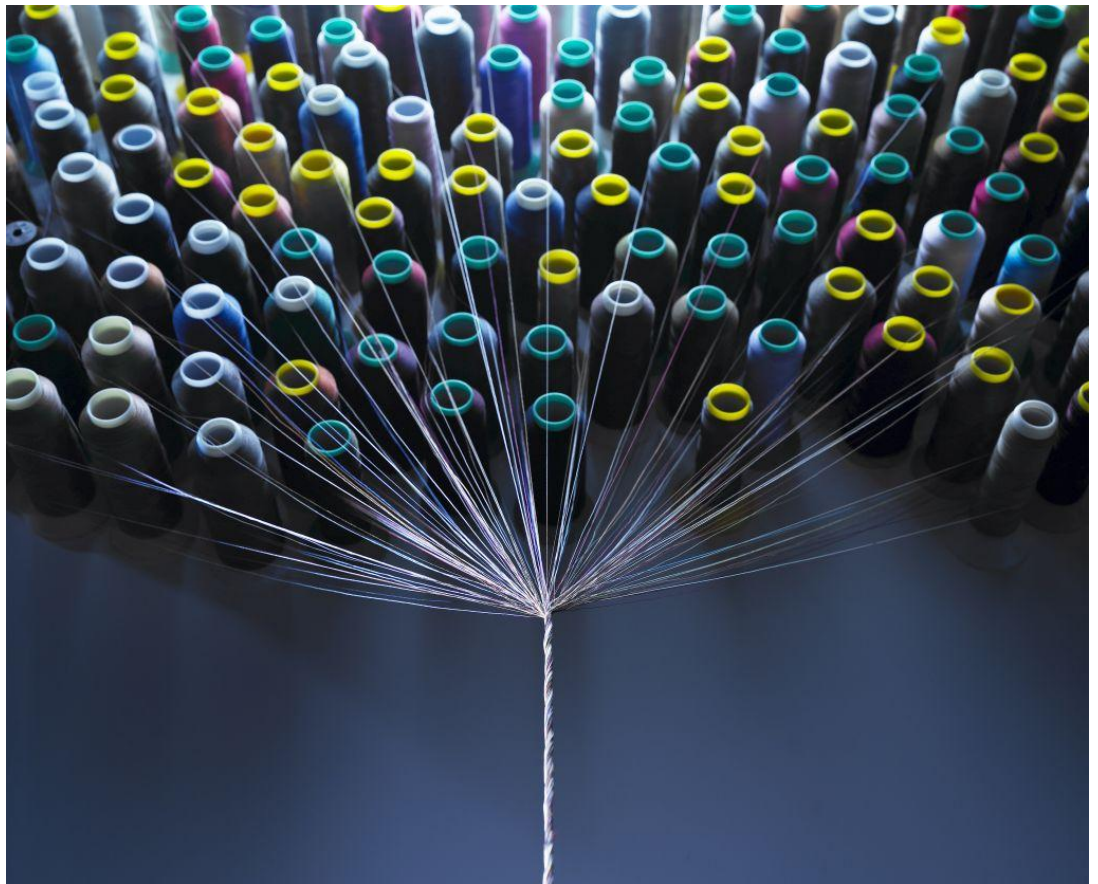


Market Access in Japan – Global changes and impact on Japan

Abstract

The role and importance of market access has increased in most geographies and with the current demographic and systemic changes in Japan will increase here as well. This paper will examine and illustrate global changes in the role of market access and challenges that come with this change and what the implications for market access functions are in Japan.



Market Access Macro Trends

Health care expenditures are growing significantly faster than GDP around the world, driving governments and payers to focus, more aggressively than ever before, on cost containment.

Health care costs continue to rise as aging population requires more care. Recent economic downturn places additional strain on patient, provider and government budgets.

“The cost of health care eats up more and more of our savings each year... This is a cost that causes a bankruptcy in America every thirty seconds.”

*President Barack Obama**

Health care reform jumpstarts the evolution towards cost and comparative effectiveness in the U.S.

European agencies continue to focus on reimbursement mechanisms (e.g. NICE)

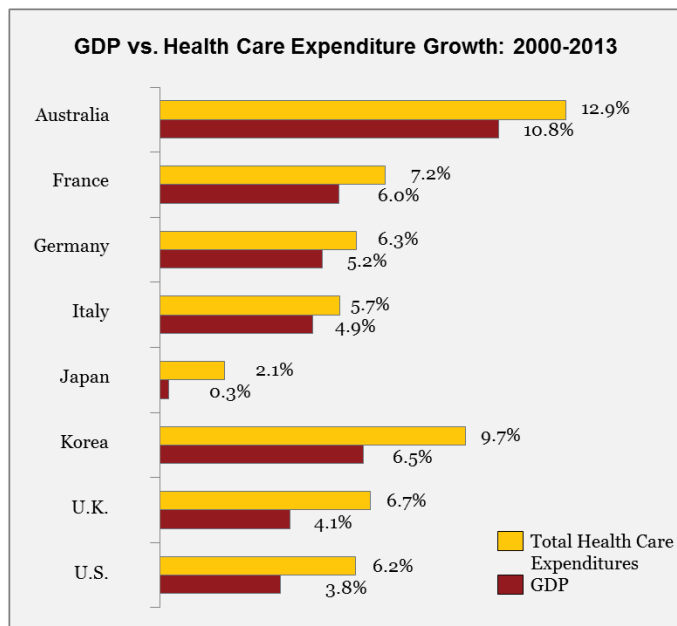
“We need reform on both sides of the cost equation. It is all about choice, competition and a focus on outcomes...”

*Prime Minister David Cameron**

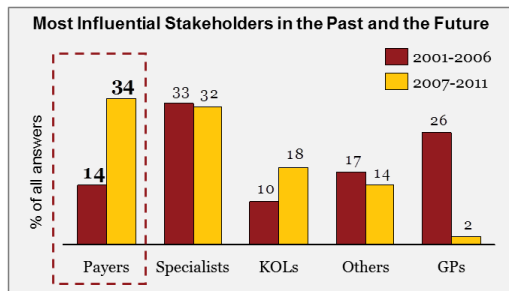
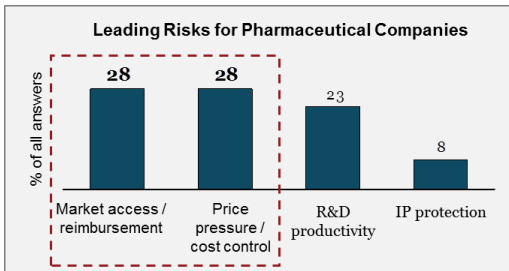
Changes in Decision Making Rationale

Access and pricing-related concerns have quickly become the biggest risks facing pharmaceutical companies – resulting in rising payer influence.

- Comparative effectiveness (and HTA) becoming the ultimate objective to pay against
- Increasing importance of Health-Economics considerations supported by “real data”
- Sophistication of stakeholders and increasing data capabilities create insights into effectiveness and outcomes
- Risk mitigation more common approach – “only pay for when it works”
- Pricing transparency (across stakeholders, across countries)
- Increasing importance of disease management / total care concept
- Increasing focus on personalized medicine / sub-population thinking



Source: Economist Intelligence Unit



Source: Deloitte Analysis, Survey of 236 pharma companies and suppliers; Financial Times Survey, July, 2011

What is Market Access?

Historically, Market Access and Managed Markets Strategies were created to ensure the right patients had access to the right drugs as easily as possible. Essentially, it was the last stop in the commercialization process and involved gaining formulary access or access with fewer restrictions and disincentives on usage (e.g. step edits, less advantageous tier). Gaining “sufficient” access (usually defined as 85% of lives covered on Tier 2 or a branded tier with reasonable patient co-pay) was often the sole measure of success or failure for a Market Access organization. If the Access group could deliver 85% on Tier 2, they did their job; if they could not, they failed. The tools available to deliver that “access” level were mostly limited to rebates negotiated with payers (and increasingly PBMs on behalf of payers) to get on formulary at the desired level and paid out when the drug was “pulled through” by doctors writing scripts.

Over the past several years, the boundaries of what constitutes “Market Access” have evolved greatly. The definition is still relatively straightforward: Access is ensuring the right patients have access to the right medications as easily as possible. In the current healthcare environment, however, achieving proper access is no longer a simple task.

Today, payers, including the Japanese ministry of health and welfare are even more rigorous in their evaluation of prescription medications and are significantly more cost conscious, with Europe leading the way and Japan expected to follow a similar route. Massive data proliferation (e.g. clinical data, claims data, epidemiology data) and improved payer analytical capabilities have led to a shift in power among healthcare stakeholders, away from the manufacturers. Payer organizations in the US and Europe have built highly sophisticated analytical capabilities to assess actual effectiveness and economic outcome data and increasingly rely on it in their access decision making process. To make matters more complex, other healthcare constituents (e.g. patients, employers, government agencies, and pharmacies) are increasingly focused on costs and are now part of market access strategy’s scope. **Increasingly the value - not just clinical, but economic - of medications is at the center of access strategies.**

Some clients have begun to recognize that formulary placement is only one element of the Market Access equation, but this recognition is still emerging and potential changes in strategy to reflect it are still being explored. The primary driver of leadership awareness is that there are increasing examples of drugs that have achieved the 85% access goal, but failed to deliver financially. Conversely, there are also examples of drugs with less than 85% access, or access at a less favorable tier level that have been successful.

Clinical differentiation, or the lack of it, certainly plays a role in success or failure of the brand with respect to access, but so do other factors like successfully selling to physicians from disadvantaged tiers (a sales and marketing competency), compensating for the effect of a less favorable tier with a strategic co-pay assistance to patients (in countries where allowed), creating patient demand via advertising (again in countries where allowed). For the most part, manufacturers have not kept pace with

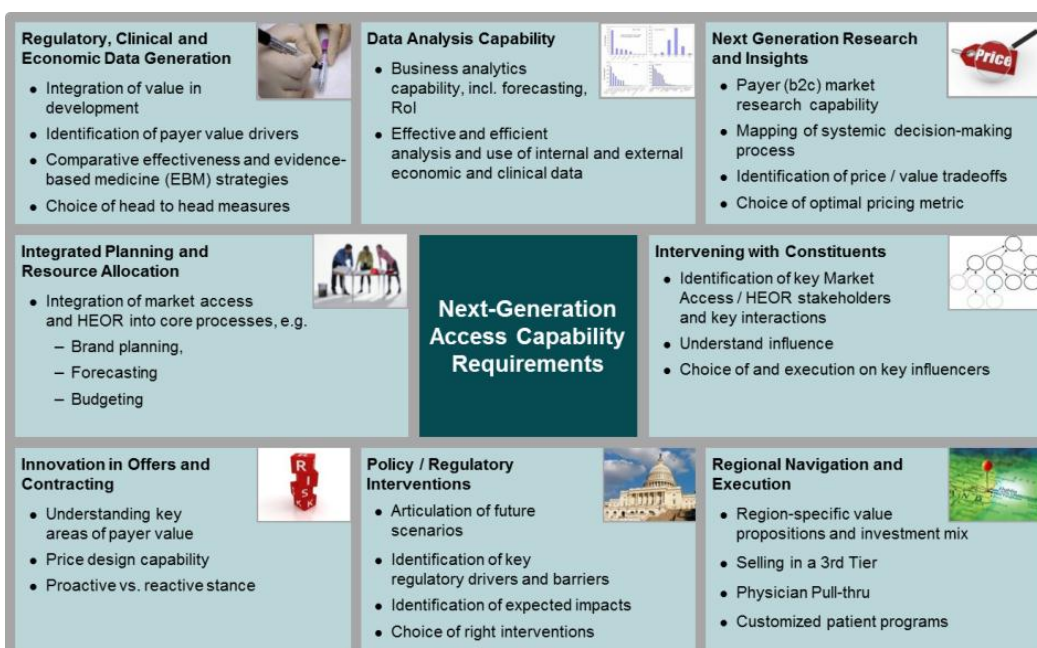
industry developments and **there is a need for stronger value propositions and better communication across the entire spectrum of economic decision makers.**

Access is bigger and more important to the success of pharmaceutical companies than ever before. Rather than approaching Access in an incremental fashion, organizations must think about how to transform – their approaches, systems, capabilities and organizations – to meet the new challenges.

Building a Market Access Strategy in Today's World

This new and broader definition of Market Access – not just formulary position – is a critically important strategic shift in the pharmaceutical industry. At Deloitte we believe achieving a company's desired objectives with a Market Access Strategy requires thinking more broadly about when and how to manage access. The entire organization must transform in order to succeed in today's world.

Building a "next-generation" market access capability will help drive competitive advantage



Source: Deloitte Analysis



Successful Access Strategy begins with deep payer insights injected early in the development process. The commercial viability of a compound (increasingly determined by properly meeting payer needs) must be analyzed and incorporated from the very beginning. Clinical trial design must reflect the ultimate questions, often economic in nature that will be asked when a new product comes to market. **Manufacturers need to be experts in data generation and analysis – specifically, evidenced-based medicine (EBM) / comparative effectiveness.** All pharmaceutical companies must factor these insights into investment decisions and strategy development in order to support the ultimate product-level value proposition.

If payer insight and Access Strategy more generally is not considered early in the development process, and consistently throughout, a number of critical business choices are likely to be sub-optimized – or made incorrectly – and the ultimate return on an asset will suffer, sometimes dramatically. Example business choices include the allocation of internal resources, physician targeting and product pricing. There are an increasing number of examples of the focus on access coming too late and thus the product was not successful at launch (e.g. Simcor, Onglyza may be facing this now). Conversely, there are a growing number of examples where firms did consider access earlier and are benefiting from that focus (e.g. Januvia, Advair).

In addition to embedding insight early and often, firms must be able to manage the expanding number of stakeholders and constituents (health authorities, advocacy groups, pharmacists, physicians, and patients) who can help unlock access barriers and support the commercial goals of manufacturers. Increasingly, gaining access involves a much broader web of organizations with differing missions and motivations. Understanding all the players involved in “Access”, determining where goals are aligned or at odds and influencing them is more important than ever.

To effectively support these new capabilities, organizations must transform as well. No longer can silos of Brand Strategy, Managed Care, Pricing, HEOR, Sales and Medical operate at arm’s length. The entire organization and each of these critical functions must operate in an integrated and aligned fashion to ensure the most powerful strategy – utilizing all the assets a company has at its disposal – is developed.

As an example, coordinating a strategic co-pay assistance program and intense physician detailing with the timing of access negotiations could reduce the cost and / or increase the return of an Access Strategy. Depending on the category and product, more money spent going directly to patients or doctors might be significantly more effective than increasing payer rebates.

Defining the capabilities required to succeed is just the beginning; those capabilities must be embedded and executed across multiple levels of organizational complexity



Driving transformation requires a number of activities that should be considered and addressed as part of a Market Access Strategy as early as the pre-clinical stages of development to help ensure:

- The market being targeted will be economically (not just medically) viable
- Trials or complementary analyses (like EVE) will generate information to meet the needs of payers, not just regulators
- The timing and targeting of marketing efforts and incentives reflects the role that each payer plays in the medical and financial buying processes for the drug category

As a product continues through the pipeline, access must be kept top of mind to ensure go-to-market access tactics (e.g. pricing and contracting) are realistic and integrated with physician and patient strategies and tactics.

Summary

In order to achieve access in today's world, organizations must deepen economic and payer insights, integrate Access Strategy early in the development process, and support strategy development with new capabilities and the right organizational structure. In our experience, most pharmaceutical companies are not prepared for today's environment.

In Japan market access will over the next few years evolve to more closely match the developments in Europe, Australia and the US. Driven by structural economic and demographic changes the government will have no choice but to further adapt similar comparative effectiveness standards (real world) and cost effectiveness guidelines as in Europe. Market access organizations in Japan will have to adapt to this.

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