
2017 Pricing and Market Access Highlights

THE TOP

5

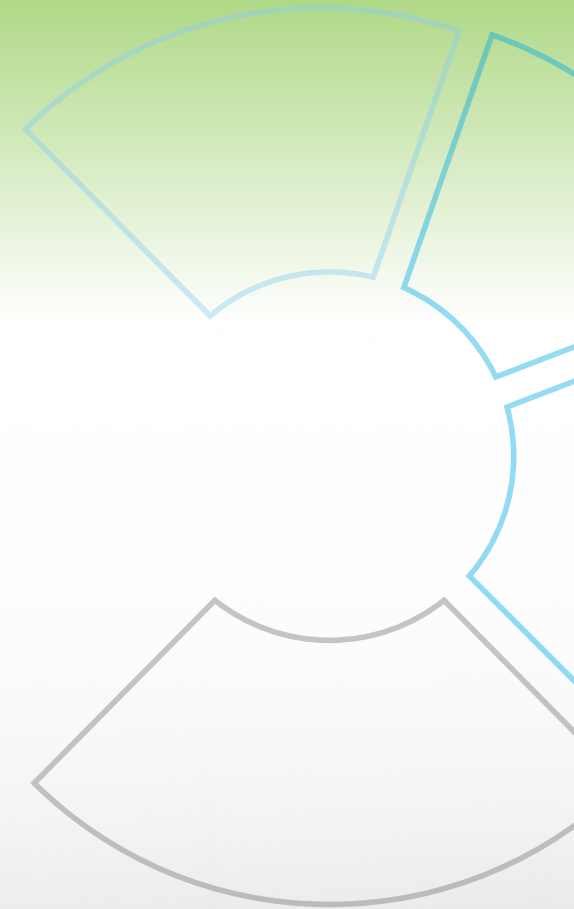
TAKEAWAYS





Each year, QuintilesIMS hosts a Market Access Conference for clients to take a deep dive into the trends, insights and levers of change that are impacting the global market access landscape. This year the conference featured presentations from industry experts and key thought leaders across QuintilesIMS who explored a range of challenges and opportunities for the life sciences industry, and how political, regulatory and economic issues are transforming market access.

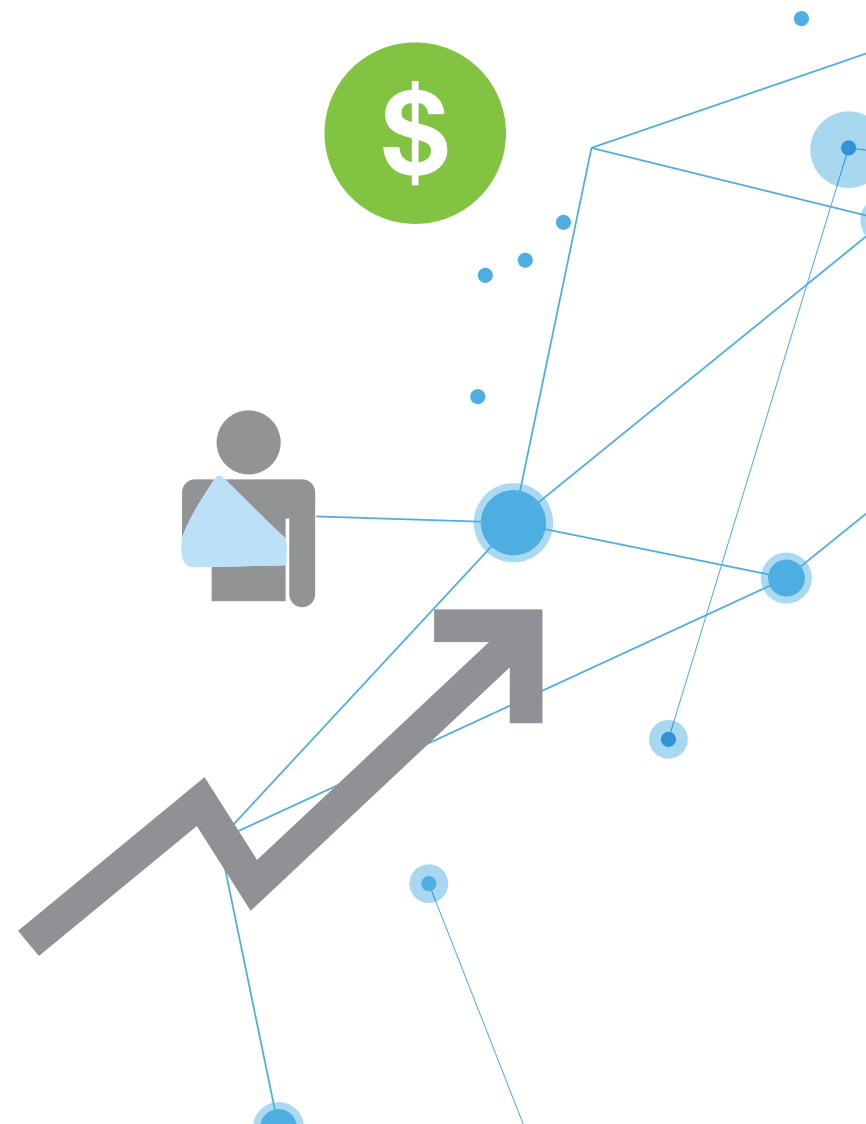
These are our Top 5 Takeaways for 2017.





The Top 5 Takeaways from these sessions point to a growing focus on more specialized and geographically targeted research, and the expectation for real-world evidence to support pricing and the value proposition of innovative products.

- ① ORPHAN DRUGS MAY HAVE LOST THEIR LUSTER
- ② BIOSIMILARS COULD GENERATE BILLIONS FOR US MARKET
- ③ PRICING DEALS CARVE ROOM FOR INNOVATION AND COMPETITIVE ADVANTAGE
- ④ REBATES DISAPPEAR... AND OTHER PREDICTIONS FOR 2027
- ⑤ WIN THE EVIDENCE WAR BY LEVERAGING RWE ACROSS YOUR ORGANIZATION



① ORPHAN DRUGS MAY HAVE LOST THEIR LUSTER:

Evidence generation will be the key to future success

Changes in regulatory, economic and commercial landscapes have led rare disease research to thrive.

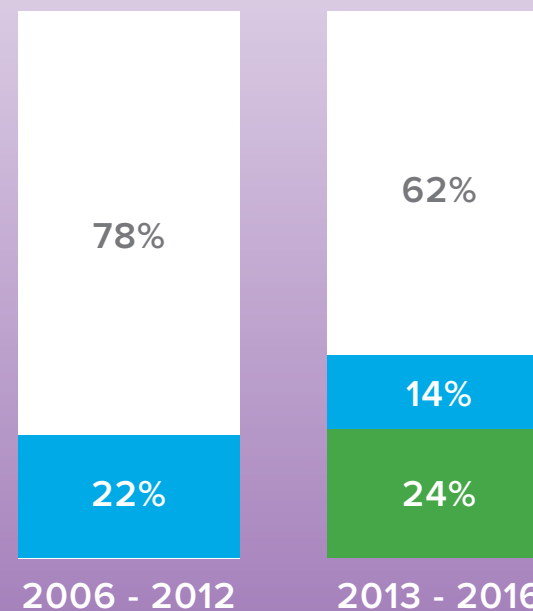
According to QuintilesIMS data, spending is stabilizing (leveling out at 9% between 2012 and 2014) and yet payer scrutiny is intensifying. Orphan disease data packages and their value propositions are increasingly under the microscope, leading to a rise in negative recommendations from health technology assessment boards.




In order to support value proposition claims for drugs, manufacturers will need to generate additional evidence and budget impact data to win over regulators and payers. The feasibility of meeting payer evidence demands will be critical to determining which orphan drugs the world will adopt.

How will payer evidence demands impact your portfolio?

Email our experts at consulting@quintilesims.com.

Restricted and negative outcomes are becoming more common in Orphan Drug Assessments



 Positive Outcome
 Restrictive Outcome
 Negative Outcome



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② BIOSIMILARS COULD GENERATE BILLIONS FOR US MARKET

The US is poised to see a boom in the biosimilars market. By 2021 the market could achieve \$40-90 billion in sales, especially as key originators hit their patent expirations. Lessons learned from the mature biosimilar market in the EU show three key trends that will inform the future:

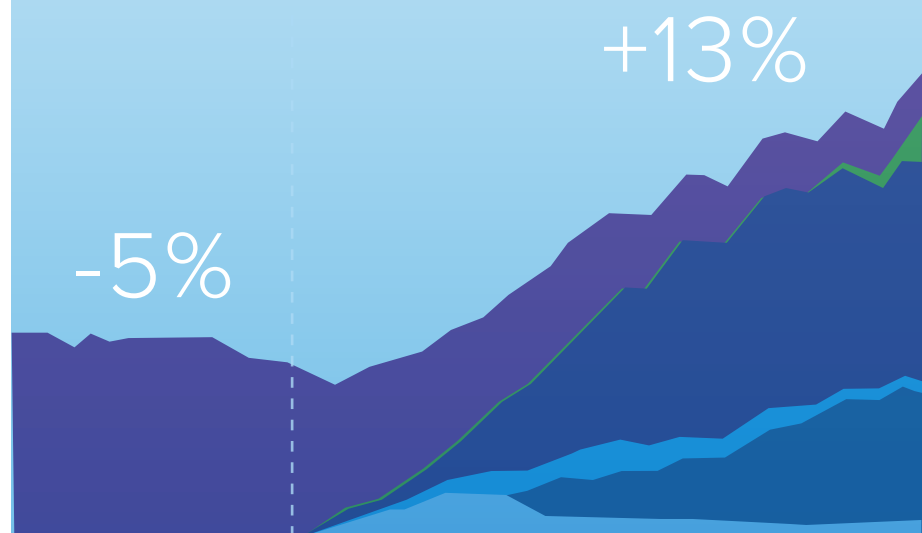
- 1. Volume growth ahead!** Sales volume grew steadily over time.
- 2. Beware of complex pricing dynamics.** With list prices 10-20% below originators, discounts and rebates of 25-45% make profit margins more difficult to interpret. Currency, which can lead to large price fluctuations, further complicates pricing dynamics.
- 3. Embracing substitutions?** FDA draft guidance on interchangeability may open the door to broader biosimilar uptake, forcing manufacturers to conduct lengthy switching trials.

Biosimilars may change the landscape, but originator brands will still exert a powerful effect on the marketplace.

How will biosimilars impact your five year plan?

Email our experts at consulting@quintilesims.com.

Reviving market growth while gaining more share



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3 PRICING DEALS CARVE ROOM FOR INNOVATION AND COMPETITIVE ADVANTAGE

The average monthly cost for new cancer drugs soared from \$2,000 in 2000 to \$11,325 in 2014, pushing industry stakeholders to explore novel pricing deals to drive access without limiting the ability to innovate.

Three pricing strategies are rising to the top:

1. Pay-for-performance provides payers with a money-back guarantee, while allowing manufacturers to maintain a favorable list price and preferred access over competitors.

2. Indication-based pricing is used where economic value can vary depending on the indicated treatment. While difficult to implement, it can help both limit price erosion and support indication expansion.

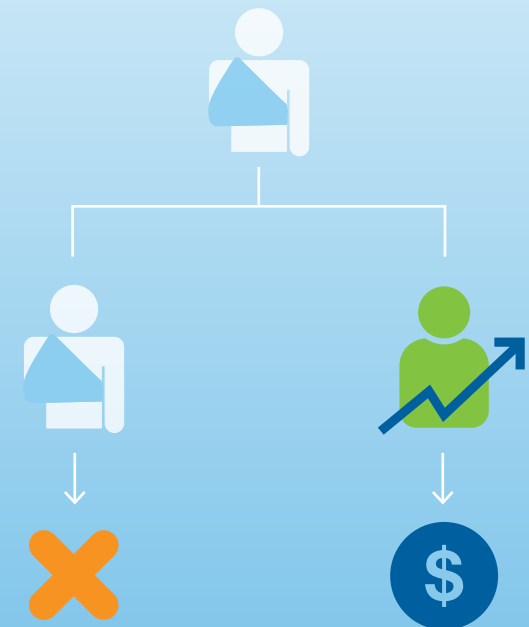
3. Portfolio subscription models allow payers unlimited use of the portfolio for a fixed fee. While still novel, they have the potential to redefine value by reducing financial uncertainty.

Over the next 36 months, the manufacturers that successfully implement and market drugs through these pricing models will not only gain a competitive advantage, they will also lead the way in driving healthcare forward.

Want to know more about how different pricing strategies could impact your bottom line?

Email our experts at consulting@quintilesims.com.

Pay-for-performance:
Payer only pays if
patient meets pre-agreed
clinical outcomes



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4 REBATES DISAPPEAR... AND OTHER PREDICTIONS FOR 2027

We are approaching the tipping point of payer price sensitivity and the willingness to pay. This shifting attitude will generate game-changing trends over the next decade, including:

- A shift away from deep rebate models;
- Increased management within the medical benefit; and
- Increased price transparency as manufacturers respond to pressure from the media, patients and the government.

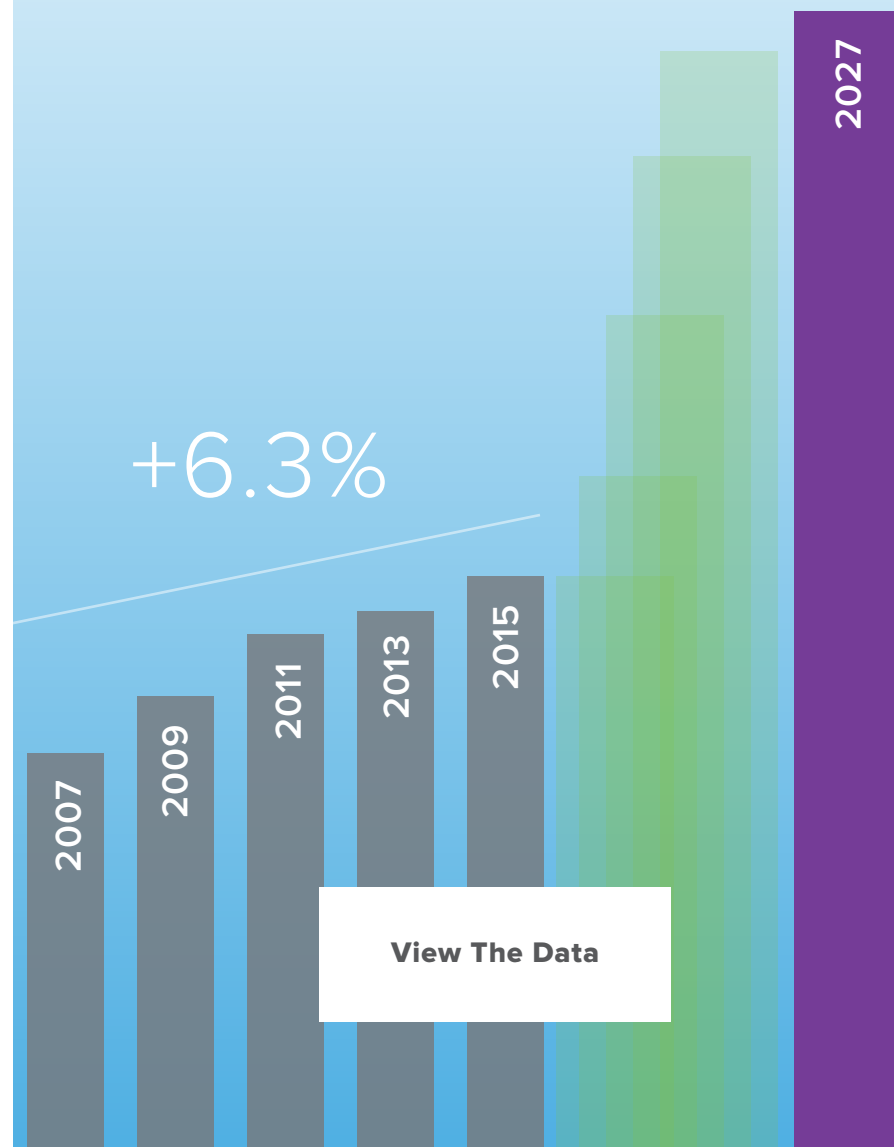
Of course there will be more of the same, but if the game changes, we will need to change our plan. What should you be doing now? Practice mindfulness:

- **Be efficient** and do more with less.
- **Be prepared** with a detailed pricing approach.
- **Be proactive** and define value-based price.
- **Monitor** and track development spend.
- **Partner** with value-based organizations.

How can your teams prepare for 2027?

Email our experts at consulting@quintilesims.com.

At current growth rates, US pharma spend will double by 2027



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5 WIN THE EVIDENCE WAR BY LEVERAGING RWE ACROSS YOUR ORGANIZATION

Real-world evidence (RWE) is being used to demonstrate value-based gains in outcomes, reduced cost of care and improvements in quality of life.

Regulators and HTAs expect RWE to support regulatory and pricing decisions; hospitals and payers use it to determine best modes of care. Using RWE to assess the costs associated with specific outcomes is becoming standard practice. To win the evidence war, you need to leverage RWE across your organization, including:

- **R&D:** Improve clinical study design, patient enrollment and overall execution for greater predictability and efficiency.
- **Medical affairs:** Identify targeted patient populations, enhance safety planning and monitoring and track effectiveness and protocol adherence.
- **Health Economics and Outcomes (HEOR):** Deliver robust HEOR and generate evidence that can confidently be used for all stakeholder needs.
- **Commercial and brand:** Get insights about how patients are diagnosed, monitored and treated so you can develop better brand plans to increase performance.

For more about RWE strategies, please contact:
consulting@quintilesims.com.

Using RWE to increase product performance



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