CAPACITY INVESTMENT PLANNING FOR MULTIPLE VACCINES UNDER UNCERTAINTY
2: Financial Risk Analysis

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Abstract: Capacity investment planning is a major decision for a vaccine company. Traditionally, due to the inherent flexibility used in almost all vaccine processes and risk-averse decisions, companies always started with limited capacities, thereby reducing the initial capital investment. However, in order to fulfil fast-growing vaccine demands, good and balanced financial risk management for capacity expansion is required to satisfy future demand without over committing capital. To complement the use of financial risk management, known probabilistic definitions of some classical risk measures such as expected downside risk (EDR), opportunity value (OV), value-at-risk (VaR) and conditional value-at-risk (CVaR) are adapted to be used in a scenario-based model for capacity investment planning for manufacture of multiple vaccines. Using these definitions, new models that manage financial risks and aid decisions are developed. Computational results and decision-making analysis methods are also presented and discussed. Numerical results show that this approach enables one to consider and manage the financial risk associated with the different designdjjf\ options, resulting in a set of solutions that can be used for decision-making.

Keywords: decision-making; financial risk; optimization; stochastic modelling; vaccine manufacturing.

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INTRODUCTION

The first part of this paper has provided a stochastic modelling approach to determine the capacity planning and investment strategy for a multiple vaccine production case study. The model involved product selection, product manufacturing and a capacity expansion strategy based on the maximization of the expected net present value (eNPV). However, the stochastic model did not provide any control on the variability over the different possible outcomes associated with the uncertainty in the outcome of clinical trials and the demands for the potential vaccine products; it assumed that the decision-maker is risk-neutral. However, most decision-makers are risk-averse, i.e., they have a major preference for lower variability for a given level of return.

The focus on planning capacity expansion in the vaccine industry has increased in recent years. Capacity expansion may require a significant amount of capital investment over a long period of time. The market demands for vaccines depend strongly on the outcome of clinical trials. An investment decision, often based on net present value (NPV), has to be made in advance: whether or not to invest in capacity expansion or research and development in order to meet the customer demands. Manufacturing capacity has typically been initially limited to the commercially attractive markets when a new vaccine is introduced. Once a vaccine is in process development, the vaccine companies will take the decision whether or not to invest in expanding the production capacity. This investment decision is significant in terms of risk. If the capacity is over-estimated, it will result in wasting a large sum of money; if the capacity is under-estimated, it will result in losing market share to competitors. There are two main aspects of making capacity investment decisions. The first aspect is the cost of constructing and operating a vaccine manufacturing plant. Generally speaking, the capital and operating costs per unit of capacity fall as more facilities are installed. However, in absolute terms:

- a larger plant is more expensive to build and operate than a smaller one;

- the capital expenditure required to serve the global market is a multiple of that required to serve a local market;
- once the facility is in place, it only delivers economic benefit to the company if it is actually utilised, otherwise it requires higher cost than a smaller, better utilized facility.

The second aspect is the relative immutability of capacity decisions (a potential concern to the Global Alliance for Vaccines & Immunization (GAVI)). Once the decision is taken, the requirements of good manufacturing practice are needed as they affect biologicals and mean that capacity expansion is both very expensive and time-consuming. GAVI is an authority which has substantial potential negotiating power with the vaccine companies to gain early access to newly introduced vaccines, if its procurement mechanism is well calculated. GAVI has the responsibility to reduce the risk of capital expenditure for the vaccine companies before any capacity expansion or new facilities are installed. It can increase the operating and capital efficiency of a plant by enabling the construction of a larger plant that would otherwise have been the case, with some proportion of its utilisation underwritten. From the company's point of view, this factor is likely to extend the period when it faces limited or no competition.

Many capacity expansion decision tools are based on linear programming concepts. However, these tools are usually formulated under the assumption that future scenarios are known with certainty. It is assumed that all of the model coefficients, constraint values, and solution values are known precisely and do not vary. Decisions are often made within an environment of risk, uncertainty, or conflict. Decision theory is concerned with decision-making under conditions of risk and uncertainty. Uncertainty cannot be eliminated; only managed. Not only are there uncertainties present, but also our assessment of their levels of uncertainty are usually quite inaccurate (Mitchell, 1995). Additional facets of uncertainty involve a lack of understanding by the decision-maker about the loss categories that exist, and which losses can occur.

The only certainty in business is the presence of risk. Risk can be defined as a chance of danger, damage, loss, injury or any other undesired consequences. A more scientific definition of risk is the extent to which there is uncertainty about whether potentially significant and/or disappointing outcomes of decisions will be realized. Inherent in this definition are the dimensions of outcome uncertainty, outcome expectations and outcome potential. The meaning of risk has been studied in many areas. Baird and Thomas (1990) defined risk according to eight different perspectives, some of which are: finance, marketing, management, strategy and psychology. The authors also stated that risk is a multidimensional construct and differs according to business function. Mitchell (1995) defined risk as the product of the probability of loss and the significance of that loss to the organization or individual. Thus, if the probability of loss is $P(\text{loss}_n)$ and the significance of the loss is $I(\text{loss}_n)$ for an event n, then the risk is given by

$$\text{Risk}_n = P(\text{loss}_n) \times I(\text{loss}_n) \qquad (1)$$

To model financial risk management, Eppen et al. (1989) first proposed a traditional financial risk measure named expected downside risk (EDR). They devised a mathematical expression for EDR to measure the cost variability in a two-stage stochastic programming model for manufacturing capacity planning. Similar EDR mathematical models were also developed by Barbaro et al. (2003) for design and planning under uncertainty. They suggested that the EDR is the risk of loss that could result from a potential decline in price of a security or other investment. Barbaro and Bagajewicz (2004a) further proved that EDR is not unvarying with risk, such that a lower EDR does not necessarily have lower risk. Later, Barbaro and Bagajewicz (2004b) applied the use of EDR to an inventory and options case study. They showed that the usual assumption that the introduction of inventory reduces risk at low profit expectations is not always true, and that financial risk management tools need to be revised with appropriate objectives. Recently, Aseeri and Bagajewicz (2004) complemented the use of value-at-risk (VaR) and proposed a new concept, opportunity value (OV), to weigh opportunity loss versus risk reduction.

Financial risk management has always been commonly used in banks, insurance companies and major financial institutes to evaluate risks. It also applies to pharmaceutical manufacturing industries to make capacity investment decisions before demand is known to minimise investment risks. Simulation models for pharmaceutical development described in the literature are mostly financially-based. Blau et al. (2000) used a probabilistic simulation model of a pharmaceutical product development pipeline to prioritize candidate drugs based on their reward : risk ratios. Rogers et al. (2002) presented a stochastic optimisation model, called OptFolio, of pharmaceutical research and development (R&D) portfolio management using a real options approach for making optimal project selection decisions. The above models assumed that all future cash flows are known.

In this work, the objectives are focused on the financial risk analysis and the decision-making analysis. The financial risk analysis step includes tasks: (1) to complement the stochastic model results using financial risk measurements in order to provide a more realistic assessment of the options, (2) to reduce the downside risk using different approaches to show how the downside risk can be managed, and (3) to determine the optimal number of suites for investment. However, different decision-makers may have different strategies to determine the 'optimal' number of suites. Thus, in order to provide a better view of how the investment strategy may be determined, alternative approaches are compared in the decision-making analysis step. The decision-making analysis step provides different decision-making criteria to handle the risk analysis in the capacity expansion study. Specifically, the decision-making criteria of capacity expansion are discussed from the standpoint of financial risk management. Each of the decision-making strategies is discussed separately, and is illustrated for the suite investment problem using the NPV metric.

The organization of this paper is as follows. The following section provides some background on uncertainty and financial risk management. The third section discusses the concept of a traditional financial risk measure, named EDR, and its relation with financial risk, and a new model using EDR as a measure of financial risk is presented. Also, it reviews the general theory of some other common financial risk measurements. The fourth section describes some financial risk management techniques to be applied to the scenario-based vaccine manufacturing model. Next, the decision theory and associated methods are illustrated. Then the sixth section presents some alternative decision-making methodologies to handle the various criteria for analysis of