Chapter 14
R&D Productivity in the Pharmaceutical Industry: Scenario Simulations Using a Bayesian Belief Network

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ABSTRACT

The pharmaceutical industry is in a R&D productivity crisis. Rapidly increasing development costs, decreasing profitability of new medical entities and missing breakthrough innovations are negatively affecting the future of the pharmaceutical industry. This complex problem requires a systems thinking approach to find effective solutions. In this study, a general pharmaceutical R&D productivity system has been modeled as a Bayesian Belief Network (BBN). This model is based on a literature review and the mental model of experts in the pharmaceutical field. The model does not only support users to understand the system but is also able to simulate different future scenarios. A blockbuster drug scenario, a generic drug scenario, and a personalized drug scenario has been modeled with three different corresponding outcomes. These simulations enables decision makers to identify the leverage points of the pharmaceutical R&D productivity system. These leverage points could be the foundation of any further strategy development. The R&D productivity system archetype is potentially applicable for other R&D intensive industries.

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INTRODUCTION

Crisis of the Pharmaceutical Industry

Life expectancy of an U.S. citizen has on average grown 3.25 months each year for the last century (Arias, 2006). Pharmaceutical innovation has partly contributed to this high life expectancy rate (Munos & Chin, 2011). However, the pharmaceutical R&D is in a productivity 'crisis' (Pammolli, Magazzini, & Riccaboni, 2011). The productivity rate is falling due to the increasing development costs and the decreasing profitability of launched New Medical Entities (NMEs). Several causes are suggested to explain the rising development costs. Some sources in literature argue that most of the 'low hanging fruits' have been picked (Cohen, 2005; Garnier, 2008; McKinsey & Co, 2012). This implicates that most of the relative easily found and non-complex cures for non-rare diseases have been produced, which resulted in a leftover of complex and relative small diseases. Another potential issue for the rapidly increasing development costs is the high failure rate and corresponding failure costs in the third and final pre-market phase being described as the 'Phase II Roadblock' (Cohen, 2005). Simultaneously, even if a novel drug reaches the market, profitability is decreasing due to increased competition, shorter product life cycles and decreased market size (Khanna, 2012; Narayan, Mohwinckel, Pisano, Yang, & Manji, 2013). During the last two decades, the pharmaceutical industry has been increasing their R&D expenditure significantly (Cohen, 2005; Munos, 2009; Paul et al., 2010). Yet, despite an increase of NMEs in the previous two years, the overall trend in NME output is still steadily declining (CDER, 2012). This leads to the crumbling of the financial and scientific reputation of the industry. R&D productivity seems to be the key to both medical and financial success in the pharmaceutical industry.

Systems Thinking Approach

In an highly regulatory, very uncertain and complex landscape such as pharmaceutical industry; decision makers, leaders, managers, and scientists are under increasing pressure to make the right investment decisions (Nguyen & Bosch, 2013). The traditional reductionist approach based on isolation and analysis appears no longer to be the only option to understand local and global problems in today's societal, and more specific, pharmaceutical world. Regardless whether these problems are in a social, natural, political, business, governmental or scientific environment, the involved decision makers, scientists, NGOs or any other stakeholders are faced with problems which are highly complex in nature (Bosch, Nguyen, Maeno, & Yasui, 2013). Although reductionist science is required for certain types of research, reductionism and traditional linear thinking can no longer lead to the most suitable solution to multifaceted complex problems. Systems Thinking approaches that leads to long-term sustainable solutions at the root causes of problems clearly appears to be more appropriate (Bosch et al., 2013; Jackson, 2009; Smith, Felderhof, & Bosch, 2007). However, in the field of pharmaceutical innovation management, little evidence is found of the use of 'Systems Thinking approaches'.

In order to cope with all the different types of uncertainty and complexity of various sources), without losing track of the 'bigger picture'(Zyphur & Oswald, 2013, a Bayesian Belief Network (BBN) modeling is applied. This adaptive management tool is used with full stakeholder involvement and is a powerful mechanism for the integration of data, information and knowledge from different sources and domains (Henriksen & Barlebo, 2008; Jensen, 2002). These BBN models allow simulations of differ-