitus | ✓ | | | Lantus (Insulin Glargine) | | | | | | | | |

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

- Country selection was based on EU countries that do not internationally reference price; other European countries directly or indirectly reference these and thus trends will hold true across markets
- Analysis based on new molecular launches from 2013 (01/01/2013 and 12/31/13); Price data obtained for April 2014 for European countries from IMS Pricing Insights
- Molecules without an available therapeutic alternative for the same patient population which were indicated for a later treatment line were compared with established therapeutic option of previous line
- Dosing assumptions
  - Max tolerated dosage was based on median dosages reported in clinical trials
  - For chronic diseases post-titration required dosage per year was calculated
  - 28 day month; 70kg patient; 65kg woman patient; 32kg child patient; 1.7 m2 average body surface (BSA)

*Source: IMS Consulting Group analysis of data from EMA, IMS Pricing Insights, reimbursement and product information reports*

FIGURE 2. NME LAUNCHES IN THE US, 2013

| Brand Name (Generic name) *MNF* | Indication | Therapeutic alternative for same population and line of therapy | Product characteristics: Orphan | Product characteristics: Specialty care | Pricing comparator: Pricing comparator | US |
|---|---|---|---|---|---|---|
| Belviq (Lorcaserin) *Eisai* | Chronic weight management | ✓ | | | Qsymia (Phentermine/ Topiramate) | |
| Breo Ellipta (Fluticasone Furoate, Vilanterol) *GSK* | Chronic obstructive pulmonary disease | ✓ | | | Spiriva (Tiotropium bromide) | |
| Brintellix (Vortioxetine) *Takeda* | Major depressive disorder | ✓ | | | Viibryd (Vilazodone) | |
| Fetzima (Levomilnacipran) *Forest* | Major depressive disorder | ✓ | | | Viibryd (Vilazodone) | |
| Fulyzaq (Crofelemer) *Salix* | Non-infectious diarrhea in adult patients with HIV/AIDS on ART | | | ✓ | Imodium (Loperamide) | |
| Gattex (Teduglutide) *Nps Pharmaceutical* | Short bowel syndrome in patients dependent on parenteral support | ✓ | ✓ | ✓ | Zorbtive (Somatropin) | |
| Gazyva (Obinutuzumab) *Roche* | Chronic lymphocytic leukemia | ✓ | ✓ | ✓ | Rituxan (Rituximab) | |
| Gilotrif (Afatinib) *Boehringer Ingelheim* | Metastatic non-small cell lung cancer | ✓ | ✓ | ✓ | Tarceva (Erlotinib) | |
| Iclusig (Ponatinib) *Ariad Pharma* | Chronic myeloid leukemia, Philadelphia chromosome positive acute lymphoblastic leukemia | | ✓ | ✓ | Tasigna (Nilotinib) | |
| Imbruvica (Ibrutinib) *Pharmacyclics* | Mantle cell lymphoma | ✓ | ✓ | ✓ | Rituxan (Rituximab) | |
| Invokana (Canagliflozin) *Johnson & Johnson* | Type 2 Diabetes Mellitus | ✓ | | | Januvia (Sitagliptin) | |
| Kadcyla (Trastuzumab emtansine) *Roche* | HER2-positive metastatic breast cancer (after treatment with Herceptin and Taxane) | | | ✓ | Herceptin (Trastuzumab) | |
| Kynamro (Mipomersen) *Sanofi* | Homozygous familial hypercholesterolemia | ✓ | ✓ | ✓ | Juxtapid (Lomitapide)# | |
| Mekinist (Trametinib) *GSK* | Unresectable or metastatic melanoma with BRAF V600E or V600K mutations | ✓ | ✓ | ✓ | Zelboraf (Vemurafenib) | |
| Opsumit (Macitentan) *Actelion* | Pulmonary arterial hypertension | ✓ | ✓ | ✓ | Tracleer (Bosentan) | |
| Osphena (Ospemifene) *Shionogi Seiyaku* | Moderate to severe dyspareunia, vulvar and vaginal atrophy in post-menopausal women | ✓ | | ✓ | Premarin (Estrone sulfate, equilin, equilenin) | |
| Pomalyst (Pomalidomide) *Celgene* | Multiple myeloma where disease progressed after other treatments including Velcade and lenalidomide | ✓ | ✓ | ✓ | Kyprolis (Carfilzomib) | |

FIGURE 2. NME LAUNCHES IN THE US, 2013 *continued*

| Brand Name (Generic name) *MNF* | Indication | Therapeutic alternative for same population and line of therapy | Product characteristics: Orphan | Product characteristics: Specialty care | Pricing comparator | US |
|---|---|---|---|---|---|---|
| Ravicti (Glycerol phenylbutyrate) *Hyperion* | Chronic management of adult and pediatric patients with urea cycle disorders | ✓ | ✓ | ✓ | Buphenyl (Sodium phenylbutyrate) | |
| Sovaldi (Sofosbuvir) *Gilead* | Chronic hepatitis C (in combination with other drugs) for genotypes 1, 2, 3 and 4 | ✓ | | ✓ | Incivek (Telaprevir)* | |
| Olysio (Simeprevir)~ *Johnson & Johnson* | Chronic hepatitis C (in combination with other drugs) for genotypes 1 | ✓ | | ✓ | Incivek (Telaprevir)* | |
| Stivarga (Regorafenib) *Bayer* | Metastatic colorectal cancer for patients who have had or were not candidates for other treatments | | ✓ | ✓ | Avastin (Bevacizumab) | |
| Stribild (Elvitegravir, cobicistat, emtricitabine, tenofovir disoproxil fumarate) *Gilead* | HIV-1 Infection (in combination with other drugs) in antiretroviral treatment-naïve | ✓ | | ✓ | Atripla (Efavirenz, emtricitabine, tenofovir disoproxil fumarate | |
| Tafinlar (Dabrafenib) *GSK* | Unresectable or metastatic melanoma with BRAF V600E mutation | ✓ | ✓ | ✓ | Zelboraf (Vemurafenib) | |
| Tivicay (Dolutegravir) *GSK* | HIV-1 Infection (in combination with other drugs) | ✓ | | ✓ | Isentress (Raltegravir) | |
| Xeljanz (Tofacitinib) *Pfizer* | Active rheumatoid arthritis (patients who have had inadequate response or intolerance to methotrexate) | ✓ | | ✓ | Humira (Adalimumab) | |
| Xofigo (Radium-233) *Bayer* | Castration-resistant prostate cancer | ✓ | | ✓ | Zytiga (Abiraterone Acetate) | |

~Treatment cost includes 12 weeks worth of follow-on cost for treatment with peginterferon alfa-2a and ribavirin

*Treatment cost includes 36 weeks worth of follow-on cost for treatment with peginterferon alfa-2a and ribavirin

#Juxtapid dosing regimen is highly variable reflective of varying tolerability amongst patients; From clinical trials we assumed an average tolerable

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

- Analysis based on new molecular launches from 2013 (01/01/2013 and 12/31/13)
- Price data for new molecule from time of launch for US; for comparator from time of launch of new molecule; Pricing data were obtained from IMS Pricing Insights
- Molecules without an available therapeutic alternative for the same patient population which were indicated for a later treatment line were compared with established therapeutic option of previous line
- Dosing assumptions
  - Max tolerated dosage was based on median dosages reported in clinical trials
  - For chronic diseases post-titration required dosage per year was calculated
  - 28 day month; 70kg patient; 65kg woman patient; 32kg child patient; 1.7 m2 average body surface (BSA)

*Source: IMS Consulting Group analysis of data from FDA, IMS Pricing Insights and product information reports*

## LIST PRICE RESILIENCE IN PRIMARY CARE

In primary care, the historical schism in pricing strategies across the Atlantic cannot be confirmed because of a lack of examples (none of the 2013 launches in the US launched in Europe that year).

Having said that, list premiums have been achieved for most primary care launches even in areas with strong competition and perceived low unmet need. Diabetes is a good example. In Europe, Tresiba (insulin degludec, type 2 diabetes) achieved premiums based on improvement in hypoglycemic events. In the US, Invokana (canagliflozin, type 2 diabetes) launched at a low premium to DPP-IVs as the first SGLT2 inhibitor.

## LIST PRICE IS NOT THE KEY TO COMMERCIAL SUCCESS

But list price success is not necessarily a measure of Pricing & Market Access (P&MA) success as net price, time to access and uptake are becoming more important considerations for the bottom line.

In Europe, this applies to both specialty and primary care areas. In the UK, for example, nearly all the 2013 launches are subject to a national level discount, either through a patient access scheme or the Cancer Drugs Fund. The exceptions are two primary care products, Lonequex for nutropenia and Lyxumia for type 2 diabetes, which were already at list parity or discount. So though payers appear to be respecting manufacturer concerns on international reference pricing, net price pressure is an enduring and perhaps intensifying challenge in Europe.

In the US, the list price (at premium, parity or discount) is becoming less of a predictor of commercial success due to intensifying net price pressure, mostly in primary care. Breo Ellipta (fluticasone furoate and vilanterol) for COPD launched at parity with price comparator Spiriva, but has fallen behind consensus forecasts. Despite net price discounts of up to 41% (analyst estimates[1]), some payers have denied coverage. Specialty care may also soon see increasing use of new pricing models with increasing numbers of highly innovative new products.

## BUDGET IMPACT

Net price pressure is driven by budget impact concerns. While a perennial theme in Europe, it is now increasingly relevant in the US. The launch of Sovaldi for hepatitis C (HCV) set off alarm bells with $2.3B US sales in the first quarter of 2014 and $3.5B in the second.

This reflected an unprecedented level of demand, as patients previously delaying treatment because of concerns about the severe side effects associated with available alternative suddenly appeared in their physicians' offices. The cost of a course of Sovaldi-based treatment is comparable to that of its comparator for genotype 1 patients, Incivek (telaprevir), and is in

1 http://www.fiercepharmamarketing.com/story/why-are-anoro-and-breo-slow-starters-gsks-new-quota-free-model-critics-say/2014-07-29

line with or lower than initial payer expectations. Payers, however, were caught off guard by the speed and level of uptake. Incivek has been completely displaced and will be withdrawn by October 2014.

Given the extraordinary demand – Sovaldi is now the most successful launch in history – many payers have sought to restrict Sovaldi use. For example, several US Medicaid programs – already the beneficiaries of mandatory 23.1% discounts[2] – have prioritized it for patients with advanced liver disease and those diagnosed with concomitant conditions like HIV. In August, the Association for the Advancement of the Study of Liver Diseases (AASLD) updated its guidelines to provide clinical support for this approach. Even some commercial payers have imposed access restrictions.

Notwithstanding Sovaldi's groundbreaking efficacy – in trials it cured over 90% of GT-1 patients in 12 weeks, with minimal side effects -- its price tag of $1000 per pill has functioned as a compelling headline in media stories calling into question the lack of price controls. Though legislative change is unlikely, public awareness and critique of list prices seems likely to continue, particularly for products that offer a less obviously compelling value proposition than Sovaldi.

European payers, meanwhile, have more tools to dampen the budget impact of Sovaldi. These include restricting the eligible patient population at national or regional level. Even then, Sovaldi is a potential accelerator of policy change. French payers in particular have suggested cross-country procurement of Sovaldi, an unprecedented move to enhance bargaining power.

In conclusion, payers seem to have been forgiving on list prices of 2013 launches, most achieving consistent premiums across the Atlantic. However, the relevance of a list price premium for commercial success and uptake is diminishing. As payers increase net price pressure, high profile launches like Sovaldi have sparked increasing public scrutiny of list price.

## WHY SHOULD THIS MATTER TO YOU?

- 2013 was a successful year for achieving premium list prices in Europe and greater consistency with the US than in previous years.
- The new products were predominantly in specialty care, partly explaining this consistency.
- List prices are becoming less pertinent to success as pressure on net prices makes them increasingly opaque, especially in the EU.
- US premiums may come at an access or perception disadvantage, especially in primary care but also in some specialty care areas.
- The public is becoming increasingly aware of list price, which may be a worrying change for pharma, particularly in the US.

2 http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Prescription-Drugs/Medicaid-Drug-Rebate-Program.html

# Payment by use: A new value paradigm for oncology

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Continued innovation in oncology is driving the use of drugs in sequential or combination regimes that leads to potentially unsustainable budget impacts and confusion about the value each agent contributes to patient outcomes. A payment by use approach addresses this issue by providing a platform for creating a more balanced delivery of value, based on a new model of collaborative engagement between industry and payers.

## MISALIGNMENT BETWEEN PRICE AND VALUE

Setting pharmaceutical prices is highly product centric: one price for one product, with variations dependent on dosing, formulation, etc. As it is challenging to redefine price with subsequent indications, lifecycle development can result in a growing mismatch between the original price and the clinical value delivered.

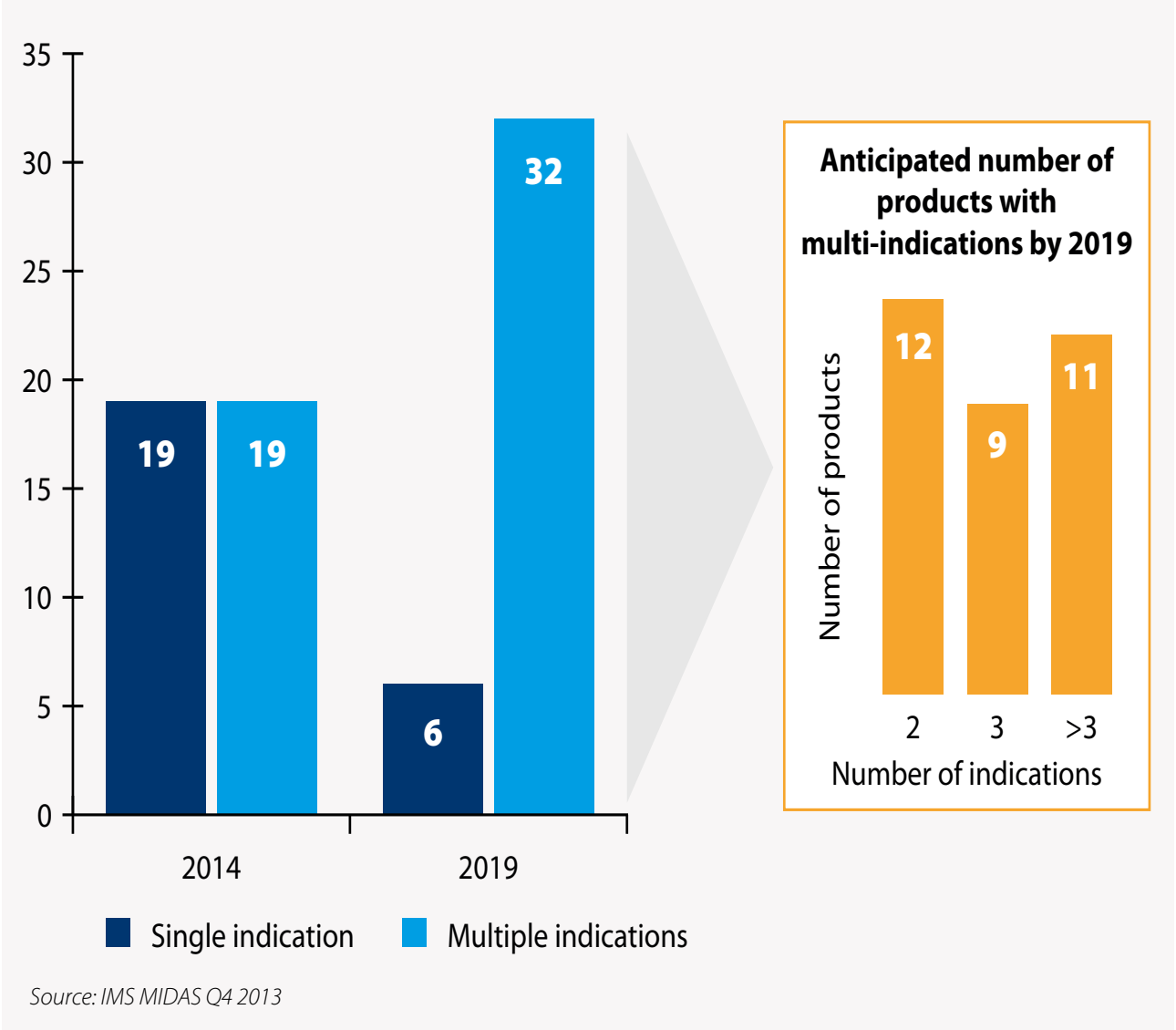
A product may be priced at a payer-acceptable level given its clinical value or cost-effectiveness in one indication. However, when expanded into another indication (e.g. tumor type), it may not. Maintaining the price for one indication can prohibit access for another; reducing it could diminish the revenue where value has been established.

The situation will only intensify as more new treatments target multiple tumor indications. In Europe, 50% of leading oncologics are currently licensed for more than one oncology indication; by 2019, more than 80% are anticipated to have multiple indications (see Figure 1). Failure to address these issues will accelerate moves to introduce even more severe measures to limit patient access.

## CURRENT APPROACHES

Traditional pricing approaches and innovative contracting have circled around the problem, but few have addressed it head-on. Attempts by payers to tackle the cost of oncology drugs have centered on guidelines and usage agreements. Pharma companies have experimented with innovative contracting and pricing schemes but with limited success.

FIGURE 1. IN EUROPE, MORE THAN 80% OF LEADING ONCOLOGICS WILL HAVE MULTIPLE INDICATIONS BY 2019




*Source: IMS MIDAS Q4 2013*

One of the key reasons no solutions have emerged has been a failure to recognize the core capability required: a real-time understanding of exactly how oncology products are being used in clinical practice, by line of therapy, tumor type and dosage.

## PAYMENT BY USE

Payment by use (PbyU) offers a potential solution because it provides a real-time understanding of exactly how oncology products are being used in clinical practice. This capability would allow us to set prices for new products as a function of their actual use (tumor type, line of therapy), and would thus allow multiple price points for a single product. PbyU would establish the knowledge base on which to build more adapted pricing schemes, such as new forms of performance or outcomes-based schemes (see Figure 2).

## CHALLENGES

Already, there has been some progress towards implementing PbyU by individual actors within the industry; the approach is actively being discussed or even piloted by a number of top ten manufacturers. However, several factors suggest the need for a pan-industry approach to what is a major paradigm shift:

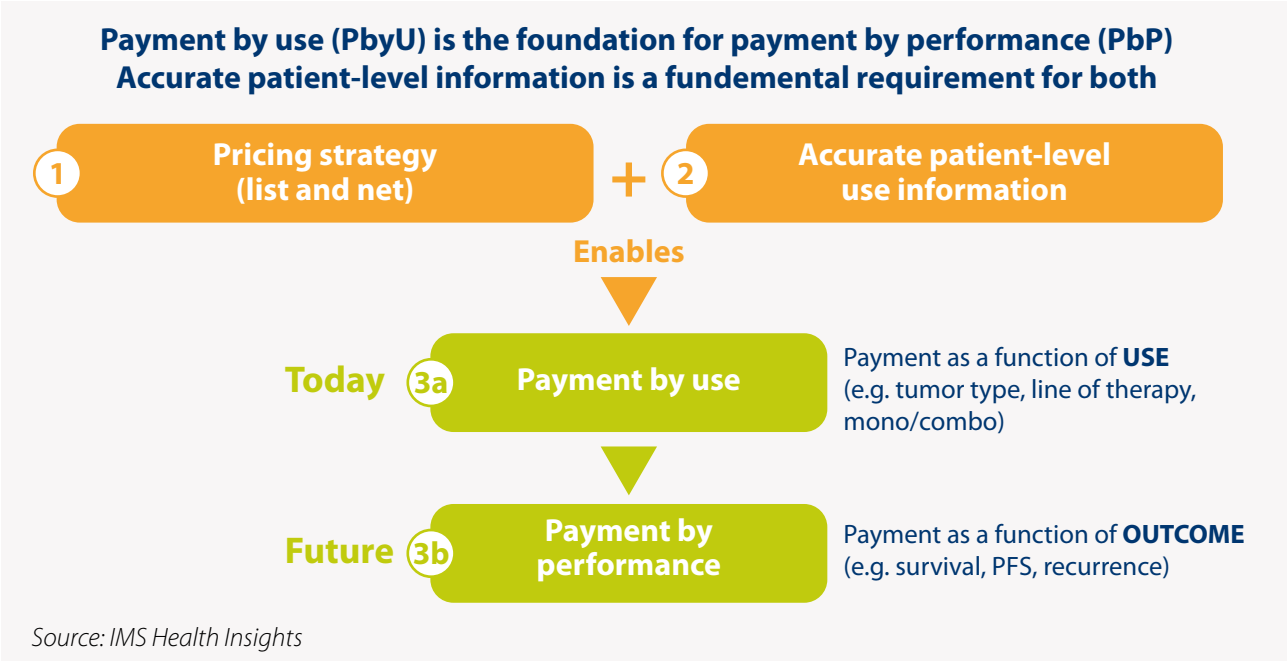
- Creating a 'win-win' with payers
- Ensuring perceived fairness for all stakeholders
- Financing the cost of gathering and managing the data
- Enabling independent information governance.

## PROGRAM SYSTEM REQUIREMENTS

With a unified strategy, the linking of clinical data with information on drug consumption is achievable. But establishing a viable PbyU system requires a coordinated, trusted system, bringing together four components:

1. **An oncology dataset** based on the systematic collection of healthcare and treatment information, ideally at a national level, covering all treated cancer patients.
2. **A trusted third-party aggregator** to de-identify and manage the data.
3. **Clear governance** of the information and rules regarding the access rights of different user types with appropriate safeguards to ensure patient anonymity.
4. **Practical application of the data** to support both the scientific and medical community as well as payers and suppliers.

FIGURE 2. BUILDING BLOCKS UNDERPINNING INNOVATIVE CONTRACTING IN ONCOLOGY




*Source: IMS Health Insights*

## IMPLICATIONS

The establishment of a PbyU system raises a number of practical issues. Industry as a whole will have to grapple with key questions in relation to:

- Identifying the necessary capabilities and assets, and agreeing which party will be responsible for their development
- Determining the right starting point for the implementation of PbyU with regard to product and territory, and planning how to build on that to deliver value over the next 2-5 years
- Incorporating all providers/payers in a market into a single system
- Determining the steps within and across different countries
- Running new and old systems in parallel mid-term
- Working with payers to demonstrate accuracy and value.

## CONCLUSIONS

The assumption of high prices and high rewards in oncology is giving way to a world where product use is based not on price maximization but on ensuring financial reward for the right product in the right indication and at an economic value that expands access to more patients. While these near-term benefits are clear to all parties, the implications downstream are less certain. However, building such an infrastructure should be a strategic priority for the healthcare industry to establish more sophisticated, sustainable, outcomes-based pricing in the future.

## WHICH PRODUCT TYPES BENEFIT FROM PbyU?

PbyU has particular applicability for products where the value:

- Differs by indication
- Depends on different dosing in different indications or patients
- Changes depending on what drugs it is combined with
- Carries a high risk of off-label or experimental use
- Has secured a relatively high price.

## WHY SHOULD THIS MATTER TO YOU?

- The emergence of novel products with multiple indications and significant budget impact will likely lead to a mismatch between price and value in different tumor types, that may result in more draconian access restrictions.
- PbyU approach offers a potential solution by determining a price based on how a drug is actually used in a specific setting.
- The infrastructure for enabling PbyU requires a collaborative industry-payer approach to harness a real-time understanding of how oncology products are used by line of therapy, tumor type and dosage.

# Opportunity hidden in plain sight: A return to primary care

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Although pharma's interest has shifted toward specialty care in recent years, primary care continues to present substantial opportunities for success if manufacturers implement strategies to optimize the Pricing & Market Access (P&MA) potential of their investments. Through an analysis of primary care disease areas, IMS Consulting Group has designed a framework to help pharma prioritize key P&MA hurdles and the levers necessary for future success.

It is no secret that in recent years there has been strong interest in specialty care in light of strong global growth and relatively lower payer management. Nonetheless, most companies continue to rely on primary care, which will still comprise the majority (~55%) of global prescription sales in 2017.[1] Moreover, primary care still has many untapped clinical needs, reflected by heavy investments in dyslipidemia (CETP inhibitors, PCSK9s) and disease-modifying therapies for Alzheimer's disease, amongst others. It is also clear that capturing value in primary care is increasingly challenging and attention to payer needs will be critical to continued success. IMS Consulting Group has segmented primary care into four categories to provide the industry with a roadmap for optimizing future P&MA potential. Our framework focuses on three key primary care levers – market definition, evidence generation, and pricing strategy – with varying levels of need. The path to success will be tough, but early and proactive market access efforts can lead to more targeted investment and a more achievable commercial opportunity at launch.

Through an analysis of primary care therapy areas, IMS Consulting Group has identified two critical factors that challenge payer management: disease nature and degree of disease fragmentation. Diseases that worsen with time typically require a more expansive set of clinical options to address the worsening symptoms and counter the underlying biological changes. Similarly, conditions with unique population segments create opportunities for

1 *Primary care therapies are defined here as those traditionally prescribed by primary care physicians*

new treatment algorithms for sub-components of the market. Both the disease nature and level of fragmentation influence the potential and severity of payer management.

Our disease framework (see Figure 1) conveys the challenges that must be addressed to deliver on the therapy area value, as opposed to highlighting commercial potential. The positions of disease areas in this framework are based on the current state but may shift with advances in science.[2]

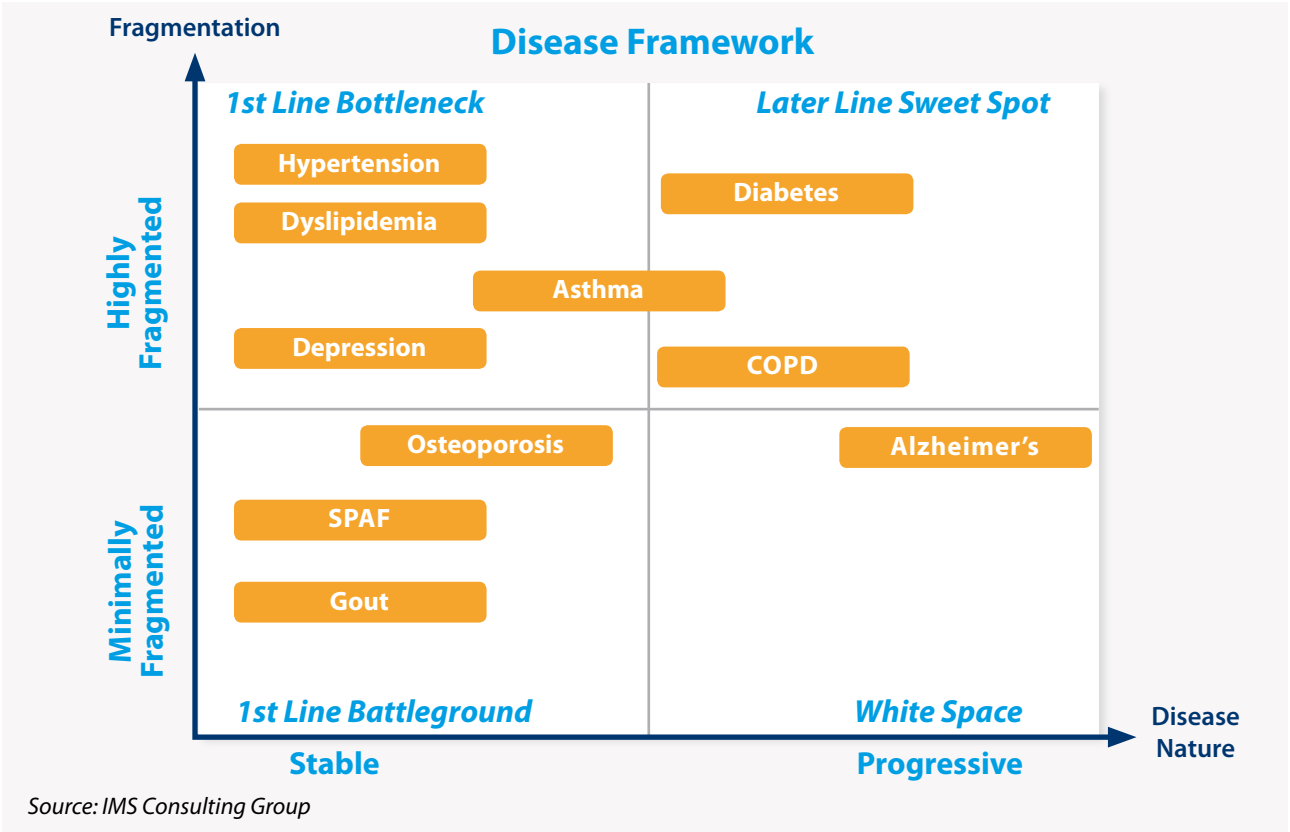
**Later Line Sweet Spot**: Characterized by remaining unmet need due to the progressive nature of the disease, predefined market segments creating clear entry points for new agents, as well as potential for entrenched competition.

**1st Line Battleground**: Stable and relatively homogenous population, typically well-served by generics, creating significant hurdles for 1st line access.

**1st Line Bottleneck**: Characterized by large 1st line population with distinct sub-populations, but potential for underserved 2nd line populations.

**White Space**: High unmet need due to few clearly defined population segments potentially resulting from gaps in science and continued disease progression.

FIGURE 1: DISEASE AREA FRAMEWORK




*Source: IMS Consulting Group*

2 *This article does not explicitly address the nature of competition in disease area markets*

For the majority of primary care conditions, easy access to competitive and effective low-cost therapies is the obstacle. Three key levers are then critical to unlocking the commercial potential: market definition, evidence generation and strategic pricing.

## MARKET DEFINITION

Market definition is the challenge of characterizing the suitable patient population. Especially high barriers exist where the market is minimally fragmented at the time of launch, requiring strong investment by manufacturers to educate stakeholders (physicians, payers, patients) on the appropriate patient segments. Such efforts, however, create a discernible and quantifiable sub-population with well documented unmet need, potentially supported with economic justification that can be advocated by both physicians and patients alike. Retrospective and observational real-world evidence studies at the market level, published literature and local advocacy data can all be employed to crystallize distinct patient segments that are currently underserved.

## EVIDENCE GENERATION

The second P&MA hurdle to consider is evidence generation, which involves building supporting claims of meaningful differentiation over competitor products. Non-fragmented markets cannot be penetrated without transformative and clinically differentiated data demonstrated through, for example, a disease-modification designation, head-to-head trial design and/or long-term clinical outcome endpoints. For example, in the case of gout medication Uloric, a large investment in market education, coupled with demonstrated superiority in head-to-head trials prior to launch, allowed Uloric to successfully capture market share from high-dose generic allopurinol. Uloric's sales performance may or may not have met initial corporate expectations but arguably has performed well based on this revised understanding of the market at launch. Progressive diseases typically have a moderately lower bar primarily due to the implicit understanding that the disease is currently inadequately served.

## PRICING STRATEGIES

Finally, pricing strategies should account for market dynamics driven by competition and clinical differentiation within a given target population. Greater pricing flexibility exists in the later-line treatment segment within a fragmented disease category. Within hypercholesterolemia, for example, payers are likely to be moderately less sensitive to anticipated PCSK9 entrants given use in a newly defined 2$^{nd}$ line-plus patient segment, with potentially significant improvements. By contrast, newer osteoporosis agents in the White Space targeted the broader market and have been constrained by very competitive pricing. Price sensitivity can potentially be mitigated with more novel approaches that focus on 'beyond the pill' solutions (see page 20), partnerships, and outcomes-based contracting. Proactive integration of these strategies in the product development program should improve the success rate of such strategies.

FIGURE 2: P&MA HURDLES AND DEGREE OF CHALLENGE BY FRAMEWORK QUADRANT

| | 1st Line Battleground | 1st Line Bottleneck | White Space | Later Line Sweet Spot |
|---|---|---|---|---|
| Disease Nature | Stable | Stable | Progressive | Progressive |
| Fragmentation | Minimal | High | Minimal | High |
| Market Definition | H | M | H | M |
| Evidence Generation | H | H | M | H |
| Pricing Barriers | H | M | M H | M H |

*IMS Consulting Group*

Figure 2 delineates the importance of each of the three key levers in setting market expectations for primary care products.

In summary, product teams that integrate realistic expectations of likely future payer hurdles early into development plans will be more prepared to uncover solutions that can set the foundation for future P&MA and commercial success.

## WHY SHOULD THIS MATTER TO YOU?

- Despite the recent shift in focus and investment toward specialty care, primary care remains a promising area for pharmaceutical investment.
- In order to optimize the P&MA potential of drugs entering the market, pharma should consider the implications of the nature of the disease and its degree of fragmentation on likely payer management.
- Dependent on the intersection of these two factors, the P&MA levers of appropriately defining the market, generating evidence and pricing optimally can be approached in different ways to promote commercial success.

# Mind the gap: Expectation versus reality in the EU biosimilar market

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The biosimilars market has fallen short of expectations in the past. Now, with €38 billion worth of biologics coming off patent by 2020, hopes are rising once again. This time, however, they are tempered by greater knowledge of how different therapeutic areas respond to these products and the degree of expected competition from new players and originator companies. This enables a more realistic appraisal of their prospects to inform better decision-making.

## BIOSIMILARS IN EUROPE

Since the European Medicines Agency approved its first biosimilar in 2006, there are now 21 such products on the market in four classes. In three of these, biosimilars are relatively well established. However, their performance has been mixed and analysis shows reasons that span from the type of competition to the treatment paradigm, and from the sales channel through to the distribution channel.

Moreover, the value of the biosimilar market, when compared with other biologic sectors, has been relatively modest. Despite this, there is enormous interest in its future performance, not least because there will be 11 major loss-of-expiry events worth approximately €38 billion between now and 2020.

Today a whole raft of originator and biosimilar-specific manufacturers are moving into the markets for such top-selling drugs as Humira, Enbrel, Remicade, Avastin and Herceptin.

## A CHANGING MARKET

However, we have been here before. Forecasting in the biosimilar space does not have the best track record with previous estimates having been wildly optimistic. The total value of the EU market was predicted to reach €12 billion by 2011, for example, whereas the actual figure was €2.6 billion.

There are three factors that suggest things will be very different with the next wave of biosimilars.

1. **Future biosimilars are more important from both a clinical and value point of view than their predecessors**
   - Driver of uptake: The future biosimilars have a higher value and more prominent position in treatment pathways
   - Restraint to uptake: Greater sensitivity around their use by clinicians.
2. **The competitive dynamics are becoming more intense**
   - Driver of uptake: A considerable number of biosimilar companies chasing the future opportunity
   - Restraint to uptake: Innovator companies have more to lose and are expected to compete more aggressively.
3. **Payer expertise with biosimilars has increased**
   - Driver of uptake: Payers have more sophisticated tools, mechanisms and experience with which to assess biosimilars
   - Restraint to uptake: Current mechanisms may still not be sufficient to change prescriber behavior.

## MARKET EXPECTATIONS

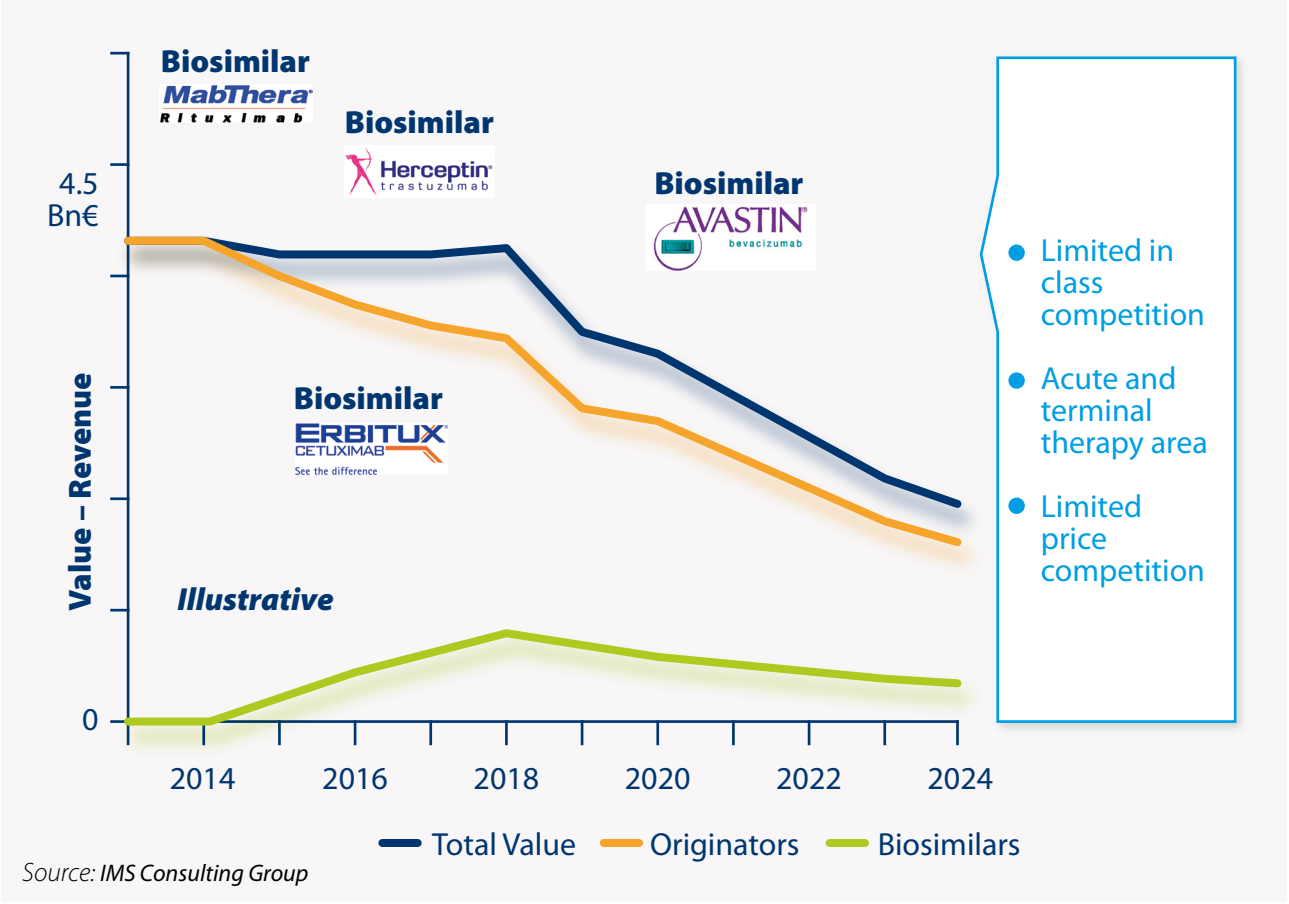
Based on these combinations of factors we envision two possible future situations.

**Situation 1: Biosimilar Resistant** (see Figure 1). This is characterized as a high-value therapeutic area with a degree of physician sensitivity around biosimilar use. It is a non-commoditized market with a relatively limited number of originator and biosimilar competitors and few effective payer mechanisms in place to drive use. A classic example would be the oncology market.

**Situation 2: Biosimilar Acceptant** (see Figure 2). This is characterized as a high-value therapeutic area with relatively limited physician sensitivity around biosimilar use. It has a significant degree of biosimilar and non-biosimilar competition meaning it is potentially a commoditized market and there are effective payer mechanisms in place to drive use. An example would be the market for rheumatoid arthritis where six major products will lose exclusivity by 2020, attracting competition from both new and established players, several new products and therefore a sharper fall in price than in a less commoditized market.

Although the value of the market will decrease in both situations, the actual outcomes for the biosimilar and originator manufacturers will vary in terms of value, volume and rate of change.

FIGURE 1. SITUATION 1: BIOSIMILAR RESISTANT: EVOLUTION OF BIOSIMILAR MARKET IN ACUTE AND TERMINAL CONDITIONS




*Source: IMS Consulting Group*

## MIND THE GAP

Simply knowing that the gap between headline expectations about the value of the market and the modeled reality is different and varies across therapeutic areas is not sufficient.

The question is how big will that gap be in specific markets because the larger the difference between expectation and reality, the greater the pressure on stakeholders to deliver in challenging environments.

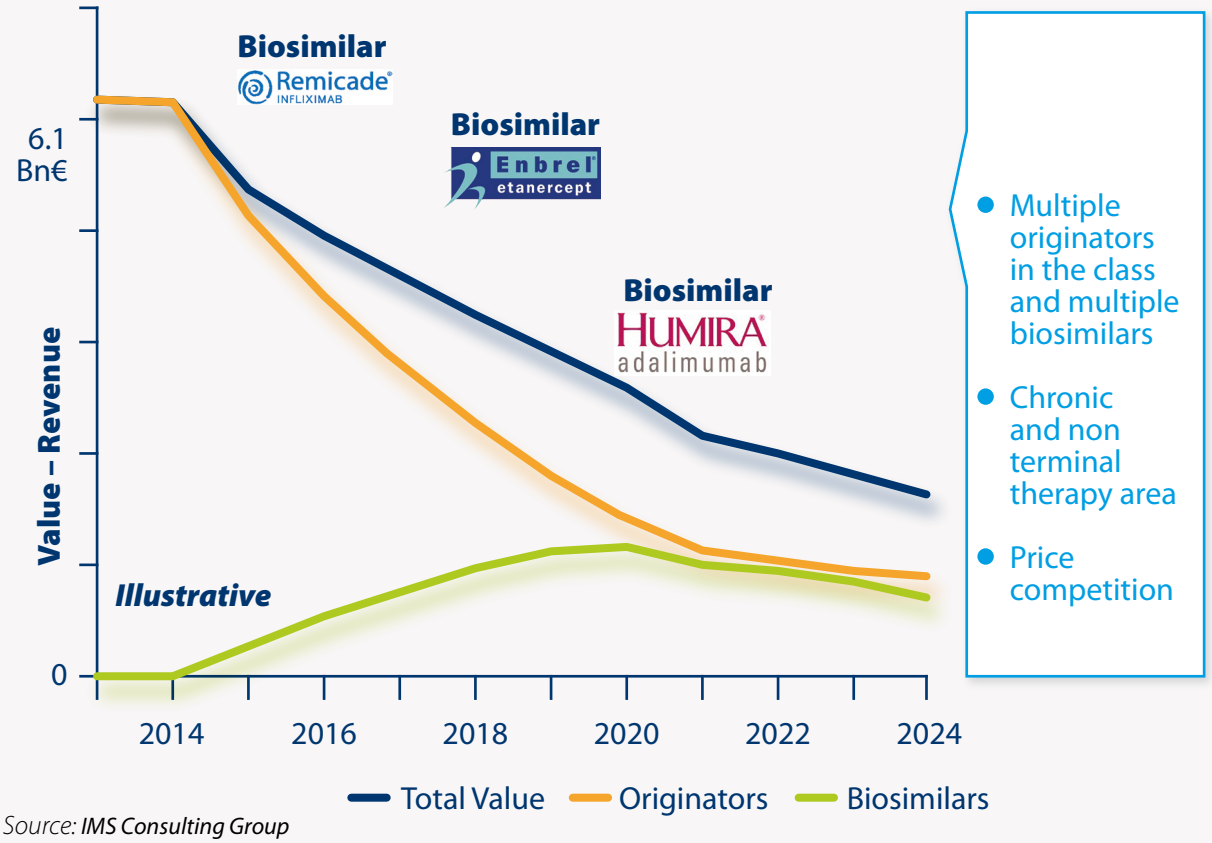
To minimize the gap and maximize the potential value to be realized, manufacturers will need to do three things:

1. **Define realistic goals:** Take an objective view of the market and define success in a realistic manner. Make sure that business assumptions and market value are realistically represented.

2. **Develop a new business approach:** Companies will need to combine generic and innovative-like behaviors such as rapid decision-making to capitalize on marginal cost advantages combined with relatively sophisticated clinical messaging, especially in the case of low physician sensitivity.

3. **Understand the therapeutic area:** There is no one size fits all approach to biosimilars. Each will require specific strategies to target the right stakeholders and deploy the right messaging.

FIGURE 2. SITUATION 2: BIOSIMILAR ACCEPTANT: EVOLUTION OF BIOSIMILAR MARKET IN CHRONIC AND NON-TERMINAL CONDITIONS




*Source: IMS Consulting Group*

## WHY SHOULD THIS MATTER TO YOU?

- There is a lot of hype around the future biosimilar market but historically the opportunity has been overestimated. Why should the estimates this time be different and why does it matter? Misaligned expectations drive investment based on unrealistic returns, creating the perfect environment for sub-optimal decision-making.
- Understanding the drivers of future opportunities, and how they are nuanced across therapeutic areas, helps prepare for and defend against biosimilar entry.
- IMS Consulting Group has modeled potential market scenarios to help prospective players understand the opportunity and plan for the future.

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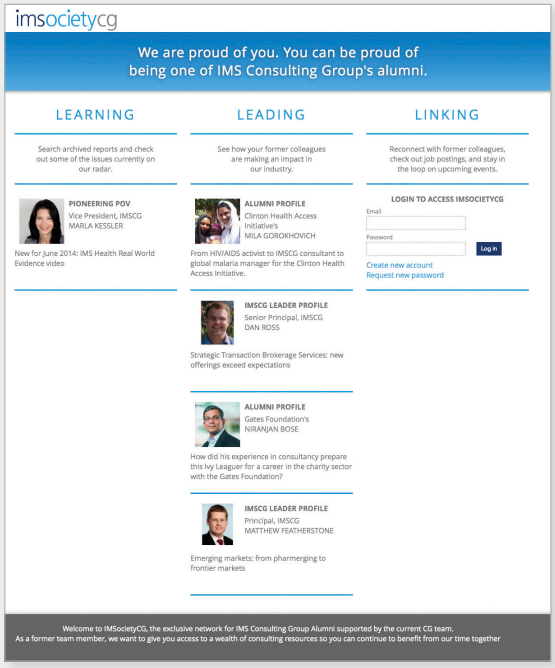


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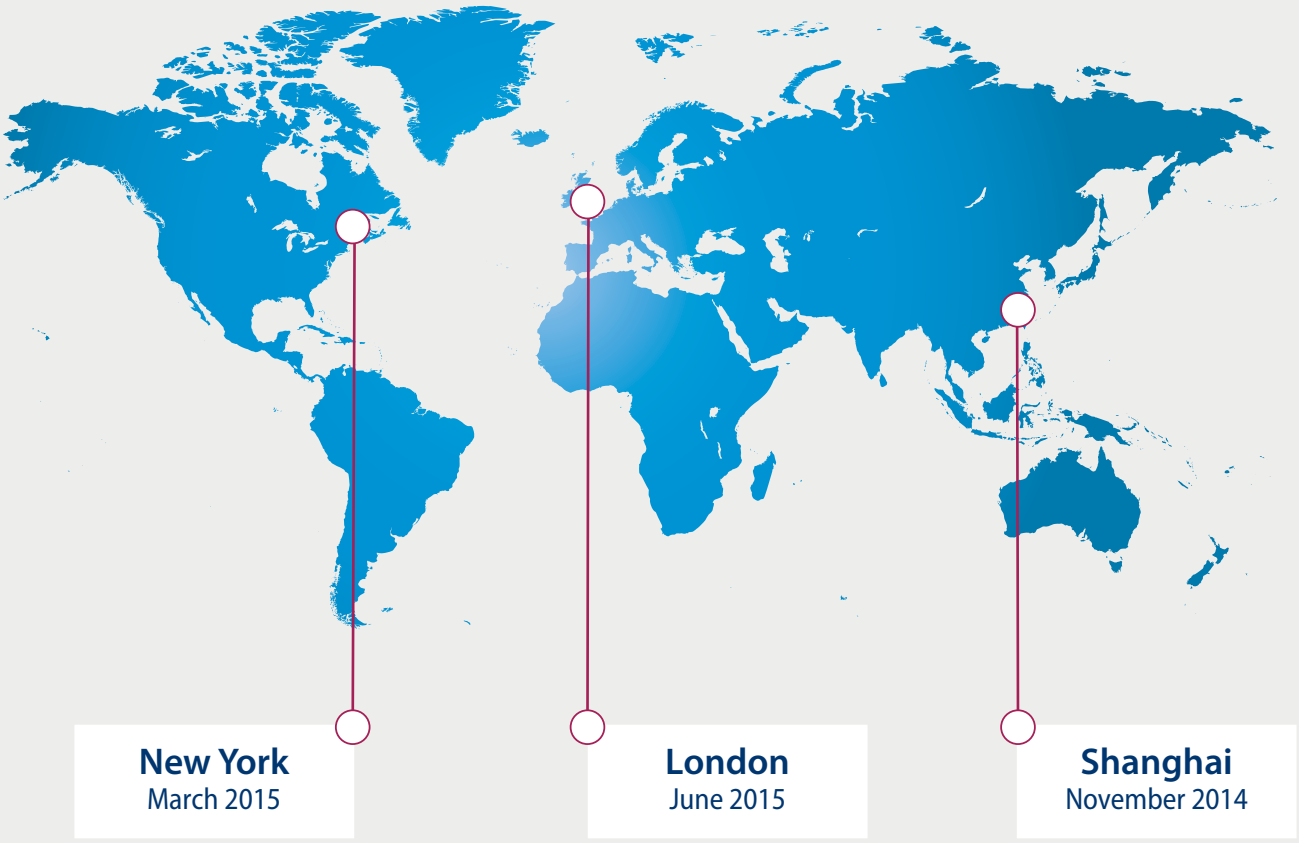


More details will be communicated about these important events.
If you would like to receive an invitation to any of these conferences, please reach out to your local IMSCG team or email us at **contactus@imscg.com**

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We believe we can help pioneer new approaches to healthcare by understanding and challenging current pathways. Our senior team is intimately involved in every project, which means that clients partner with the people who create and propose the work we do at every stage of the process. Seniors do not merely steward, they do.

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