

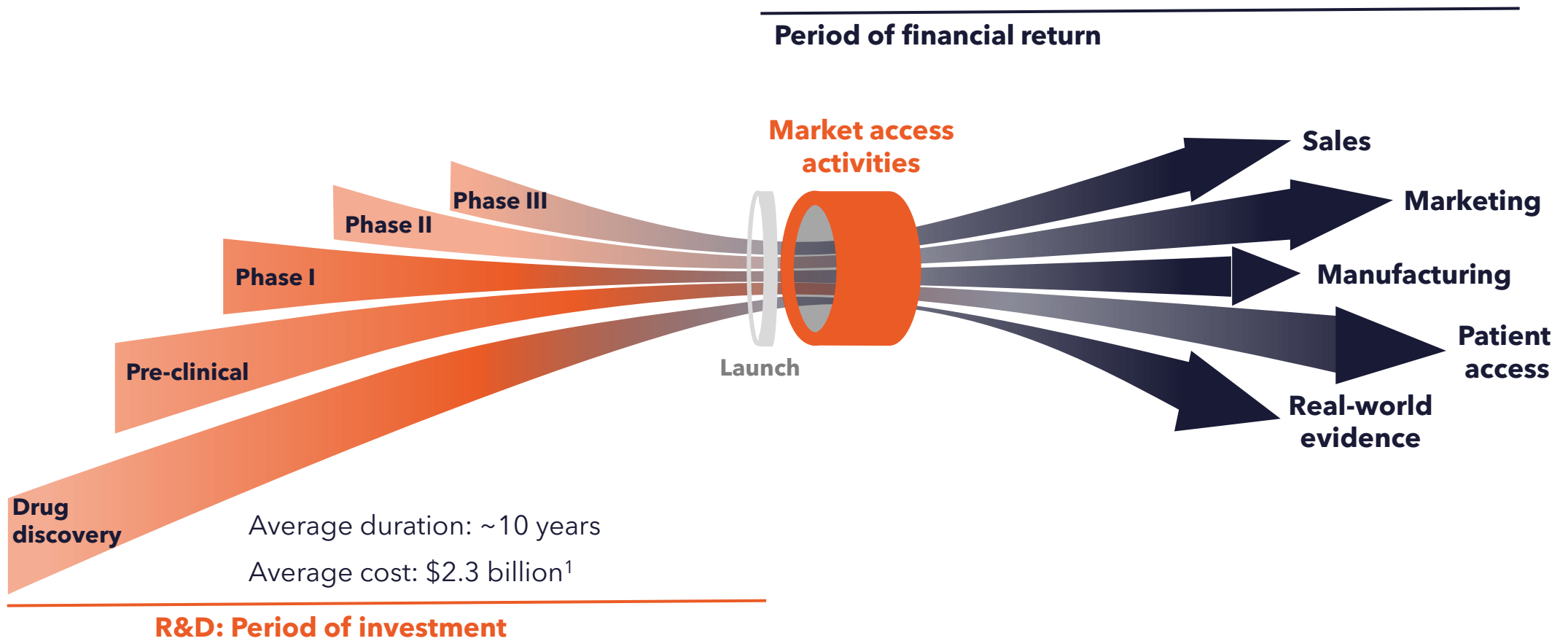


*Four Ways to Leverage
Market Access Buy-In:
Unleashing the Power
of Strategic Entry*

1

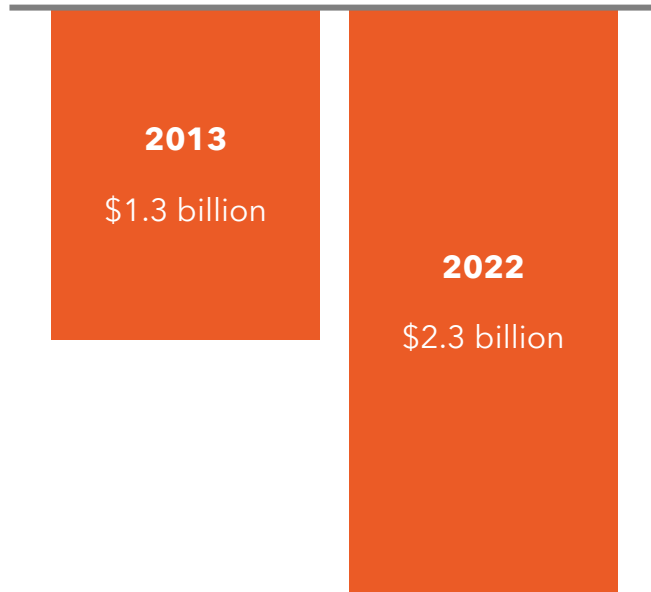
Effective Market Access Planning is the Catalyst for Recouping Significant R&D Investments

Market access activities are the catalyst for product success



Costs of developing pharmaceutical products are rising while return on investment is decreasing

Average cost of developing a product from discovery to launch has increased*¹



Average peak sales per asset have decreased**¹



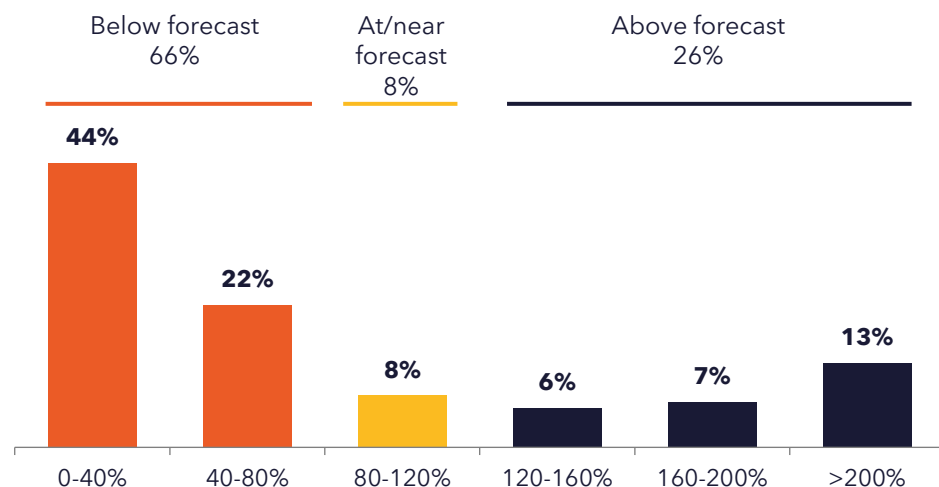
In 2022, ROI was **1.2%**, the lowest it had been since research started in 2010.

*Data based on a survey that included a cohort of 15 leading biopharma companies. †Represents forecast sales over the next 21 years, with peak sales being tabulated over a one-year period. ROI, return on investment.

Most products do not recover their R&D costs

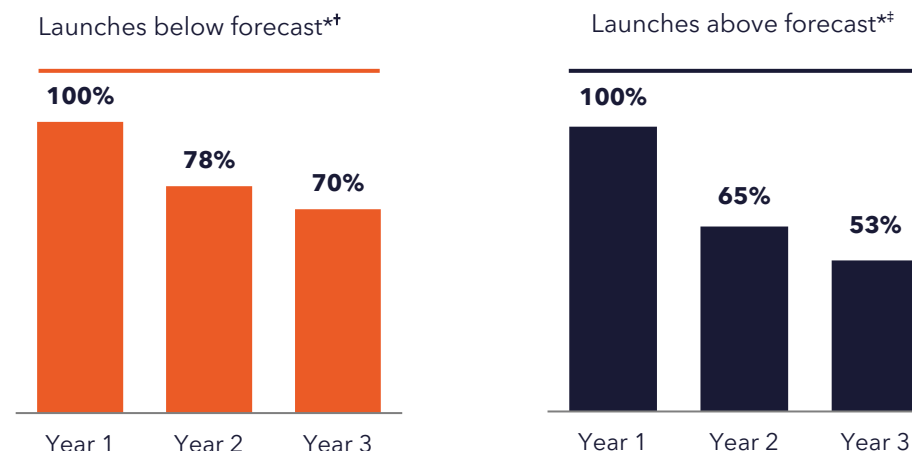
- Only approximately a third (34%) of compounds that enter the market recover their risk-adjusted R&D costs.²
- A half of products do not even achieve 50% of forecasted sales.²

Launches with sales below, at, or above forecasts^{*2}



- Products that do not meet forecasts in the first year after launch are unlikely to recover in subsequent years.²

Product performance over time stratified by performance in Year 1²



*Full sample includes 210 new assets launched between 2003 and 2009 for which forecasts were available 1 year prior to launch. †Includes launches that lagged forecasts (66% of full sample) and a half of samples that were at or near forecast (4% of full sample) in Year 1. Data for Years 2 and 3 represent the percent of launches that continued to lag forecasts. ‡Includes launches with sales above forecasts (26% of full sample) and a half of launches that were at or near forecasts (4% of full sample) in Year 1. Data for Years 2 and 3 represent the percent of launches that exceeded forecasts.

Market access issues are a key driver of failing to meet expectations

Analysis of 50 drug launches that failed to meet expectations in Year 1 showed:³

50%

Had issues with
market access

46%

Did not
understand
market needs

44%

Had poor product
differentiation

“In most markets, pricing and reimbursement conditions are the single most important value drivers at the time of launch.”²

②

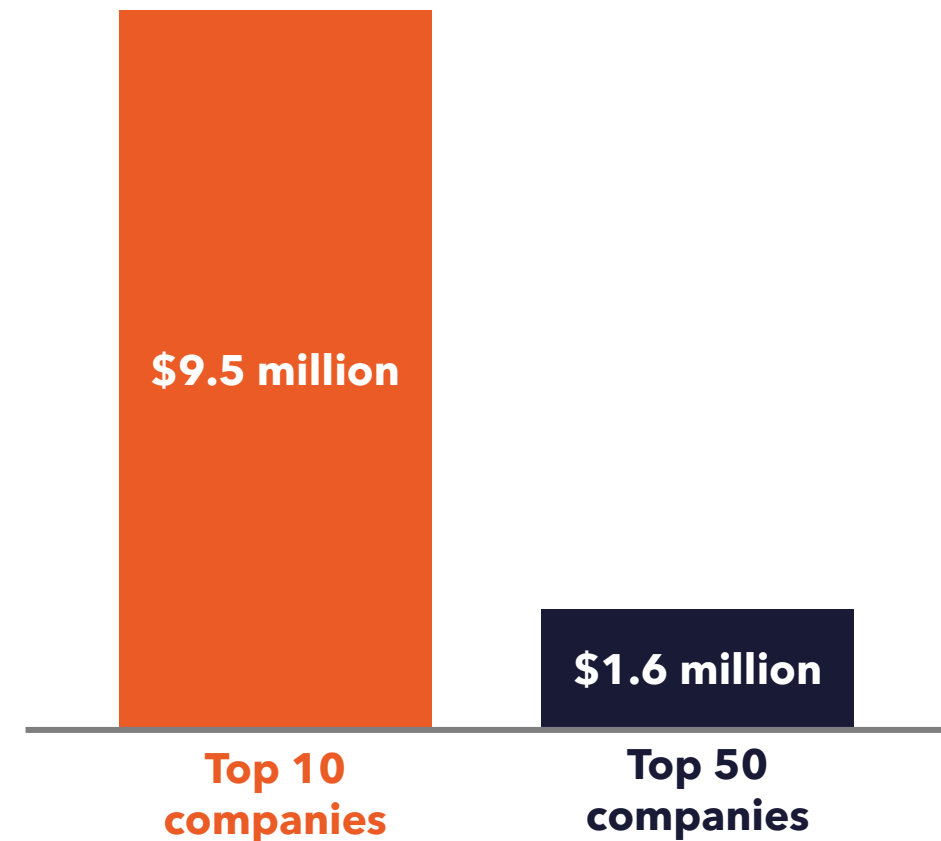
*Increased Investment in Market Access
Activities can Improve Company Success*

Top-performing pharma companies allocate larger budgets to market access activities

On average, the top 10 companies spent **~6 times more** on market access activities than the top 50.⁴

I.e., companies ranked 11-50 spend much less on average than the 10 most successful companies.

Average **market access** spending in 2016⁴



Budget for market access is substantially smaller compared with other activities

Total **R&D** spending by top 10 companies in 2021:⁵
\$107.2 billion

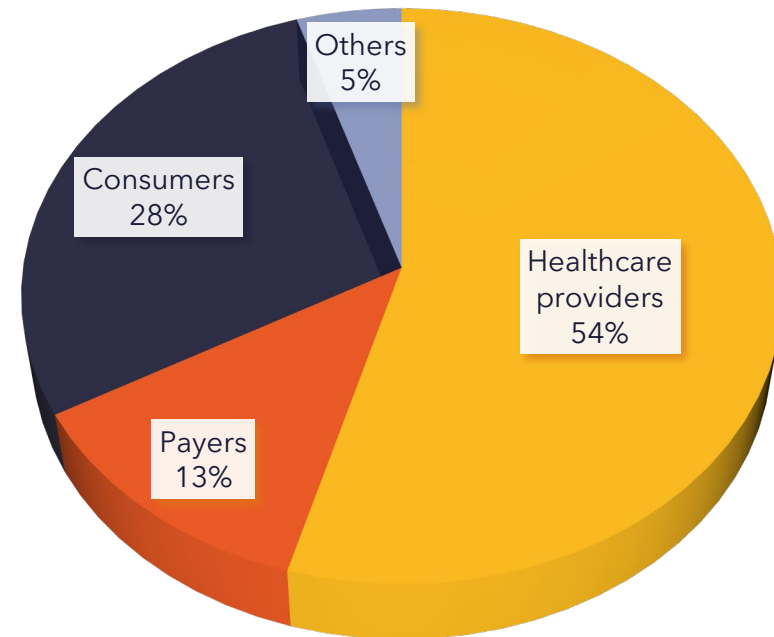
Mean total **marketing** budget,
including marketing to payers in
2022:⁶

\$9.3 million

Companies spend 4-fold more on marketing to healthcare providers than to payers

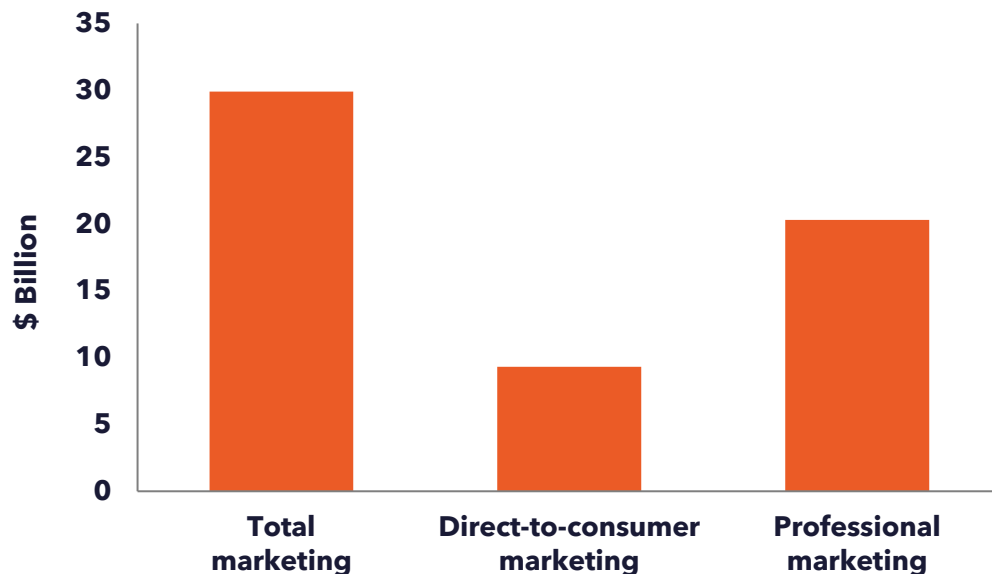
- A 2022 survey of pharmaceutical marketing leaders showed that only a small proportion of the average \$9.3 million marketing budget was spent on payers.⁷

Proportion of the total marketing budget spent⁷



Despite the declining influence of practitioners in decision-making, large budgets are dedicated to marketing to practitioners

**Total spending on marketing activities
in the US in 2016*⁸**



- In 2016, total marketing spending on prescription drugs in the US was **\$26.9 billion**, representing **8.18% of total spending** on prescription drugs.⁸
- Prescription drugs marketing spending included the following components:
 - Direct-to-consumer marketing: **\$6 billion**
 - Product detailing to professionals: **\$5 billion**

*Includes spending on marketing of prescription drugs, disease awareness campaigns, health services, and laboratory testing.

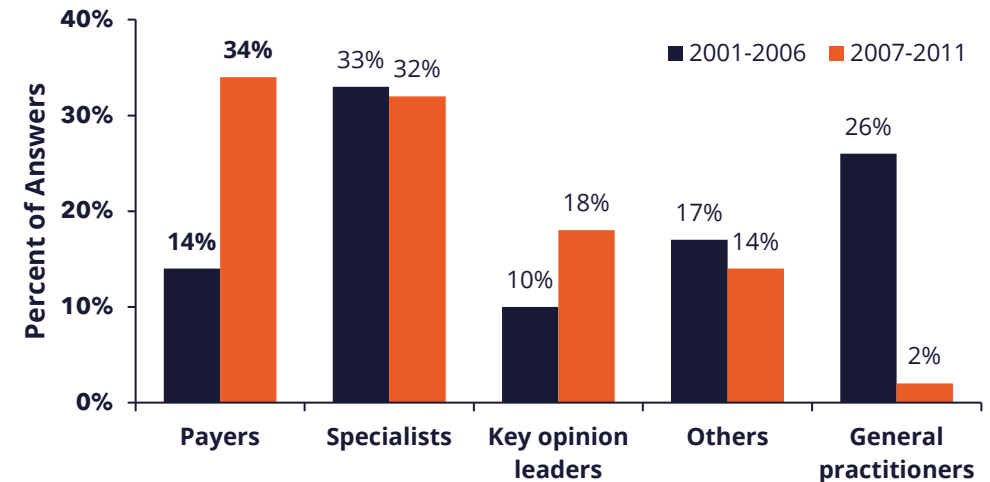
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Payers Have Increasing Influence on Product Success, Necessitating a Strategic and Tailored Approach to Reimbursement

Influence of payers is increasing

- As demands on healthcare systems continue to increase, payers have become increasingly influential in determining product success.⁹
- In a survey of more than 200 pharmaceutical company executives, payers were reported to have gained influence over time.⁹
- From 2007-2011, payers were considered to have as much influence as medical specialists, surpassing that of key opinion leaders and general practitioners.⁹

Influence of stakeholders*⁹

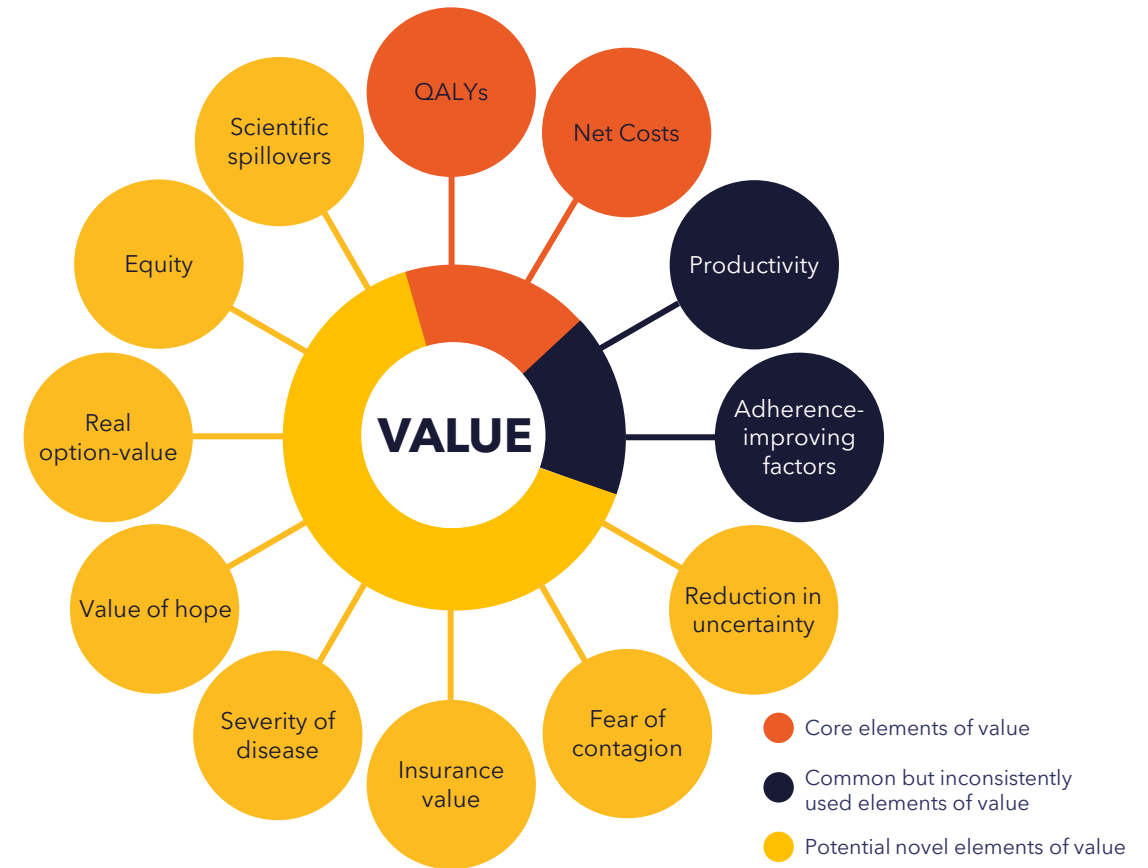


*Based on a survey of 236 executives from large and mid-sized pharmaceutical companies.⁹

As the market becomes more competitive, demonstrating product value is becoming more complex

- With the rapidly changing market access landscape, the definition of product value is also changing.¹⁰
- Product value is influenced by an interplay of clinical effectiveness and safety, cost-effectiveness, and societal value.¹⁰
- Market access teams can add value during clinical development by ensuring that evidence generation includes endpoints that are important to patients and payers.

Elements of value¹⁰



Modified from Lakdawalla et al. (2018).

4

Companies That Fail to Fully Leverage the Expertise of Market Access Teams Risk Substantial Loss of Product Value

Market access perspectives are frequently not included in product development

- A substantial proportion of companies surveyed did not include key components of HTA/payer perspectives in their target product profiles:^{*11}
 - 45% did not include adverse events of treatment and related cost.
 - 73% did not include hospitalizations.
 - 64% did not include patient insight based on descriptions of disease burden and unmet need.
 - 73% did not include societal value.

HTA/payer perspectives included in target product profiles¹¹



^{*}Based on a survey of senior management from 11 companies.
HTA, health technology agency.

Failure to consider market access perspectives can lead to delays in reimbursement

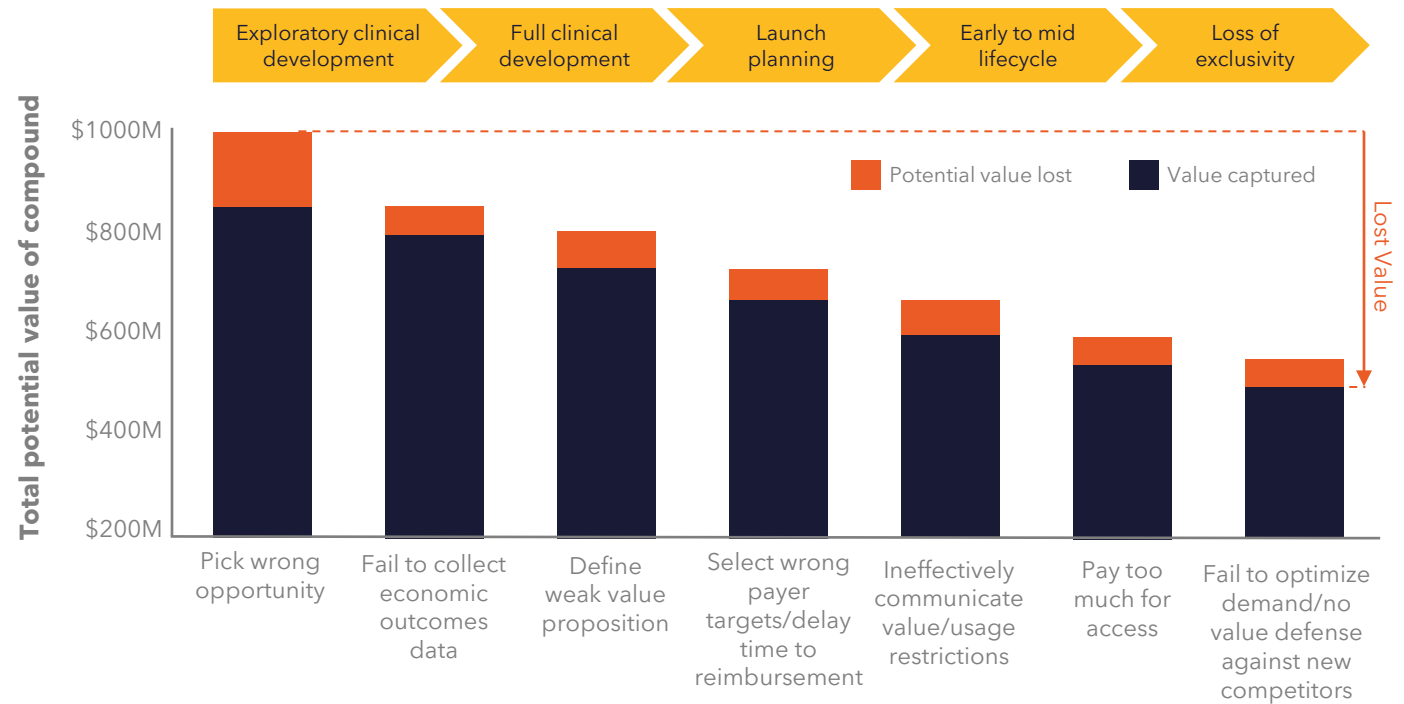
- In a study of HTA strategy of 169 products from nine international companies, HTA requirements were implemented in evidence generation plans for only **63%** of products.¹²
 - Omission of evidence required by HTA agencies from the initial submission led to requests for additional data in **46%** of submissions.¹²
- Many of the requests for additional evidence were related to market access perspectives:¹²
 - Locally relevant competitor: **44%**
 - Subgroup analysis: **35%**
 - Contextualize evidence to local population: **24%**
 - Different analysis methodology: **21%**
 - Use of network meta-analysis: **13%**
 - Requests for trial data in the local population: **10%**

HTA, health technology agency.

Failure to engage market access teams early enough can lead to a loss of value over the lifetime of the product

Poor market access decisions can result in a loss of product value at various stages of development⁹

- Market access activities should start at least 18 months before a drug is to be marketed; however, many companies miss this opportunity.¹³
- Failure to implement a robust market access strategy can negatively impact a product's financial returns throughout its lifecycle.⁹



Involving market access teams early in the development process can improve sales

Case study of two products illustrating the importance of market access activities:¹³

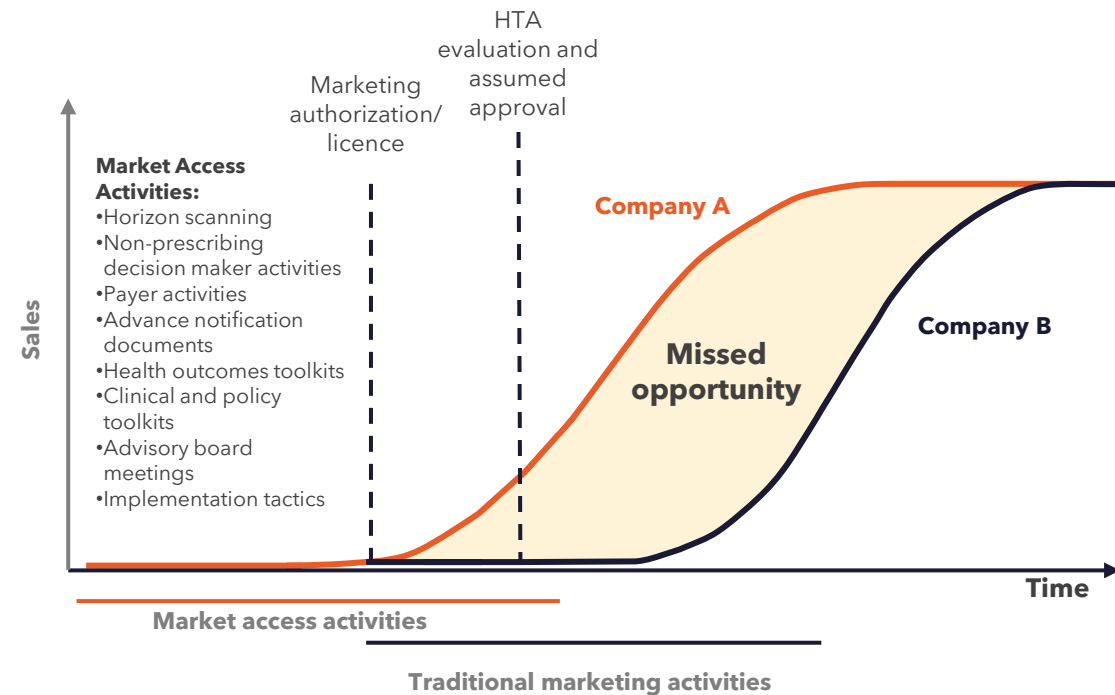
Company A - Early Initiation of Market Access Activities:

- Activities designed to demonstrate the potential clinical and service impact of Product A were initiated.
- Sales began as soon as the license was granted and increased substantially in the following months, particularly after a positive health technology appraisal in England.

Company B - No Early Market Access Activities

- The company had no established system for market access activities at an early stage.
- Decision-makers were unaware of the impact of introducing the product until conventional marketing activities started.
- Uptake of the product was delayed, and the manufacturer lost around a year of potential sales (~€20 million in the UK market alone).

Case study of two major pharmaceutical companies that anticipated a UK license for anti-cancer agents:¹³



HTA, health technology agency.



Summary and Key Insights

Effective market access strategy is a key to successful market entry

1

Effective market access strategy can substantially improve returns on R&D investments.

2

Increased investment in market access activities can improve company success.

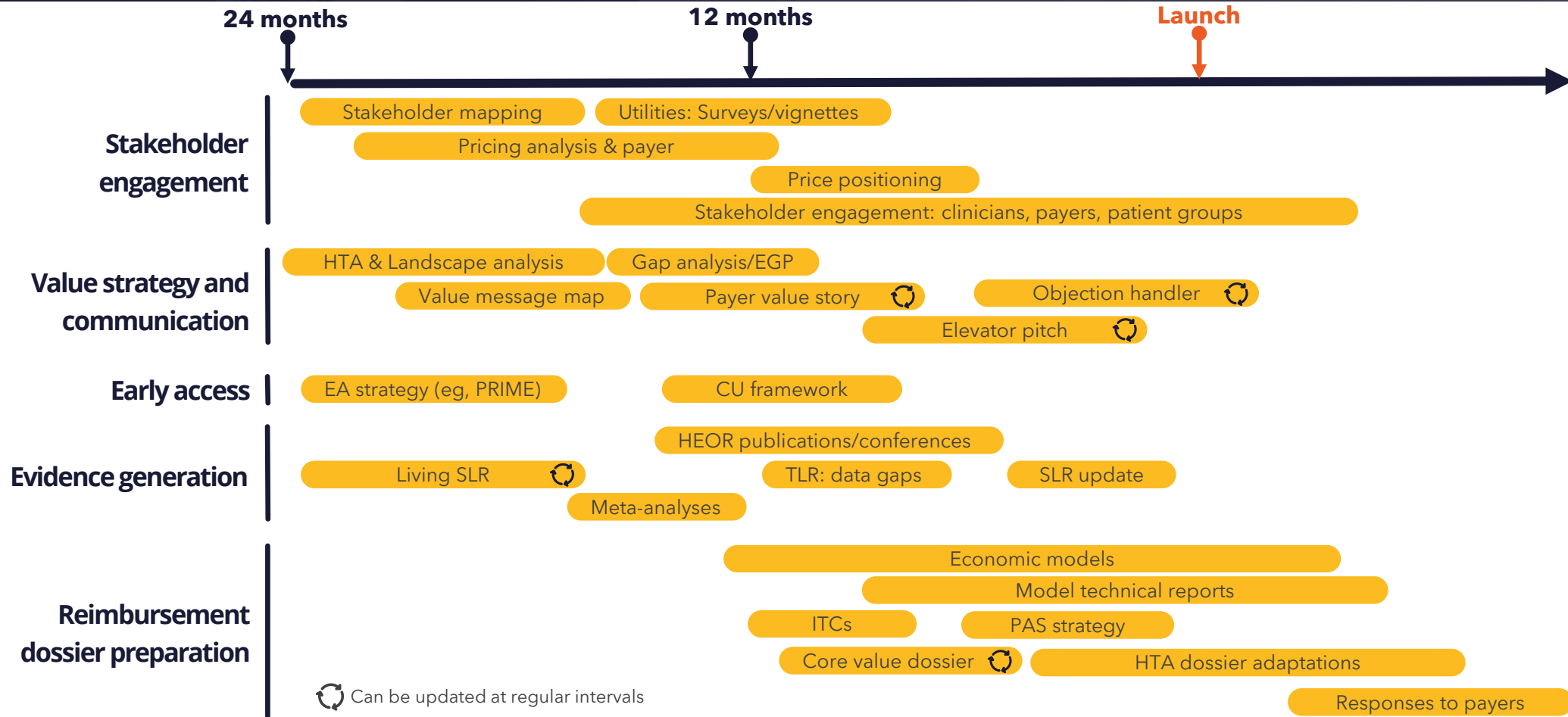
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A strategic and tailored approach to reimbursement is needed to adapt to the evolving role of payers.

4

Leveraging the expertise of market access teams early in the product development process can optimize return on investment.

Plan for early and consistent market access engagement to amplify product performance



CU, compassionate use; EA, early access; EGP, evidence generation plan; HTA, health technology agency; ITC, indirect treatment comparison; PAS, patient access scheme; SLR, systematic literature review; TLR, targeted literature review.

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