Chapter 8

Enterprise Risk Management: A Case Study in the Pharmaceutical Industry

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ABSTRACT

How a company successfully implements an Enterprise Risk Management (ERM) program, to identify and manage potential risks, can mean the difference between financial freedom and financial despair. The Committee of Sponsoring Organizations (COSO) guidelines, a voluntary private-sector organization in the United States, has developed internal control guidelines to provide guidance to executive management and governance entities on critical aspects of organizational governance, business ethics, internal control, fraud, and financial reporting. This chapter will discuss an approach to build an ERM implementation plan within a pharmaceutical company by outlining the responsibilities and influences of industry participants, sales forces, middle-management and senior leadership and the ways in which they focus on monitoring and developing the risk mitigation process. The influences of technologies are integrated and new directions, such as e-media and e-detailing (Virtual Sales Representatives) are also explored.

INTRODUCTION

In today’s business world, the accelerating pace of change and new product launches has increased at an alarming rate. Companies, which are first to market and launch their products to meet consumers’ demand, have done so by effectively managing their internal and external information utilizing an environmental scanning process. Monitoring and evaluating economic indicators will help detect and aid in predicting future trends and outcomes. In strategic planning all organizations have the ability to benchmark economic conditions, which
affect and contribute to improved profitability, market expansion and market penetration.

Predicting market trends, which may influence consumers’ buying decisions, will help guide companies in making informed strategic decisions with the goal of achieving their short-term or long-term goals. By focusing on these forces and trends from each of their respective environments, the relevance of these forces or trends will determine the ability of these companies to strategically adapt to these forces or trends and possibly avoid potential threats facing their own companies. Several tools are available to assist a company in analyzing their environment, such as strategic thinking sessions where high-level goals and forecasting are developed that align with its mission, operational effectiveness measurements to ensure efficient use of resources, routine report reviews, and adherence to monitoring for compliance with applicable laws, processes and regulations.

By examining the strengths, weaknesses, opportunities, threats and managing the risks, companies will be better able to capitalize on emerging opportunities or minimize potential risks by leveraging the company’s strengths and resources. The objectives of this chapter are to discuss the importance of ERM in the pharmaceutical Industry, relate ERM concepts to the pharmaceutical Industry’s external environment, and training, managing, and motivating employees involved with the ERM process.

BACKGROUND

In the midst of several high-profile corporate scandals and subsequent regulatory legislations and compliance policy violations, “TAP Pharmaceuticals settles with Dept of Justice for $875 million” (Healthcare Financial Management, 2001) or more recently “Pfizer’s $2.3 Billion-Dollar Settlement” (Forbes, 2009), the development and implementation of strict internal control systems has become an organizational requirement. These requirements have led many organizations to review their risk management areas and deem them as vitally important. Although the Sarbanes Oxley Act of 2002, a major regulatory policy in the United States, covered a part of an organization’s total risk management policy, many organizations felt compelled to develop comprehensive systems, which covered all aspects of risk management. The development and implementation of these comprehensive systems are termed Enterprise Risk Management programs.

Enterprise Risk Management programs are simply a framework of preventable, detective and corrective measures in which the effective application of them to an overarching strategy across the entire organization, designed to identify potential events or risks within a specified comfort level and to provide reasonable assurance on the achievement of company’s objectives. Several risk management best practices are available by reviewing the Committee of Sponsoring Organizations of the Tread way’s (COSO) Internal Control Integrated Framework system (COSO, 2008) and considered industry standards in building solid internal controls systems. COSO formed in 1985 to sponsor the National Commission on Fraudulent Financial Reporting; an independent private sector initiative aimed at studying the causal factors, which could lead to fraudulent financial reporting in the USA. This committee developed recommendations for public companies and their independent auditors, the US Security Exchange Committee and other regulators, and educational institutions. Their outcome provided an internal control process, which enacted “by an entity’s board of directors, management and other personnel was designed to provide reasonable assurance regarding the achievement of objectives in the following categories:

- Effectiveness and efficiency of operations
- Reliability of financial reporting
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