COGS Principles – The Perspective from BMGF

PDP Conference

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Jennifer Shulman – Duff & Phelps

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BILL & MELINDA GATES *foundation*

Agenda

- Principles
- Allocation Keys
- Broad Cost Categories
- Specific Cost Categories

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Principles

In pursuit of its mission to help ensure that vaccines and other necessary health-related products are available and affordable to those most in need in the developing world, the Bill & Melinda Gates Foundation (the “Foundation”) makes grants to and other investments in manufacturers who produce vaccines and other health-related products.

In evaluating these investments, the Foundation needs to collect relevant production cost data from manufacturers in order to assess investment opportunities and establish fair and reasonable price targets.

Recognizing that manufacturers may account for such costs in different ways, the Foundation has established a standard methodology that it uses to evaluate the production costs of a particular vaccine in a particular market. The Foundation will share its standard methodology with manufacturers.

Principles

The Foundation's methodology for data gathering, aggregating, and allocating cost components is aimed at increasing the Foundation's ability to understand the Vaccine's fully-loaded cost base.

Using a robust and appropriate methodology to estimate costs lies at the core of a fair and sustainable system for providing critical vaccines to the developing world in a manner consistent with the following objectives:

- Vaccine access and affordability is improved in lower-income markets
- The manufacturer earns an appropriate return on investments (and does not earn a return that would be inappropriate in light of the Foundation's charitable mission and status)

The intent of collecting cost data pursuant to a standard methodology is to ensure that the Foundation uses for its own analysis only those costs that are tied directly to the development and production of a specific vaccine for particular countries or regions (i.e., markets), and other costs (i.e., those attributable to or already absorbed by the other markets, such as developed world countries) are appropriate allocated or excluded.

Principles
Cost Data

- The Vaccine's fully-loaded cost base should be estimated based on actual historical costs adjusted to reflect the average production yields and volumes expected over the period being analyzed
  - If historical cost information is not available, then projections based on the manufacturer's past experience with similar products may be used

- Because vaccines are often produced in shared facilities and delivered to multiple markets (some of which may be outside the scope of the costing analysis), allocation keys are used to apportion shared costs and expenses included in the Vaccine's fully-loaded cost base

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Allocation Keys
Why Allocate Costs?

- There are generally two reasons for allocating costs:

1) To isolate the costs of resources used in the manufacturing of the Vaccine, where the manufacturer is involved in the production of multiple products
2) To isolate the costs of production specific to a particular geography, where the Vaccine is sold in multiple markets

Allocation Keys
Why Allocate Costs?

- For the purposes of the Foundation's costing analysis, the choice of allocation key should balance accuracy, simplicity, and equity, with the greatest emphasis placed on accuracy:

  - Accuracy – The allocation key should reliably reflect the cost drivers
    - **For example, if the cost of the fill/finish is primarily driven by the amount of time it takes to fill/finish a particular vaccine, and the time it takes to fill/finish two different vaccines is approximately equal on a per-dose basis, then allocation by volume would provide a reasonable estimate of the resources used by each vaccine**

  - Simplicity – The allocation key should be easily and inexpensively obtained
    - **For example, production volume is often readily available, whereas actual time spent by employees on particular activities may be unavailable or require additional, and perhaps costly, analysis**

  - Equity – The allocation key should take into consideration the ability to bear the cost
    - **For example, a higher margin product earning a larger return should bear a greater proportion of investment costs and indirect costs associated with production. In this way, products sold in higher-income countries may have a fully-loaded cost base than (nearly) identical products sold in lower-income countries**

Allocation Keys

- The primary allocation keys used are:
  1. Volume
  2. Revenue

- There are other common allocation keys (some noted below)
- Any observable characteristic could be used as an allocation key provided that it leads to a reasonably accurate apportionment of costs

- When allocating costs:
  - The manufacturer should avoid using “rules of thumb” that are not based on the actual production of the Vaccine
  - The manufacturer should always ensure that the allocation method employed would not lead to over-allocation of costs if applied to all of the manufacturer’s products (e.g., allocating 30% of overhead costs to each of its 10 vaccine products, which would lead to a total allocation of 300% of overhead costs)

Allocation Keys
Volume

Definition	Costs are allocated to different products and markets based on the relative volume sold
Examples	100 million doses of a vaccine are produced and sold in different countries: • 90 million are sold in high-income countries • 10 million are sold in low-income countries • Based on a volume allocation, 10 percent of costs would be allocated to production for low-income countries A fill and finish facility with a 25 million dose capacity is shared between two vaccines. • 5 million doses of Vaccine A are sold by the facility • 20 million doses of Vaccine B • Based on a volume allocation, 20 percent of costs would be allocated to Vaccine A
Guidelines	This allocation key implicitly assumes that the cost to produce a single dose does not vary across products Note that volume sold may differ from volume produced (e.g., stockpiling inventory, wasted batches)

Allocation Keys
Revenue

Definition	Costs are allocated to different products and markets on the basis of revenue
Example	20 million doses of a vaccine are produced and sold in different countries. • 10 million are sold in high-income countries at $9 per dose • 10 million doses are sold in low-income countries at $1 per dose • Based on a revenue allocation, 10 percent of costs would be allocated to low-income countries (By comparison, if this were using a volume allocation, then 50% of costs would be allocated to low-income countries.)
Guidelines	**Note:** *A "Price Allocation," where costs are apportioned based on the relative selling price of joint products, is sometimes used as a shortcut to a revenue allocation. This should be avoided. In instances where the relative volume of outputs is stable with the level of inputs, allocation by price is identical to allocation by revenue. However, a price allocation may lead to a misleading fully-loaded cost base when the ratio of inputs to outputs varies.* *For example, bulk antigen (the input) can be used to produce vaccines for both high-income and low-income countries (the outputs) in whatever proportions a manufacturer chooses. If the costs of bulk antigen are allocated based on price, then the allocation of costs is independent of volume. This can lead to misleading results, such as the total cost of bulk antigen to produce a single dose for high-income countries is the same as the total cost to produce 1 million doses.*

Allocation Keys
Other Allocation Keys

Definition	Other allocation keys may be appropriate in apportioning costs to different products and markets in certain circumstances
Example	**Example #1 (Time):** Use of a bulk production facility is split between two vaccines. Every year, the facility is used by Vaccine A for 13 weeks and by Vaccine B for 26 weeks, with the remaining 13 weeks necessary for transitioning the facility between vaccines. Based on a time allocation, 33 percent of costs would be allocated to Vaccine A and 67 percent of costs to Vaccine B **Example #2 (Square Footage):** If a building has production split between two suites, then it may be appropriate to allocate the indirect building costs based on the suites' square footage or the relative value of assets employed by each suite **Example #3 (Headcount):** Costs of employee benefits may be most appropriately allocated based on the number of employees engaged in a particular activity
Guidelines	Allocation keys other than volume and revenue may be used wherever appropriate cost drivers can be identified, so long as their application improves the accuracy of cost allocation without unwarranted additional effort

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Broad Cost Categories

- Investment Costs vs. Ongoing Production Costs
- Direct Costs vs. Indirect Costs
- Fixed Costs vs. Variable Costs
- Sample Cost Category Breakdown

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Specific Cost Categories

- Property, Plant, and Equipment (PP&E)
- Research and Development (R&D)
- Depreciation
- Repairs and Maintenance (R&M)
- Consumables and Packaging Materials
- Overhead
- Labor
- Licensing Income / Expenses
- Costs to Commercialize

Q&A

Jennifer Shulman, PhD

Managing Director

Duff & Phelps Canada Limited
Bay Adelaide Centre
333 Bay Street
14th Floor
Toronto, ON M5H 2R2
T +1 416 361 6751
F +1 647 317 1800
Jennifer.Shulman@duffandphelps.com

Dr. Jennifer Shulman is a managing director in the Toronto office of Duff & Phelps, and has extensive experience in the transfer pricing service industry. Before joining Duff & Phelps Jennifer was a vice-president with NERA in Toronto also specializing in the field of transfer pricing. Prior to NERA, Jennifer was a managing director in KPMG LLP's Economic and Valuation Services practice in Chicago, where she specialized in domestic and cross-border transactions involving complex transfer pricing issues. Her recent client work includes, for example:

- For a global pharmaceutical company, evaluated the intercompany cost and pricing associated with the global supply chain, including areas such as R&D, clinical trials, manufacturing, marketing, and distribution.
- Analyzed the cost of production and appropriate pricing model associated with an “orphan” cancer drug for a global pharmaceutical company.
- Developed and managed the cost and pricing for the IP portfolio for a Fortune 200 diversified industrial manufacturer. The analysis included assessing the cost base, developing the pricing methodology, and defending the prices to Tax Authorities in certain jurisdictions.
- Assisted companies with determining global transfer pricing policies in conjunction with supply chain planning and merger and acquisition integration.
- Served as the principal investigator for several different impact studies of the economic and fiscal impact of company’s new and/or increased investment in local counties and cities in the US.

Dr. Shulman has worked with clients in numerous industries, including: Automotive; Chemicals; Consumer Products; Energy; Industrial Equipment; Industrial Manufacturing; Oil & Gas; Pharmaceuticals; Pulp & Paper; Medical Devices and Equipment; and Financial Services.

Prior to KPMG, she worked for Ernst & Young LLP's international transfer pricing group. Jennifer has been a speaker at several transfer pricing and international tax conferences. She received her PhD and MA in political science from the University of Michigan, with a major in international political economy and a minor in statistical and quantitative methods. Her dissertation studied US trade disputes with Canada, the EU, and Japan. She earned her BA with honors from McGill University.