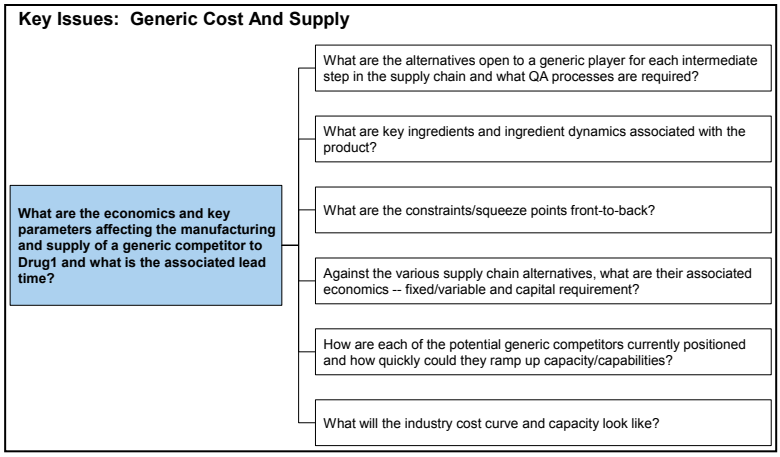
Understanding And Anticipating The Impact Of Generic Entry On A Multi-Billion-Dollar Drug Product: Financial And Manufacturing Planning For Loss Of Exclusivity At BigPharma

The Challenge: BigPharm achieved great success marketing Drug1 in the U.S. and in foreign markets. Now a multi-billion dollar drug product for BigPharm, Drug1 had drawn the attention of the large players in the generic industry and was the subject of numerous generic manufacturer patents and FDA filings aimed at generating a first-to-market advantage. BigPharm had little experience dealing with generic intrusion in the evolving regulatory environment and wanted to understand the financial and manufacturing implications of generic entry to Drug1.

The team leaders for Drug1 asked us to perform the following:

- Provide a situational analysis, including:
  – A process map of the manufacture and supply of Drug1, including identification of bottlenecks, constraints, etc.
  – Estimated cost and lead time (vis-á-vis supply chain hurdles) for a generic firm to enter the market
- Financial and manufacturing implications of alternative generic launch sequences across global markets
  – Create a financial and manufacturing planning model:
  – Capable of performing sensitivity calculations and analyses around pricing, capacity, costs, etc.
  – Enabling quantification of revenue impact from various scenarios/alternatives being explored
- Present recommendations for moving forward

The Partnership:



Analysis: Our diagnostic activities, carried out via plant visits and interviews with manufacturing, financial, and sales/marketing management, focused on mapping the Drug1 supply chain and establishing the economics. Contrary to BigPharm's ingoing hypothesis, it became clear that the raw materials and conversion capabilities required to produce Drug1 were widely available. Thus, focus shifted to establishing a sharper understanding of likely entry scenarios assuming various legal and regulatory process outcomes, and quantifying the impact of these scenarios for the BigPharm organization and for generic entrant(s). By assembling a database of historic erosion rates we were able to extrapolate branded share and price erosion dynamics and establish generic economics relative to the branded manufacturer (in molecule markets with more than 8 generic competitors, price erodes to cost). We then conducted a competitive capacity, supply chain and corporate strategy intelligence survey for each potential generic entrant.

Strategy: Using the results of analyses, we created an economic model for the U.S. Drug1 market which enabled testing various marketing scenarios, e.g. migration of patients to alternative dosage forms. These economic scenarios were used in conjunction with the probable legal outcomes regarding the defense of outstanding intellectual property rights. The U.S. model, once constructed, then became a template for establishing likely economics in large markets worldwide.

Execution: We held workshops with worldwide team leaders to train them on the model's use and to assemble inputs necessary for corporate financial and manufacturing planning. By aggregating individual country models, a complete worldwide economic and manufacturing planning picture was created for BigPharm.

The Results: Although Drug1 has yet to lose exclusivity in all markets, the ability to plan the end of product lifecycle enabled BigPharm to save millions on what would have been uneconomic marketing spending. Additional benefits include the ability to proactively manage organizational changes, e.g., shifting managers to new drug products, and a strategic management framework for handling other drug loss of exclusivity in the future.