
Understanding Cost of Goods and Pricing for Product Development Partnerships

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PDP Access Group

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Key questions for Discussion

- **Why is industry so reluctant to share COGS data?**
- **How does industry think about the link between COGS and price?**
- **What are major COGS categories and drivers?**
- **What are typical expectations for return on investment for industry?**
- **How does industry think about “access agreements” and “access pricing”?**
- **What happens to COGS when production volume increases significantly?**

Sharing COGS Data

- **Manufacturers are reluctant to share COGS data because the data expose margins and may change expectations on pricing.**
- **For biopharma companies in particular, prices to different customers vary widely, and margins can appear to be very high.**
- **Manufacturers are very concerned about reference pricing, and the potential that, if discovered, COGS data could be used as leverage to reduce prices.**

Relationship between COGS & Pricing

- In many cases there is absolutely no relationship between COGS and pricing.
- PREVNAR pricing was considered by many to be a fundamental shift in vaccine economics and was established based on health economics.
- Price increases are often linked to general inflation measures rather than true increases (or decreases) in production costs over time.
- At very low rates of return, the cost accounting methods become very important in determining price.

Major Categories of Industry COGS

- **Research & Development**
 - R&D expense is usually significant, may be treated as a “portfolio” cost, and timing/depreciation assumptions are very important. Includes pre-clinical and clinical trial costs.
- **Fixed Costs**
 - Fixed costs are usually driven by plant and equipment. Shared facilities and specialty equipment require careful analysis. Depreciation rates, location, and taxation are important considerations.
- **Variable Costs**
 - These range from true variable costs (e.g., vial, stopper, etc.) to more complicated costs that may not increase linearly as volume increases. Allocation is important for high-volume production.
- **Other Costs**
 - Include royalties, taxes, transfer pricing, etc.

Expected rates of return

Manufacturers have expectations on rates of return that vary by product / project:

- **Cost of capital**
- **Risk profile of investment**
- **Franchise value**
- **Available capacity**
- **Volume & other commitments from purchaser**
- **Competition**
- **“Soft” considerations**

Other Considerations

- **Reputation vs. Economic Return**
 - **Manufacturers may be willing to reduce their expectations for economic return if there is an opportunity to enhance corporate reputation**
- **Lifecycle Considerations**
 - **It is probably easier to negotiate better “access” pricing towards the end of the product lifecycle. However this continues to promote health access disparities.**
- **Is there a trend towards better prices for low-income markets?**
- **Price transparency**
- **Role of PAHO**