Pricing Medicines:  
An Integrated Framework for Developing P&R Strategy

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1. Pricing Basics
2. Global Drug Pricing Environment
3. Pharma Pricing Strategy Framework
The Dual Role of Price

Price is a marketing concept

- Price is the point at which we *capture* the value generated in the product

Price is a financial concept

- Price is a *direct* component of profitability.

- The goal of pricing strategy is to effectively *capture product value* in a way which *maximizes long term profitability* for the company.
Dual Perspective on Price

A viable price range will balance both the Market and Company needs and perspectives.

Market Perspective
- Sets upper limit price achievable
- Perceived value to customer in context of alternatives
- Places downward pressure on price “what the market will bear”

Company Perspective
- Sets lower limit price required
- Reasonable gross margin and ROI
- Places upward pressure on price “what the company needs”

VIABLE PRICE RANGE
Company Costs and Return on Investment

- “Cost” is not just the cost of manufacture
- A holistic net present value (NPV) projection needs to be made and updated throughout development - price is a factor
Value Based Pricing

The perceived value of a *product* to a *customer* is based on....

\[ V = R \pm D \]

- **V** Perceived Value
  - Reference Value (Price of the Best Alternative)
  - Differential Value (Value of the differentiation)

- **R** Reference Value
- **D** Differential Value
Value Based Pricing and pharma challenges

\[ V = R \pm D \]

Pharma challenges.....

- **What is your product?**
  - “V” differs depending on indication, positioning, target patients

- **What is “R”?**
  - What if you have a breakthrough product?
  - What about generics?

- **What drives “D”?**
  - How do you measure it?
  - How do you prove it?

- **Value to whom? Who is the customer?**
  - Payer? Prescriber? Patient? Who really counts?
Agenda

1. Pricing Basics
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Changing paradigm for access to drug markets

Old paradigm
Registration approval
“the race is finished”

New Paradigm
New Hurdles:
• Safety, Quality, Efficacy
  …..and……
• Cost-effectiveness
• Affordability
How did we get here? → increasing tension between costs and funding

Increasing costs, but reduced funding ability......using traditional funding paradigm

- Innovative Medical Technologies
- Longer life -> Aging Population
- Higher demand for healthcare
- Higher Prices

++ Costs
++ Funding

-- Smaller worker base

How have payers responded?
Payer/Country Response to Cost Pressure

- Higher Prices
- Costs
- Higher demand for healthcare
- Aging Population
- Innovative Medical Technologies

Hurdles

Cost Shifting
Some hurdles focus on redefining value

- Evaluate seriousness of condition/ health gain
- Assess level of advance in therapeutic benefit, demanding:
  - Higher quality evidence
  - Outcomes data
  - Comparative studies
  - Real world data
- Value for Money Assessments:
  - Cost per QALY (quality-adjusted-life-year) metrics
Other hurdles are purely cost control mechanisms

• Reference Pricing:
  • Therapeutic referencing
  • Geographic referencing
• Mandatory Price Cuts
• Budget Caps
• Price-Volume Agreements
• Rebates
• Generic Substitution
Price referencing and parallel trade
Increasing Global Interdependency

- Price reference or trade patterns
Cost shifting to patients is prevalent

- Increasing co-pays
- Tiered Formularies
- OTC
- Delisting
- “Lifestyle” Drugs
Trends and strategy implications

**Payer Key Trends**

- Increasing Hurdles
- Cost Shifting
- Globalization

**Strategy Implications**

- Focus on Value
- Understand the Customer(s)
- Managing Tradeoffs
- Global Perspective
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Three core analytical constructs form the basis of P&R strategy development

Understanding the “buying system”

Understanding the relationship between the offering and perceived value

Understanding the tradeoffs within and across products and markets

Value Based Pricing

Purchase Decision Analysis

Global Optimization
Value Based Pricing

Understanding the relationship between the offering and perceived value
What is our “Product”? - Product Positioning

• A molecule is not a product.....for price estimation purposes we must define its “positioning”

• “Positioning” (here) = place in the treatment regimen

Positioning variables

- Line of therapy?
- Target Patients?
- Prevention or treatment?
- Monotherapy or combination?

...different implications for.....

- Reference Price
- Positive Differentiation Value
- Negative Differentiation Value
- Perceived Value
“In a blow for Novartis, the UK National Institute for Clinical Excellence has published preliminary recommendations saying that Fujisawa's immunomodulator, tacrolimus (Protopic), should be used on the NHS for the treatment of atopic eczema, but that Novartis's pimecrolimus (Elidel) should not.

NICE notes that although the products have similar mechanisms of action, pimecrolimus is approved in the UK for first-line use in mild to moderate atopic eczema, while tacrolimus is licensed for the second-line treatment of moderate to severe disease.

On the basis of the assessment group's model of pimecrolimus compared with topical corticosteroids, the committee agreed that pimecrolimus was not cost effective. Clinical experts told the committee that they would not recommend either of the immunomodulators as first-line treatments, because topical corticosteroids provide effective first-line management of the condition and because of the higher cost of the newer products and their potential unknown long-term adverse effects.”

SCRIP 6 Apr 2004

Important to align your positioning → value proposition → price

• Note: Following an appeal by Novartis, pimecromilus was subsequently recommended for use in the same patient groups as tacrolimus.
What-if scenario modeling
Needed to incorporate P&R impact of alternative strategies

SCENARIOS
• Product Profile
• Target Patient Profile
• Clinical Development Strategy

P&R IMPLICATIONS
• Value
• Price
• Market Access

EXPECTED NPV
• Price
• Volume
• Time to Market
• Costs
• Risk
Understanding and framing the reference
“R” is critical

<table>
<thead>
<tr>
<th>Positive Differentiation Value</th>
<th>Negative Differentiation Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reference Price</td>
<td></td>
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The Reference:
- is usually the current “Standard of Care”...
- may not be a drug
- may be old and generic, or go generic before we get to market
- may be indirect – an analog
- may vary across countries
- may still be in development in a competitor’s pipeline
- is dynamic and changes with competitive or environmental developments

There **always** is a reference!
• Value of differentiating attributes must be:
  • Relevant to the customer – especially the payer
    • Payer perspective should be incorporated prior to finalizing Phase 3 endpoints
  • Robustly supported by data – both clinical and, increasingly, outcomes and economic
    • Adopting the “4th hurdle” requirement is the payers’ way of formalizing and quantifying their computation of differential value
  • Effectively communicated to customers → timely preparation of the “payer market” is increasingly important
    • Particularly important where large drug budget impact anticipated
Example: Differential Value Estimation based on cost savings

Focusing purely on cost savings – ie. without taking account of any mortality/morbidity improvements – Product Z is projected to justify a high “D” …..of course, the challenge is proving it…

Illustrative Data

Estimated “D” over current gold standard – measured by cost offsets in clinical practice

<table>
<thead>
<tr>
<th>Offsets</th>
<th>Additional cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>Drug cost</td>
<td>max</td>
</tr>
</tbody>
</table>

| AC monitoring | 0.9-1.1 USD/ day |
| LFT | |

Cost off-sets

£/ day

0 1 2 3 4 5
Example: Product X for Stroke Treatment - Differential Value based on Cost/QALY

Cost-Effectiveness
Product X used first line represents better Value for Money than standard care in eligible patients.

Cost/QALY increasingly used as a notional benchmark (e.g. $50,000/QALY in US; £30,000/QALY in UK)

Cost/QALY metric can be used to estimate breakeven price

→ Price forms upper end theoretical threshold for price estimation

Illustrative Data

- (1) Product X vs stan care (0-6h)
- (2) Product X vs placebo (0-3h)
- (3) Product X vs tPA (0-3h)
- (4) Product X+tPA vs tPA (0-3h)
- (5) Product X vs placebo (3-6h)
- (6) Stroke prevention
- (7) Alzheimer's
- (8) MI
Value across segments

Revenue = Volume times Price

Smaller patient segments may yield higher economic value and higher revenues/profits
Purchase Decision Analysis

Understanding the “buying system”
Who is the Customer?

The “buying system” comprises multiple purchase decision makers each with different value perceptions, influence on uptake, and on each other.

Payer
- Disease Priority/ Unmet Need?
- Clinical Innovation?
- Budget Impact?
- Quality of Evidence?
- Health Economics?
- Political Motives?

Prescriber
- Clinical Improvement?
- Patient Financial Impact?
- Personal Financial Impact?

Patient
- Co-Pays/ Out of Pocket?
- Humanistic Impact (Q of L)?

“Should I reimburse this product/ add product to formulary?”

“Should I prescribe this product?”

“Should I accept this script/ fill this script?”
Affordability/ budget impact is increasingly a payer barrier

The 2 main payer concerns are:

1. **Is it worth it?** (value for money)
2. **Can we afford it?** (budget impact)

- Requires careful consideration of options and trade-offs:
  - **Price vs patient access** (consideration of subpopulations)
  - **Strategies to facilitate increase in budget headroom**
- Requires early assessment and build into development & commercial strategy
Global Optimization

Understanding the tradeoffs within and across products and markets
Global Optimization

- Global optimization across different “entities” → a key part of pharma pricing strategy development:
  - **Geographic** price optimization – across countries, managing
    - Price referencing
    - Parallel trade
  - **Indication** price optimization – same molecule, >1 indication
  - **Dose** price optimization – same formulation, different doses
  - **Formulation** price optimization – new formulations, line extensions
Optimization across countries – Overview Approach

1. Assess individual market price/demand dynamics
2. Overlay global context and optimize
3. Implement and maintain a Global Pricing Strategy

US
France
Germany
UK
Canada
e.tc

Optimization Modeling

Individual Demand curves

Cross Market Interactions

Cohesive Global Strategy
- Global floor or corridor
- Launch sequence
- Price targets
Role of Pricing Strategy Development

- **Price Setting**
  - "what should the price be?"

- **Influencing Value Generation**
  - "How do we align the value generation activities to maximize the pricing opportunity?"

- **Price Support**
  - "How do we support and justify the price?"

Tight and constant integration between:

- Development & Commercialization Strategies
- Product Profile
- Pricing Opportunity

VALUE GENERATION

VALUE CAPTURE
Thank You