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Strategy Consultants to the Pharmaceutical and
Biotechnology Industries

Mitigating the Risks in Risk Sharing Agreements

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Introduction

- Innovative, risk-sharing access agreements are becoming commonplace in launching new drugs in key European markets
- While these agreements offer an avenue to find common ground with payers, their complexity can introduce a range of new risks for biopharmaceutical manufacturers to manage
- This presentation reviews the types of agreements being executed and the manufacturer risks they introduce, and reviews case studies illustrating potential risk mitigation strategies

Acknowledgments

- This is not an exhaustive review – it is intended to provide ideas and stimulate thought about a very complex and timely topic
- Thank you to Putnam colleagues and clients as well as other experts in the field for providing experiences and helping to shape our thinking
- Please ask questions and provide your own thoughts!
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Innovative access agreements bring potential benefits to manufacturers and payers

Motivating Rationale for Payers

- Improves budget certainty
- Allows patients access to innovative therapies (political motivations)
- Aligns with motivations to pay for value
- Fosters partnerships with manufacturers to produce better health outcomes
- Establishes deal terms not possible through transparent price reductions

Motivating Rationale for Manufacturers

- Achieves access in challenging environment
- Maximizes returns given payer constraints
- Fosters partnerships with payers to produce better health outcomes
- Demonstrates of belief in efficacy
- Protects differential prices through non-replicability

These agreements have arisen to meet payer concerns when granting access to new biopharmaceutical products

Payer Concerns When Considering New Product Access

Solutions?

Effectiveness Concern: Drug does not produce expected levels of clinical outcomes

Adverse Event Concern: Use of the drug results in adverse events in certain patients requiring additional treatment (and additional costs)

Expanded-Use Concern: The drug will be utilized in non-approved populations where benefit is unproven

Dosage Concern: Higher than expected doses of the product will be utilized (required or not) resulting in increased costs

Budgetary Concern: The drug will be utilized more heavily than expected within indication stressing budgets

Performance Guarantees

Financial Guarantees

Innovative access agreements can be based on performance or financial metrics at the population or individual levels

Agreement Basis

		Performance	Financial
Measurement Level	Individual	<p>Dependent on Individual Outcomes</p> <ul style="list-style-type: none"> ▪ Discounts based upon clinical outcome measures (e.g., cholesterol levels, tumor response rates) ▪ Example: (Italy) Tassigna refunded for patients not achieving a hematologic response 	<p>Patient Cost Capitation</p> <ul style="list-style-type: none"> ▪ Cap on the maximum dosage, treatments or dollar amount reimbursed per patient ▪ Example: (UK) Lucentis reimbursed for a max. of 14 injections per eye
	Population	<p>Dependent on Aggregate Outcomes</p> <ul style="list-style-type: none"> ▪ Discounts based upon achievement of clinical (or adherence) outcomes in a broad population ▪ Example: (UK) Additional discounts for MS drugs contingent on population outcomes 	<p>Volume Threshold Discounts</p> <ul style="list-style-type: none"> ▪ Discount levels tied back to overall volume, sales or market share ▪ Example: (France) Nearly all recent launch ambulatory drugs

However, significant manufacturer risks exist; identifying them a priori will help in constructing optimal deal terms

Financial Guarantee Risks

- Not understanding the true size of addressable market
- Not appreciating patient flow dynamics
- Mismatching overage discounts with usage risks
- Entering into total budget envelopes with competitors

Performance Guarantee Risks

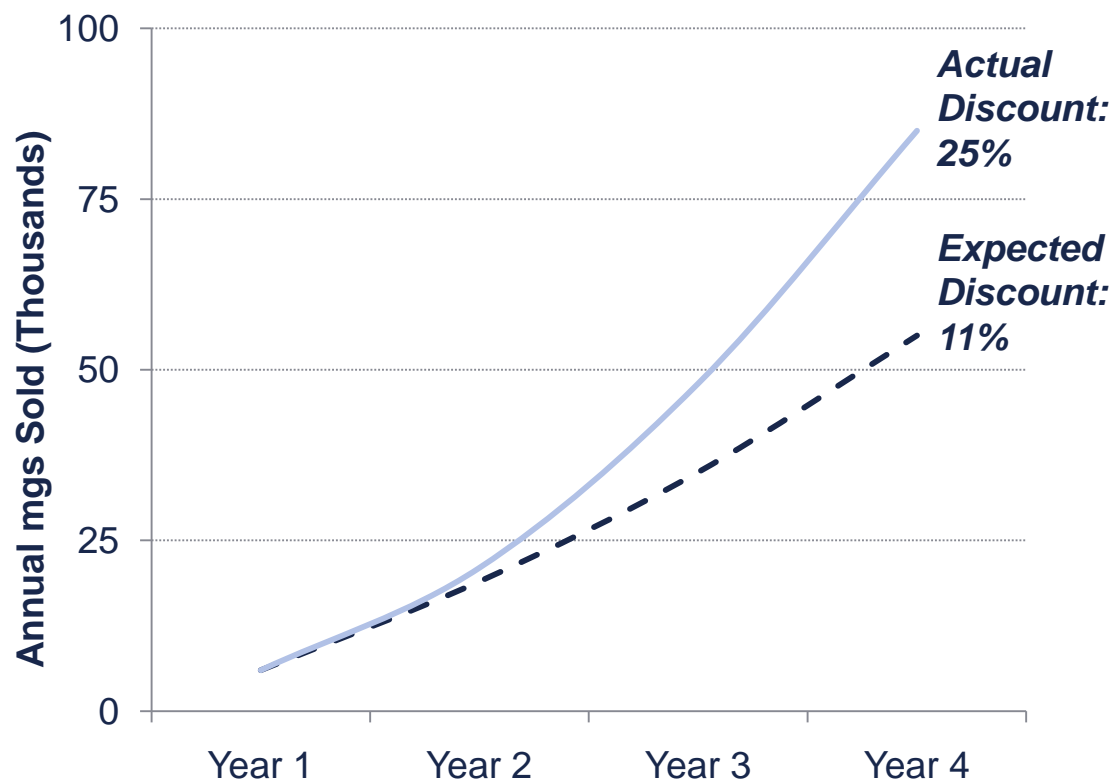
- Expecting real world to match clinical outcomes
- Creating cumbersome enrollment/monitoring programs
- Not addressing needs of all stakeholders in value chain

Shared Risks

- Using deterministic, as opposed to probabilistic modeling to evaluate deals
- Defining the duration of the agreement too broadly

Financial Guarantee Example: Price Volume Agreement in France for a Specialty Product

Actual vs. Expected Total Milligrams Sold



Three fundamental mistakes

- ▶ Did not appreciate how long patients would stay on therapy
- ▶ Did not appreciate how high adherence would be
- ▶ Created high final tier discount to maximize up front price

Key Lessons

- ▶ Patient flow modeling is critical
- ▶ Have a fact-based, rigorous understanding of patient adherence
- ▶ Know where your key uncertainties are and plan the deal terms accordingly

Note: New launch product into a non-competitive space

Performance Guarantee Case Example: Developing a Risk Sharing Agreement in Italy

Product Context and Options

Specialty Care Product: Series of 8 weekly injections



Potential Risk Sharing Solutions:

1. Full refund for patients receiving 4 or fewer doses
2. Payment only for patients with no evidence of progression
3. Payment only for patients with measured improvement

Key Uncertainties Identified




- ▶ Questions on how closely real world will match trials
- ▶ Questions of how deal itself will impact use

Solutions to Mitigate Uncertainty

- ▶ Develop strategies for approximating real world outcomes
- ▶ Develop a broad menu of options
- ▶ Develop programs to improve patient outcomes (e.g., through adherence)

An additional consideration in any innovative access agreement is the spillover risk of effective discount terms

Innovative access agreements are typically tailored to address needs in a particular market – this has several implications:

-  **Benefit:** Deals can be difficult for other payers to implement, potentially restoring an ability to differentially price according to value
 - ▶ Consider deal transparency and downstream reference pathways
-  **Risk:** No deal is guaranteed to remain non-transparent
-  **Risk:** Heterogeneous deals increase logistic and management costs

Example: “Commercial in Confidence” Deals in the UK

- Non-transparent patient access schemes promise to allow discounts to achieve cost-effectiveness thresholds without spillover to other markets, but...
 - ▶ Risk of terms being leaked
 - ▶ Risk of deal with NICE signaling willingness to offer sizeable discounts
 - ▶ Risk of discount levels being back-calculated

There are a number of factors to consider when deciding whether to enter, and how to structure, innovative access agreements

Key Considerations:

- Place in Product Lifecycle
- Therapeutic Category
- Availability of End-Points
- Cost of Therapy
- Competitive Landscape
- Clinical Outcome Uncertainty
- Future Indications
- Dosing Uncertainty
- Adherence Risks
- Uncertain Target Population

Summary

- Rising healthcare costs, general budget austerity measures, and an increasing focus on value is leading to a more restrictive access environment for newly launching biopharmaceutical products
- Innovative access agreements are a potential solution
 - Since they often employ discounts, these agreements may be viewed negatively by manufacturers
 - In reality, however, they can provide a pricing mechanism for optimizing returns across market environments with different needs and priorities
- The complexity of these agreements requires a great deal of sophistication on the part of biopharmaceutical manufacturers to ensure risks are understood and mitigated where possible
- Biopharmaceutical organizations that can identify the right risks to take on for the right products will be most successful in meeting the challenges of the evolving access environment

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Mr. Auger heads Putnam's Global Pricing and Reimbursement practice and is a leader in Putnam's US and Global Franchise Strategy practices. Having joined Putnam Associates in 1996 and become a Partner in 2005, he brings 16 years of strategy consulting experience in the pharmaceutical, biotechnology, and life sciences areas, including extensive engagements in both US and global markets. He has helped develop and revitalize pricing and reimbursement platforms (value propositions and economic analyses) for a range of high-profile products in pre-launch, mid-lifecycle, and LOE phases. His therapeutic area expertise spans a wide range of specialty categories including Infectious Disease / Vaccines, Women's Health, Immunology (including RA and Psoriasis), Oncology, CNS, GI, and CV. Prior to joining Putnam, Eric began his strategy consulting career at Bain & Company in Boston. He holds a BA in Economics from Providence College, an MA in International Relations from Boston University, and completed post-graduate studies at MIT's Sloan School of Management.

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Mr. Riordan is a leader in Putnam's Global Pricing and Reimbursement and US and Global Franchise Strategy practices. He joined Putnam in 2003 and has worked extensively in oncology and other specialty categories managing therapeutic area strategies, product growth strategies, and pricing & reimbursement strategies. Prior to joining Putnam Matt worked for a retirement policy think tank conducting analysis on the drawdown of Social Security and Medicare trust funds. He graduated magna cum laude, phi beta kappa from Boston College with a degree in economics, and earned his MBA from the Yale School of Management in the focused Healthcare MBA program.

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