



Navigating Uncertainty: The Effectiveness of Scenario Planning in Pharmaceutical Product Launch

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Abstract English

The successful development and launch of new drug products describe the core business of pharmaceutical companies, driving growth and making significant contributions to society. However, a considerable number of pharmaceutical product launches fall short of expectations, highlighting the need for effective strategies in this highly competitive landscape. Scenario planning as a strategic tool has long gained recognition in the industry, yet research on its impact on launch success remains limited. This study aims to fill this gap by examining the interplay between scenario planning and launch success in the pharmaceutical industry. Through a comprehensive review of relevant literature, this research provides valuable insights into risk and uncertainty in the industry as well as identifying critical success factors for pharmaceutical product launch. The qualitative content analysis of semi-structured interviews complements the theoretical discussion and enables a deep exploration of experts' perceptions on and experiences with the strategic tool and pharmaceutical product launch in practice. The findings affirm the effectiveness of scenario planning in enhancing launch success, shedding light on its potential to mitigate risk and uncertainty in the industry. Furthermore, it offers best practices and practical recommendations to industry experts and launch leaders, empowering them to leverage scenario planning as a strategic tool in pharmaceutical product launch.

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Key words: Pharmaceutical Industry, Pharmaceutical Product Launch, Scenario Planning, Launch Success, Strategic Tools, Risk and Uncertainty

Abstract Portuguese

O desenvolvimento e lançamento bem sucedidos de novos medicamentos descreve o negócio principal das empresas farmacêuticas, impulsionando o crescimento e fazendo contribuições significativas para a sociedade. No entanto, um número considerável de lançamentos de produtos farmacêuticos fica aquém das expectativas, destacando a necessidade de estratégias eficazes neste ambiente altamente competitivo. O planejamento de cenários (Scenario Planning), como ferramenta estratégica, há muito que ganhou reconhecimento na indústria, mas a investigação sobre o seu impacto no sucesso do lançamento permanece limitada. Este estudo visa preencher esta lacuna examinando a interação entre o Scenario Planning e o sucesso do lançamento na indústria farmacêutica. Através de uma revisão abrangente da literatura relevante, esta pesquisa fornece informações valiosas sobre o risco e a incerteza na indústria, bem como identifica fatores críticos de sucesso para o lançamento de produtos farmacêuticos. A análise qualitativa do conteúdo das entrevistas semiestruturadas complementa a discussão teórica e permite uma exploração profunda das percepções e experiências dos especialistas com a ferramenta estratégica e o lançamento de produtos farmacêuticos na prática. As conclusões afirmam a eficácia do Scenario Planning no aumento e na melhoria do sucesso do lançamento, iluminando o seu potencial para mitigar riscos e incertezas na indústria. O estudo também oferece melhores práticas e recomendações práticas para especialistas do setor e líderes de lançamento, capacitando-os a aproveitar o Scenario Planning como uma ferramenta estratégica no lançamento de produtos farmacêuticos.

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List of Abbreviations

R&D	Research and Development
OSPA	Oxford Scenario Planning Approach
TUNA	Turbulence, Uncertainty, Novelty, Ambiguity
NPL	New Product Launch
FDA	U.S. Food and Drug Administration
EMA	European Medicines Agency
SCM	Supply Chain Management
SWOT	Strengths, Weaknesses, Opportunities, Threats

1. Introduction

1.1 Introduction

Developing and launching new drug products is one of the most critical activities for pharmaceutical companies. Not only does it drive companies' growth, but it as well ensures them contributing to society. Nevertheless, two-thirds of drug product launches fall below expectations (Ahlawat, et al., 2014, p. 2). Besides naturally involving high investments in all kinds of resources, the process of launching a new product takes place in a highly uncertain and volatile environment that due to many possible disruptors is unlikely to decrease in the future. To meet this challenge, skills and competencies in foresight and strategic planning will continue to be of great importance for the industry. One approach that has particularly gained scholarly interest is scenario planning. Despite the fact that scenario planning has become popular in the industry, there is limited research that reflects the interplay between scenario planning and pharmaceutical launch success. This research aims to close that gap and is structured as follows.

The research starts with a thorough review of existing literature relevant to the research topic. Based on that holistic overview, preliminary answers to the research questions are given and a hypothesis on the effectiveness of scenario planning in pharmaceutical product launch is stated. Next, the methodology chapter describes the research method for the qualitative content analysis of semi-structured interviews, including the definition of the methodology and the overall research design. Then, the results of the analysis are presented, and in a final chapter are discussed and linked to the literature review.

1.2 Problem Statement

The pharmaceutical industry is characterized by a high degree of uncertainty, and that uncertainty is compounded by the fact that pharmaceutical companies as part of the healthcare industry operate with the main goal of saving lives before making profit (Sutcliffe, 2011, p. 137). In addition, the industry places high investments in research and development (R&D) activities, achieving the highest ratio to net sales in comparison to other industries (Matikainen, et al., 2015, p. 175), and is yet considered with low success rates (EFPIA: Key Data 2018, 2018, p. 6). The launch of new products therefore is one of the most crucial activities that requires strategic planning. Scenario planning as a strategic tool has long gained recognition in the industry, however, there is a notable gap in research on delivering a comprehensive understanding of the conjunction between launch success and the tool.

1.3 Research Objective

To address this gap, this research aims to analyze the effectiveness of scenario planning as a strategic tool in pharmaceutical product launch. The goal of the study is to first identify the main drivers of risk and uncertainty during launch, and second, to determine concrete success factors. Ultimately, the research seeks to deliver best practices and recommendations for industry experts and launch leaders. The concrete research questions are defined in the following section.

1.4 Research Questions

RQ1: What are the primary drivers of risk and uncertainty in pharmaceutical product launch?

RQ2: What makes scenario planning a successful tool in mitigating risk and uncertainty in pharmaceutical product launch?

RQ3: What are best practices and recommendations for pharmaceutical companies to implement scenario planning into their launch processes?

2. Theoretical Discussion

2.1 Literature Review Design

This literature review is conducted to identify whether relevant research on scenario planning in pharmaceutical product launch exists. The chosen approach is a narrative literature review with the objective to represent the current state of knowledge on a particular topic and follows the main steps described by Pautasso (2020). In accordance to the author, in a first step the topic and audience is defined (see Introduction), literature is searched upon key words and by checking references cited in the selected papers, and notes are taken and reviewed in an iterative process (Pautasso, 2020, pp. 299-302). Next, an integrative review approach is chosen to find shared understandings in the reviewed literature that are then critically examined (Pautasso, 2020, pp. 203-305). Lastly, the findings are structured and formulated in a narrative style that allows readers to view and understand the broader context of the topic (Pautasso, 2020, p. 305).

2.2 Terminologies

2.2.1 Introduction

Scenario planning has attracted great interest among strategists and organizations in recent years. Considering the high uncertainty and risk related to pharmaceutical product launch, it is not surprising that the approach has gained recognition in the industry.

To understand the relevance of scenario planning as a strategic tool in pharmaceutical product launch, it is necessary to explain some of the terminology first. For this purpose, the following sections aim to deliver definitions and a shared understanding of foresight, strategic planning, and scenario planning.

2.2.2 Foresight and Strategic Planning

Foresight is a term widely used in the context of strategic planning and academics find many ways to define it. While a small proportion of definitions refer to the tool as being a rather quantitative approach, it is more commonly described as a systematic view into the long-term future that aims to provide insights that impact the way we are making decisions today (Cuhls, 2020, p. 3). Foresight describes the strategic scanning of the environment for changes, including quantitative techniques or not, and holds the purpose of deriving measures from it that ultimately influence how we respond to that information in the present (Arokodare & Asikhia, 2020, p. 4). By applying the appropriate tools and techniques, qualitative and quantitative (Webb, 2021, p. 24), it allows users to anticipate change and their consequences,

and conclusively make better-informed decisions (Buehring & Bishop, 2020, p. 410). It therefore is a technique that enhances an organizations ability to deal with uncertainty and risks, as well as to view causalities and links to alternative decisions and strategic plans that can be derived from that knowledge (Arokodare & Asikhia, 2020, p. 5). However, research shows that besides the linkage between the future and a current state, foresight is not reduced to the exploration of only one possible future but refers to a plural of possible alternatives. Further, it is not to be mistaken as an attempt to forecast the future, or to be equated to actual strategic planning.

While forecasting is interchangeable with predicting, foresight relies on the premise that the future is unknowable but imaginable, especially over longer horizons (Behar, 2021, p. 3). For that reason, foresight needs to be distinguished from forecasting and is understood as a tool that provides information about possible futures and supports managers in making plausible assumptions. Being a technique rather than a process, it needs further distinction from strategic planning, which ultimately takes information and assumptions gathered through foresight, and translates them into actual decisions (Grant, 2003, p. 493). While the desired outcome of foresight is establishing multiple futures, the intention of strategic planning is a specific plan including implicit objectives, strategies, and decisions (Buehring & Bishop, 2020, p. 414).

Conclusively, researchers agree that foresight and strategic planning are complementary procedures. Foresight provides context and a broader future, while strategic planning takes that information and derives decisions, measures, and actions from it. In identifying multiple futures, based on measurable and validated information, foresight functions as a subset of strategic planning. Another tool that is commonly used in that context is scenario planning, which will be defined and explained in the following section.

2.2.3 Scenario Planning

Scenario planning is a term that has been widely discussed in literature in recent years. Not only do consulting firms and companies debate it, but academics and researchers have found increased interest in the topic as well. While it seems as if at first glance the term means different things to different organizations and strategists, it is observed that the wider understanding of the concept is mostly based on the same three fundamental pillars: the overall principle of scenario planning, the timeframe it refers to, and the ultimate intention.

First, the principle of scenario planning is the creation of a small set of different possible futures (Behar, 2021, p. 13), that describe informed, plausible and imagined alternative environments (Moats, et al., 2008, p. 401), by the help of descriptive stories of the different paths that the future might take (Buehring & Bishop, 2020, p. 414). Authors agree that scenario planning involves the creation of multiple futures that are supported by plausibility and descriptive in nature. Thus, scenario planning is not only a creative process, but it involves the validation of those descriptions and therefore can involve quantitative elements without that being a requirement. Further, scenarios generally speak against the assumption that the future can be predicted since they exactly emerged for that being untrue (Chermack, 2022, p. 15). By presenting various scenarios, we can better understand the uncertainties and complexities that exist, and acknowledge that the future is often unpredictable and subject to change.

Second, scenarios built in the process should evolve over a sufficiently long horizon, where choosing the concise timeframe is of high importance as it determines to what extent users will open their minds (Behar, 2021, p. 13). This observation supports the idea of scenario planning and the precisely chosen point in time in the future influencing the mental models that decision makers have when deriving measures from the scenarios established in the process (Grant, 2003, p. 493). Besides, using the present tense when discussing created scenarios further supports how users respond to those and increases their overall willingness to open up to the idea of change (Behar, 2021, p. 13).

Third, the intention of scenario planning unanimously is to derive measures from possible future outcomes that influence how we act in the present. It is observed that especially in a business environment being as volatile and uncertain as it is in recent years, companies are well advised exploring their present possibilities instead of tying themselves to strategies that are based on a single set of events (Ramírez, et al., 2017, p. 1). In this, scenario planning is more about exploring how to act today considering alternative futures, than viewing the future from the present state. Scenarios therefore are not an attempt to predict what will be happening in the future, but they aim to limit uncertainty and provide a basis on which conscious and informed decisions can be made (Webb, 2021, p. 23).

The most used methodology for scenario planning, pioneered by Royal Dutch/Shell and further developed by the University of Oxford, is examined in the following section.

The Oxford Scenario Planning Approach (OSPA)

In the late 1960s and 1970s, following World War II and the major oil crisis in 1973, scenario planning first gained recognition after being recreated by Pierre Wack, head of long-range planning at Royal Dutch/Shell, and implemented to cope with the disruption (Moats, et al., 2008, p. 401). Today several approaches to scenario planning have emerged. One that has evolved from the concept by Shell and today is mentioned most frequently in research is the Oxford Scenario Planning Approach, short OSPA, established by Rafael Ramírez and Angela Wilkinson (Ramírez & Wilkinson, 2016).

Developed at the University of Oxford, OSPA is based on the idea of collaborative work where individuals and groups of all functional levels within an organization are engaged to discover various factors that influence the future and, by that, to reframe their shared understanding of the present (Ramírez, et al., 2017, p. 2). Being a methodology rather than a sophisticated method, it does not aim to provide a step-by-step guide from which no deviation is allowed. Rather, it involves creating a customized scenario experience that aligns with the needs of the learners and the specific objectives of a project (Chermack, 2022, p. 19). Based on the assumption that a business environment is turbulent, unpredictably uncertain, novel and ambiguous (TUNA), it aims to offer an incentive for organizations to view those conditions as opportunities to reframe strategies and innovate rather than classify them as threats from the beginning (Ramírez, et al., 2017, p. 2). Reframing describes one of the fundamental pillars of the approach.

Considering the original work on OSPA, strategists today are well advised eliminating the thought of strategies as a way of predicting and controlling the future, and instead giving higher priority to strategy as a learning process for individuals and organizations (Ramírez & Wilkinson, 2016, p. 3). By this, the authors underline one core element of OSPA, namely, the approach being an interactive, creative and iterative process of discovery and invention that allows participants to enhance perspectives, and adjust strategies according to changing conditions. Reframing finally supports users to gain awareness of the frames they are currently applying on the world, and offers the opportunity to explore alternatives, re-perceive action options as well as the present itself (Ramírez & Wilkinson, 2016, p. 4).

In order to achieve a better understanding on how the scenario planning process is realized in practice, the following section examines guidelines as described in literature.

The Scenario Planning Process

In literature, different ways of conducting scenario planning are found. While some authors choose to divide the process in a larger set of sub-steps, others concentrate on a smaller selection. After reviewing variations, the scenario planning process is divided into four main steps: preparation, research, scenario creation and scenario usage.

The first step in scenario planning focuses on the sufficient preparation of the process, and highlights the importance of clearly defining a purpose as well as the actual users of the scenarios (Moats et al., 2008, p. 402). By this, a shared understanding is ensured which further affects the ultimate design of the scenarios (Ramírez, et al., 2017, p. 5), meaning, the way scenarios are built and used. Various publications further highlight the fact that scenarios can be built in many ways and for almost any purpose, and by this, are used to “challenge, surprise, or inspire” (Behar, 2021, p. 11). For instance, they can be written in broad descriptions and open-ended, or rather focused. The objectives are equally versatile, starting at searching for a potential solution to a specific problem, ending at deciding between different options to an endeavor.

The second step focuses on researching trends and uncertainties with the intention of creating a broad range of factors and perspectives, and in the following laying a foundation to the overall analysis (Moats, et al., 2008, p. 402). This is by analyzing the internal and external environment by gathering information in any common way, using quantitative or qualitative research methods. Best practices have shown that traditional data analysis as well as interviews, external and internal, or expert masterclasses prove to be sufficient in order to collect information and identify uncertainties of relevance (Behar, 2021, p. 12).

The third step describes the actual creation of scenarios. As Pierre Wack has already described during the scenario planning implementation at Shell, a scenario planning process starts by constructing a first draft of exploratory scenarios, which will then be transformed into more established scenarios from which actual decisions are derived (Wack, 1985, p. 9). This implicates that the scenario planning process is iterative, and an increase in time and information leads to certainty about action options and decisions. Besides, authors agree that the best way to create scenarios is in collaboration through workshops or dedicated hands-on sessions where cross-functional teams come together and integrate their knowledge into a common set of scenarios. The idea of collaborative work also aligns with the original OSPA (Ramírez & Wilkinson, 2016). Further, when creating scenarios the point in time must be

carefully deliberated as it determines to what degree users open their minds (Behar, 2021, p. 13), which influences their openness to change. As indicated before, scenarios can be further complemented by data quantification or modelling in order to assure internal consistency or to validate a specific point. However, they are sufficient in qualitative format as well.

The fourth step in the scenario planning process describes how scenarios are ultimately used. It is important to highlight that scenarios themselves are not the ultimate outcome of the process, but they function as further input for strategic planning (Behar, 2021, p. 16). Well-established and profound scenarios will deliver valuable insights that allow informed decision-making and the derivation of actions. Considering the classic “Thinking Fast, and Slow “ by Kahneman (Kahnemann, 2012), it can also be observed that ultimately even people with a quantitative disposition are better at dealing with stories than with data. Therefore, the scenarios main intention is to broaden users’ perspective, aid further engagement, and help moving from scenarios to actual decisions (Moats, et al., 2008, p. 402).

Before the theory of scenario planning is tested upon practical experience in pharmaceutical product launch, it is important to first analyze the industry and the pharmaceutical product launch process in general. The following section will focus on that objective.

2.3 The Pharmaceutical Industry

2.3.1 Introduction

The pharmaceutical industry is defined as a group of organizations, processes and actions involved in the invention and innovation of pharmaceutical products (Moosivand, et al., 2019, p. 1104). In recent years, the industry has experienced far-reaching disruptions that make it necessary for pharmaceutical companies to rethink strategies and open up for change. A shift in product profile from high volume low mix, to low volume high mix further highlights how pharmaceutical companies in recent years more than before have relied on the successful launch of new drug products in order to drive growth (Ahlawat, et al., 2014, p. 1). Since this challenge is unlikely to disappear in the future, it is essential to prioritize launch activities and explore new strategies. Nevertheless, McKinsey&Company analyzed the launch of 210 new drug products and results have shown that two-thirds of pharmaceutical product launches fail to meet sales expectations for the first year after launch, and they typically do not improve in following years (McKinsey&Company, 2014, p. 3). The consultants’ opponent Deloitte comes to the same conclusion and states that 36% of launches fail to meet expectations and miss performance objectives (Corvino, et al., 2022, p. 4). In order to combat that

underperformance, an understanding of the emerging criticality of launch activities is required, and skills and competencies in foresight and strategic planning need to be enhanced.

The following chapter reflects the conjunction between scenario planning and pharmaceutical product launch as presented in literature. First, the explicit characteristics of pharmaceutical product launch, including the overall process and characteristics, risks and uncertainties, and success factors are examined. Second, evidence of scenario planning in the industry is collected and analyzed.

2.3.2 Pharmaceutical Product Launch

New product launch (NPL) describes the process of bringing a product to the market for the first time (Rabea, 2022, p. 89). It is a crucial activity for companies' long-term success, yet highly expensive and connected to high rates of failure (Kuester, et al., 2012, p. 38). The NPL process is complex and associated with very specific characteristics that are described in the following section. Unless otherwise noted, the abbreviation NPL in this research refers to the launch of pharmaceutical products in specific as opposed to general products.

Process and Characteristics

Before the NPL process begins, new pharmaceutical products are discovered and developed, with R&D in the pharmaceutical industry undoubtedly being a long, cost-intensive and high-risk process. The R&D phase for new pharmaceutical products takes an average of 10 to 15 years with estimated costs of \$1.2 billion for each product to reach approval for clinical use (Sun, et al., 2022, p. 3050), or a similar result, 12 to 13 years to average costs of \$1.9 billion (EFPIA: Key Data 2018, 2018, p. 6). Success rates are low, and only one or two out of 10,000 drug substances in discovery pass all stages of clinical research (EFPIA: Key Data 2018, 2018, p. 6), while 90% fail before reaching approval by medical and regulatory affairs (Sun, et al., 2022). Even after approval, 36% of launches are considered unsuccessful (Corvino, et al., 2022, p. 4), while only two out of ten launched drugs meet or exceed expectations (Matikainen, et al., 2015, p. 175). Interestingly, a much older study first published in 1997 comes to the same conclusion and argues that about 60% of product launches do not meet expectations (Griffin, 2003, p. 431), even though focusing on general NPL and not specifically the launch of pharmaceutical products. Ultimately, authors agree that NPL in general as well as in the pharmaceutical industry is a critical activity and determines organizational performance in the long run. To get a better understanding of the activities

taken within NPL, the process is divided into five main phases, categorized by Rabea (2022) as follows:

1. Launch Planning
2. Launch Preparations
3. Internal Introduction
4. External Introduction
5. Launch Evaluation

According to the author, the entire NPL takes an average of four years, where the process begins one to two years prior to approval and continues two years after (Rabea, 2022, p. 92). Launch planning and preparations both refer to NPL-activities prior to the actual launch and are considered critical success factors (see Success Factors). This is underlined by a report published by Deloitte that suggests pharmaceutical companies to increase investments in the pre-launch phase as opposed to high investments in market access in the past (Ucci, et al., 2018, p. 6). The external introduction of the product represents the core of the NPL, whereas the internal introduction is often neglected and its importance underestimated. A study conducted to complement the general view that NPL is a rather outward directed process supports that argument by concluding that internally directed activities such as internal product introduction are a crucial part of the overall launch process and further, determine how NPL teams perform (Kuester, et al., 2012, p. 38). The launch evaluation takes place post-launch and considers measures such as customer acceptance or other performance indicators (Rabea, 2022, p. 101).

Risk and Uncertainty

Pharmaceutical companies' main objective is to deliver products in the right quantity, to acceptable quality, to the right place and the right patients and by that, support the overall goal of the healthcare system to guarantee the human right of access to medicine (Jaberidoost, et al., 2013, p. 1). At the same time, the industry is operating in a highly volatile, uncertain and complex environment, which makes it a challenging task to reach these objectives. The main risks and uncertainties for pharmaceutical companies mentioned in literature are outlined in the following.

Regulatory Hurdles, Austerity Measures and Authority Approvals:

Besides rather general aspects that are affecting all kinds of industries such as globalization, technological advances or the latest COVID-19 pandemic, the pharmaceutical industry faces

very specific challenges. Expiring patents pressure companies to launch new drug products to drive growth and stay competitive, while simultaneously austerity measures increase and regulatory requirements make market access more difficult and launches are becoming smaller but more numerous (Ahlawat, et al., 2014, p. 1). The difficulty of overcoming regulatory hurdles and get approvals from authorities such as the U.S. Food and Drug Administration (FDA), or European Medicines Agency (EMA) respectively is one of the main risks mentioned in literature, with the FDA being the most important institution as it is often taken as a benchmark by other authorities (Festa, et al., 2022, p. 1667). According to a report published by Deloitte, no more than 0.1 % of pharmaceutical products outlast preclinical trials to be tested on humans, and further, only 20 % of clinical trials are approved (Ucci, et al., 2018, p. 2). It seems particularly challenging in view of the fact that approvals usually go hand in hand with the planned launch date and a rejected approval causes massive time delays and additional costs, if it does not threaten the entire NPL (Rabea, 2022, p. 89). Accordingly, regulatory risks are evaluated as another main risk in pharmaceutical supply chains (Jaberidoost, et al., 2013, p. 5), and therefore highly affect the success of NPL.

Competition, Demand and Expectations:

Other uncertainties frequently mentioned in literature, are changing competition, demands and expectations. Patients are seeking more information and personalized medicine as well as treatments linked to an ageing population are gaining in popularity (Palermo, 2023, p. 9). Besides, global demand in general is expected to grow, especially from emerging countries and specific kinds of medicine such as vaccines will additionally play a greater role in the future when dealing with increasing global health issues (Palermo, 2023, p. 11). Further, developing economies will not only cause an upward shift in demand, but they will also pose greater competition for leading industrialized countries due to rapid growth in the R&D environment that is almost outperforming industrialized countries (EFPIA: Key Data 2018, 2018, p. 4). Competition further increases due to treatment possibilities across the market, respectively, making launch decisions and strategies more relevant (Rabea, 2022, p. 104), while simultaneously patients are realizing that there is no sufficient differentiation between providers, putting even more pressure on launching companies to outrival competitors (Ucci, et al., 2018, p. 2). On top of that, stakeholders' expectations and needs are widely spread, varying from patients seeking better health care to convenient prices and research institutes seeking scientific progress, while pharmaceutical companies themselves pursue health care improvement whilst making profit (Ucci, et al., 2018, p. 5).

Supply Chain Risks:

A study explicitly focusing on supply chain risks states that 40 % of risks discovered in their research are related to supply and supplier risks, among others including delivery, quality and compliance issues, or supply interruptions, all of them threatening production and timely delivery to customers and patients (Jaberidoost, et al., 2013, p. 2). This is underlined by another recent study that explicitly focusses on pharmaceutical industry risks and uncertainties, and mentions supplier risks among the most important risks followed by financial, operational, environmental, governmental, and organizational risks (Sharma, et al., 2023, p. 3). Other risks associated with the supply chain management (SCM) of pharmaceutical companies refer to potentially risky bottlenecks, finding the right balance between lowest material cost and transportation, as well as guaranteeing the overall manufacturing flow and managing alignment between all locations of laboratories, factories and warehouses (Jaberidoost, et al., 2013, p. 2). Especially the latter seems important, as other authors account the entire NPL process to 200 to 700 activities across different departments and functions within an organization, requiring extensive progress monitoring of global, regional and affiliate activities against the roadmap in order to see early signs of failure and react in a timely manner (Ahlawat, et al., 2014, p. 1). Another study specifically conducted on strategic issues in pharmaceutical supply chains further underlines those arguments by emphasizing not only time, quality and quantity as crucial parameters, but coordination across and costs for supply chain networks as well (Singh, et al., 2016, p. 235).

Ultimately, risks and uncertainties in the industry are interrelated and identifying those relationships is the first step of mitigation (Sharma, et al., 2023, p. 4). The key success factors found in literature are summarized in the following.

Success Factors

Literature discusses numerous factors and activities that are having a positive impact on launch success. As previously mentioned, launch planning and preparation are considered pre-launch activities and highly relevant for the success of NPL (see

Process and Characteristics). The pre-launch phase begins 12 to 24 months prior to launch, and is given highest priority due to the fact that during this phase companies will decide whether the product is ready to launch, while not launching is a drastic failure considering the high upfront investment related to the entire NPL process (Rabea, 2022, p. 107). The key elements of success for the pre-launch phase are sub-categorized by Rabea (2022) as follows

and can be understood as transferable to the later phases, internal introduction, external introduction and launch evaluation, since they are discussed in that way by various other authors as well.

Cross-functional Collaboration and Allocation of Resources:

Cross-functional teams generally consist of core members that are pursuing different functions across an organization, and therefore are bringing different sets of knowledge, skills and experiences to a team. Literature on team dynamics and success factors is abundant, yet not many focus on NPL team performance in specific. A recent study addresses the gap and finds that cross-functionality of teams explicitly involved in product development and launch has a positive impact on overall team performance, and is supported by a common understanding of goal stability, clarity and support (Durmusoglu & Calantone, 2023, p. 27). This result is underlined by various authors who as well emphasize cross-functionality and unified goals as critical success factors for NPL and the pre-launch phase in particular, such as Deloitte highlighting the importance of cross-functional collaboration early on in order to streamline NPL from development to commercialization (Ucci, et al., 2018, p. 5). Authors further agree that cross-functional collaboration is a challenging task since different functions inhabit different procedures, practices and principles, but that it remains indispensable to collect necessary information and develop a strategy. Considering McKinsey&Company (2014), launches include 150 to 200 employees across an organization, accumulating knowledge and skills among others from marketing, medical, clinical or regulatory departments. Besides establishing cross-functional teams, the study goes one step further and adds the establishment of a training academy to build specific NPL skills and enhance a launch mindset (McKinsey&Company, 2014, p. 5), further highlighting the importance of a well-working collaboration across the launching organization.

Market Analysis & Pricing Strategies:

Literature states that 50 % of drug launches fail due to limited market access and insufficient knowledge of market and customer needs (Corvino, et al., 2022, p. 4). Therefore, extensive market analysis and well-thought-out pricing strategies are logical, inevitable and extremely significant components of successful NPL.

The main goal of market research in NPL is to gain insights such as the epidemiology and burden of the disease in a country, existing treatments in the market, as well as the patients' journey from diagnosis to treatment decisions (Rabea, 2022, p. 110). This summary is

supported by McKinsey&Company suggesting the classification of launches into four archetypes, Go for Gold, Category Creator, Stand out from the Crowd, and Market Shaper, where new products are assigned according to their level of clinical differentiation and the perceived burden of the disease (Ahlawat, et al., 2014, p. 6). Another article published in recent years defines eleven macro forces that traceably have an effect on our future, despite lying outside of a companies' control, such as the environment, demographics, government, geopolitics and economy, which in collusion with one another or further emerging signals of change, will cause major disruptions (Webb, 2021, p. 20). Although not specifically focusing on NPL in the pharmaceutical industry but foresight in general, the approach is transferable since it allows pharmaceutical companies to investigate early signs, anticipate risk, and react accordingly at an early stage. A strong understanding of market conditions further allows pharmaceutical companies to set optimal launch prices.

Literature on NPL pricing strategy is abundant and deriving a universal approach seems neither simple, nor reasonable, because no NPL mirrors the other and price decisions are a complex field. Research has shown that in order to decide on the right pricing strategy, it is especially important to investigate some specific factors, such as country regulations, reference benchmarking, profitability, and acceptance by patients (Rabea, 2022, p. 113). In particular, regulatory differences between countries seem to have a critical impact on pricing strategies and launching companies are well-advised being aware of them. A study conducted on pharmaceutical price regulations within the EU defines reference prices as the price of the cheapest substitute in the domestic market and declares reference benchmarking an effective containment tool introduced by policy makers to drive down costs for patients (Kaiser, et al., 2014). This is reflected in another study as well, which focuses on the impact of parallel imports on pricing and launch decisions and declares reimbursement regulations by governments and insurance firms as crucial components of reducing costs for patients (Altug & Sahin, 2019, p. 258). Nevertheless, the focus of that same study lies on parallel imports that are emerging from differences in prices and regulations between countries and are having the direct consequence of unauthorized parties purchasing the product from lower-price regions and selling elsewhere (Altug & Sahin, 2019, p. 258). The awareness of this risk gives launching companies the opportunity to derive well-considered decisions and set prices accordingly, especially in regards of the industry not being able to profit from a cost leadership position as lower prices are often related to lower quality and this is neither desired by companies nor by authorities or patients.

Positive Relationships to External Stakeholders:

To overcome these hurdles, it is particularly important for companies to be in close contact with governments and health authorities and negotiate prices wisely (Rabea, 2022, p. 114). Besides, patients are the most important external stakeholders for pharmaceutical companies. Literature agrees that close interaction and positive relationships should be established early in the NPL process and long before launch (Matikainen, et al., 2015, p. 184), for instance by implementing early access programs for patients without alternatives (Rabea, 2022, p. 97). This will build trust among stakeholders and therefore ensures successful market adoption of the new product (Corvino, et al., 2022, p. 4). Further, close cooperation with medical affairs enhances clinical trials and builds a basis for market introduction at a later point in time by spreading awareness and knowledge on the disease and the treatment among experts (Rabea, 2022, p. 97). At the same time, engaging with external stakeholders delivers exclusive data to the launching company about true patients' needs as well as delivering early indicators of acceptance in the target market (Matikainen, et al., 2015, p. 184).

Production and Supply Chain Management:

Although literature on supply chain management risks and uncertainties in the pharmaceutical industry is not found redundantly from the past, the topic is frequently mentioned in studies that are more recent. This change in interest indicates an emerging importance of the activities surrounding SCM, which is the result of several influencing factors. High costs and time involvements are making SCM a complex and challenging activity, and changing trends in demands and product portfolios, shorter life cycles, outsourcing decisions, as well as globalization and technological advances further play an important role (Singh, et al., 2016, p. 235). Besides, arising competition, variations in customer demands and increasing shipment and production costs are major stressors that are elevating the awareness of SCM activities for NPL (Moosivand, et al., 2019, p. 1103). To handle those challenges, several competencies are discussed in literature. Most frequently mentioned are dynamic capabilities in production such as flexibility and responsiveness to market demands as well as a strong customer orientation and reliability in terms of delivering the right product, quantity and quality to the right customer and timing (Moosivand, et al., 2019, p. 1105). Flexible production capacities and inventory management, optimized stock levels, forecasting and foresight methods, budgeting and cost analysis, and an overall positive relationship across SCM networks describe further key success factors in mitigating supply chain risks in the industry (Sharma, et al., 2023, p. 20).

Conclusively, SCM in the pharmaceutical industry is a highly complex but crucial part not only in NPL, but also for the overall competitiveness of organizations. Therefore, effective SCM can be understood as the final success factor for NPL since at the end of a long journey of facing complex risks and uncertainties it determines whether a company is able to make the product available for patients and the market (Rabea, 2022, p. 114). The following section investigates evidence of scenario planning in the industry.

2.3.3 Evidence of Scenario Planning in the Industry

The utilization of scenario planning in NPL has not explicitly been well researched and established in literature. However, researchers frequently discuss how the pharmaceutical industry, health care systems, the overall health of society and, in general, medicines will evolve over time. Some examples are explicitly referring to scenarios while others are solely describing alternative futures without consciously naming it scenario planning. Examples that are either explicitly referring to scenario planning, or are describing a similar approach without giving it the name, are presented in the following.

A paper, amongst others published by Rafael Ramírez, the originator of OSPA (see The Oxford Scenario Planning Approach (OSPA)), focuses on the utilization of scenario planning as a strategic tool for companies to better deal with uncertainties that they are facing. As a benchmarking example, the article mentions the Royal Society of Chemistry that in 2014 is implementing a long-term planning initiative, where participants create multiple future outcomes for the chemical industry in the next 10 to 20 years, with the goal of identifying the impact on the industry and society (Ramírez, et al., 2017, p. 4). Interestingly, the initiative is not named scenario planning, even though what they do is the exact same thing. The example shows that although scenario planning is widely used among different industries, it is not necessarily categorized as such. Consequently, literature on scenario planning at first glance seems scarce, but if one broadens the perspective and considers the application of very similar tools that are named in different ways, the spectrum of publications becomes much wider.

Another example of this happening is illustrated in an article published in 2022, which discusses four future scenarios of medicines and social policy for the year 2030. In consideration of various impacting factors and industry trends, the “scenario project” is initiated to, first, identify relevant uncertainties, second, derive two primary scenario drivers, and third, develop four alternative futures that the industry might face in the future (Leufkens, et al., 2022, p. 2252). Despite not referring to scenario planning explicitly, the authors assign

several attributes to the scenarios built in the project, which are in line with the general definitions of scenario planning given in literature (see Scenario Planning). As described by the authors, scenarios are narrative in nature, however, reflecting plausible alternative futures based on viable hypothesis that can be complemented by quantitative data without intending to deliver exact predictions (Leufkens, et al., 2022, p. 2258). By this, the scenario project described in the article fulfills the primary characteristics of scenario planning and therefore, is categorized as such.

In addition, another example of scenario analysis is found in an article that discusses the current and future challenges of the pharmaceutical sector by the example of India. The article, published in 2022, follows the purpose of identifying opportunities and issues of the pharmaceutical industry in India by the use of qualitative and quantitative research, the development of a SWOT analysis and ultimately, the derivation of four scenarios from the research results (Festa, et al., 2022, p. 1662). The scenario analysis begins with the provision of a generic overview of possible industry scenarios, including extensive descriptions and conclusions in regards of trends and dynamics in the industry. The article lays special emphasis on the SWOT analysis as a basis for the scenarios that are a result of the detailed analysis of possible exploitation of existing strengths and opportunities as well as the mitigation of weaknesses and threats. As a result, the established scenarios allow the deduction of theoretical and practical implications for the industry (Festa, et al., 2022, p. 1663). By taking a SWOT analysis, complemented by quantitative data, as a basis for the scenarios, this approach again fulfills the primary characteristics of scenario planning described in literature (see Scenario Planning), and therefore is as well categorized as such.

Besides academic references, scenarios are widely used in the consulting world (Webb, 2021, p. 23), and various publications by consulting companies further underline the efficiency of scenario planning as an uncertainty and risk mitigating tool for pharmaceutical companies during launch. Considering McKinsey&Company, it is usually possible, despite high uncertainty, to create a number of scenarios that are based on solid assumptions and either connected to a known or unknown probability of occurrence, and ultimately provide guidance for launching companies to better deal with risk and uncertainty (McKinsey&Company, 2014, p. 12). The consulting firm states that the creation of multiple scenarios allows organizations to benefit from future opportunities and threats, as well as being prepared for disruptions to occur while relying on a single expectation of the future would claim a false sense of certainty (McKinsey&Company, 2014, p. 13). The authors describe four steps to integrating scenario

planning into the NPL process, from identifying uncertainty, prioritizing the findings according to likelihood of occurrence and impact, identifying concrete scenarios, to deriving measures to take in the present and upon sudden occurrence (McKinsey&Company, 2014, pp. 13-14). Another report, published by the firms counterpart Deloitte, as well mentions scenario planning as an important component of successful NPL in terms of gaining competitive insights and assessing risks among the market, especially in consideration of the fact that mostly, firms are deriving strategies from knowledge of the past instead of looking ahead and creating new opportunities (Ucci, et al., 2018, p. 7).

2.4 Conclusion

The thorough review of literature on foresight, strategic planning and scenario planning constitutes a comprehensive fundament for this study by providing a shared understanding of the terminologies that are indispensable for the overall comprehension of the research topic. The deep investigation of NPL in the pharmaceutical industry including the identification of related risks and uncertainties as well as drivers of success, further provide the context needed to investigate the relation between scenario planning and NPL. With this literature review being performed, the research questions are preliminary answered as follows.

First, literature on the primary drivers of risk and uncertainty is found abundantly (see Risk and Uncertainty) and provides a sufficient answer to RQ1. The main findings on risk and uncertainty in the pharmaceutical industry are:

- Regulatory Hurdles, Austerity Measures and Authority Approvals
- Competition, Demand and Expectations
- Supply Chain Risks

Second, the research on scenario planning as a strategic tool (see chapter Scenario Planning) in relation to the identified success factors for NPL (see Success Factors) allows a first answer to RQ2. According to the literature, scenario planning includes the extensive analysis of the business environment through collaborative work and the consideration of various parties involved. Those characteristics are in line with NPL success factors found in literature, which allows the conclusion that by its nature, scenario planning contributes to successful NPL. Essentially, the success factors identified are:

- Cross-functional Collaboration and Allocation of Resources
- Market Analysis & Pricing Strategies
- Positive Relationships to External Stakeholders
- Production and Supply Chain Management

Third, best practices and recommendations are not extensively represented in literature (see Evidence of Scenario Planning in the Industry). However, consulting firms frequently highlight the efficiency of scenario planning in enhancing NPL success, and are as well giving advice on how to implement and use the tool. This suggests that scenario planning is as effective tool in NPL, but leaves space for further investigation in order to give a complete answer to RQ3.

Overall, it is observed that literature on scenario planning in general is abundant while the conjunction to NPL is rarely given. Most articles related to both the pharmaceutical industry and scenario planning focus on general prospects on the future of the industry, and are not specifically referring to NPL in that context. Therefore, the literature review allows preliminary answers to the research questions but leaves a research gap that offers the opportunity to further investigate the topic. The hypothesis that arises from the literature review is as follows:

H1: Scenario planning effectively enhances pharmaceutical product launch.

3 Methodology

3.1 Introduction

This chapter outlines the study's research methodology that is used to close the research gap identified in the literature review. On this account, a qualitative content analysis is conducted to collect further data and gain extensive insights into practitioners' experiences. The chapter includes the definition of qualitative content analysis (see chapter Definition of Qualitative Content Analysis) and the practical implementation of the empirical study (see Research Design). The aim of the empirical analysis is to complement the current state of the master's thesis with the help of expert interviews and a qualitative content analysis that allows to thoroughly answer the research questions and the hypothesis.

3.2 Definition of Qualitative Content Analysis

In literature, numerous interpretations of qualitative content analysis exist. This study focuses on the predominant interpretation described by the scientist and academic Philipp Mayring (2000; 2014). The author defines qualitative content analysis as an approach of empirical, methodological analysis of texts gained through communication, following content analytical rules and models, without classical quantification (Mayring, 2000, p. 2). By this, qualitative content analysis is defined as a mixed methods approach and does not seek to degrade the advantages of quantitative analysis, but represents another form of empirical analysis that may have inherent benefits over the solely quantitative kind (Mayring, 2014, p. 8). By this, the approach does not only try to analyze objects, contexts and processes and thereby explain them, as quantitative science does, but tries to get into the individual and understand it.

3.3 Research Design

3.3.1 Data Collection

The data for this analysis is collected by conducting a total number of ten online interviews in November and December 2023 with experts from four different companies, located in five countries. All interviewees represent different functions within pharmaceutical companies and offer extensive experiences in launching pharmaceutical products. Each interview lasts approximately half an hour and follows a semi-structured style that preserves the possibility of further probing and clarifying statements while they proceed. The underlying guideline (see Appendix A) is shared with the interviewees in advance to allow a minimum of preparation, if wished. Table 1 gives an overview on the pseudonymized companies and informants participating in the interviews.

Table 1 Overview of Case Firms

#	Industry Sector	Employees	Firm Age	Country	Informant	Interview Code
1	Biopharmaceuticals: Research and Development	>18,000	>30 years	United States, located in Portugal	Brand & Product Manager	Product Expert
2	CDMO: Contract Developing and Manufacturing Company	2,000	>50 years	Portugal	Production Director Pharmaceutical Operations	CDMO Expert
3	Healthcare: Pharmaceuticals & Diagnostics	>100,000	>125	Switzerland	Global Sourcing & Technical Transfer Lead	Technical Expert
4	Healthcare: Pharmaceuticals & Diagnostics	>100,000	>125	Switzerland	Launch Lead	Launch Expert
5	Healthcare: Pharmaceuticals & Diagnostics	>100,000	>125	Switzerland	Digital Strategy Delivery Lead	Digital Expert
6	Healthcare: Pharmaceuticals & Diagnostics	>100,000	>125	Switzerland	Product Supply Chain Leader	Supply Chain Expert
7	Biotechnology	>10,000	>40	United States	Supply Chain Management Network Planner	Network Expert
8	Healthcare: Pharmaceuticals & Diagnostics	>100,000	>125	Switzerland	Supply Chain Transformation & Project Management Lead	Project Expert
9	Healthcare: Pharmaceuticals & Diagnostics	>100,000	>125	Switzerland	Product Strategy Leader	Strategy Expert
10	Healthcare: Pharmaceuticals & Diagnostics	>100,000	>125	Switzerland, located in United Kingdom	Head of Supply Chain Integrated Planning	Planning Expert

3.3.2 Data Analysis

To analyze the information gained through the expert interviews, all conversations are recorded and transcribed as clean reads (Mayring, 2014, p. 45). All interviews are then analyzed according to the deductive analysis approach established by Mayring (2000; 2014), where, based on the previously conducted literature review, categories are established before interviews are coded. For this purpose, the following seven steps are performed:

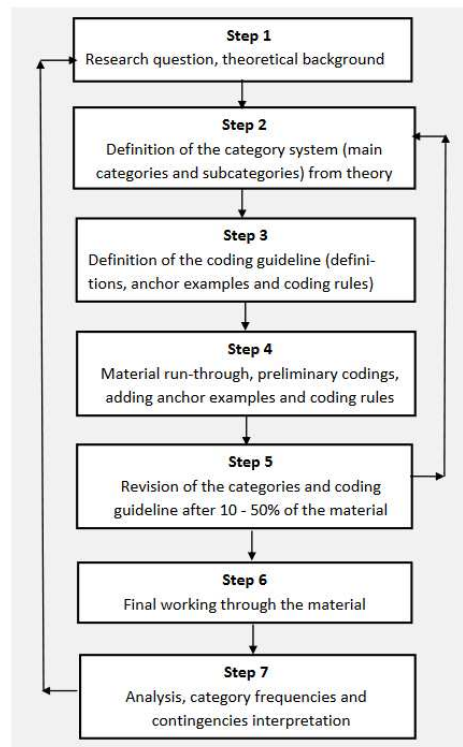


Figure 1 Steps of Deductive Category Assignment (Mayring, 2014, p. 96)

The first step is done in chapter 1.4 Research Questions, and chapter 2. Theoretical Discussion. The results of the literature review including preliminary answers to the research questions are depicted in the conclusions part of the chapter. On this basis, in a second step nominal and ordinal categories are built and complemented by definitions to ensure a common understanding. After a first run through the interview transcripts, anchor samples and encoding rules are added to ultimately allow the unambiguous allocation of text passages to given variables and values. The resulting coding agenda for this research is shown in Table 2. The ultimate points of discovery for each variable and value are presented in Table 3 and a summary of all quotes assigned to the coding agenda is shown in Appendix B. Adherent to the seven steps defined by Mayring, the coding agenda is revised and verified after approximately 40% of the material is checked, before the material run-throughs are completed and the final analysis is performed.

3.3.3 Research Conclusion

By the use of the Mayring methodology, this research follows a clear structure in performing research based on a deductive and qualitative approach. When exploring issues that are not well researched, flexibility is a crucial characteristic that allows reacting to the interview flow and by that to gain further insights into the individual experience. Giving informants an extraordinary voice and conducting the interviews one-to-one are essential, as interviewees are viewed as knowledgeable agents and this approach maintains the possibility to directly respond and interact (Gioia, et al., 2013, p. 17). For this reason, semi-structured interviews and the transcription as clean reads is deemed appropriate for this study. Further, the deductive approach is considered applicable in regards of the preceding literature review that allowed preliminary answers to the research questions, but required further investigation. The research design ultimately supports the intent to thoroughly answer the research questions and the identified hypothesis accordingly.

4 Analysis and Results

4.1 Introduction

This section presents the findings of the qualitative content analysis based on the Mayring approach. In consideration of the research questions and the theoretical analysis, Table 2 represents the coding agenda for this analysis. In a first step, categories are derived from theory, which, on the one hand, allow answers to the research questions and hypothesis, and, on the other hand, help identify relevant text passages from the interviews. In subsequent steps, the interviews are coded deductively according to the coding agenda with the goal of answering the research questions and hypothesis. In this context, it is particularly important to explain that the coding agenda explicitly aims to answer RQ1, RQ2 and H1. As the preceding theoretical analysis could only produce a conditional answer to RQ3, and therefore, a deductive categorization is not considered suitable in this sense, RQ3 is analyzed purely interpretatively and for this reason is not given an own value in the coding agenda. However, Appendix C represents a collection of quotes from the interviews that include recommendations and best practices and allow answering RQ3.

Table 2 Coding Agenda (Mayring, 2014, p. 102)

Variable	Value	Definition	Anchor Sample	Coding Rules
Scenario Planning Characteristic	C1: Narrative	Description of informed, plausible and imagined alternative futures, by the help of narrative stories.	“In the last months, I would say, the decision making process has been more formalized and more structured. When there is a financial relevance, we need to formalize the decision that we need to take. Here, we also need to describe the scenarios and the options.” (Supply Chain Expert)	No numerical / quantitative aspects are mentioned.
	C2: Numerical	Creation of alternative futures based on quantitative analysis and/or described in numbers rather than words.	“Scenario planning is in terms of volume and supply chain. [...] That scenario plan goes more into the supply chain forecasting statistical world.” (Strategy Expert)	No narrative aspects are mentioned.

	C3: Mixed	Narrative description of alternative futures, complemented by quantitative data or numbers.	“It's more like tables and figures that show different values. Hybrid. It is written and of course with numbers.” (Launch Expert)	Both, narrative and numerical / quantitative aspects are mentioned.
Primary Drivers of Risk and Uncertainty	P1: Regulatory Hurdles, Austerity Measures and Authority Approvals	The drivers mentioned are in line with the values of P1 that are found in literature.	“There's a lot of uncertainties in terms of access and lots of diversity especially in Europe where regulatory institutions and departments in states usually have different approaches to the same kind of information.” (Product Expert)	The aspects mentioned can be clearly assigned to at least one value in P1.
	P2: Competition, Demand and Expectations	The drivers mentioned are in line with the values of P2 that are found in literature.	“Then, you have uncertainties in the demand landscape and bad forecast. You need to figure out how to have processes that is agile enough to dynamic demand.” (Strategy Expert)	The aspects mentioned can be clearly assigned to at least one value in P2.
	P3: Supply Chain Risks	The drivers mentioned are in line with the values of P3 that are found in literature.	“Our main risks are the supply chain, so the access to raw materials, for instance.” (CDMO Expert)	The aspects mentioned can be clearly assigned to at least one value in P3.
	P4: Complementary	Additional drivers that are not represented in the values P1-P3 but fit the overall context are mentioned.	“There's a lot of uncertainties in terms of the timing to launch.” (Product Expert)	The aspects mentioned are not equivalent to P1-P3 but fit the overall context.
Success Factors	S1: Cross-functional Collaboration and Allocation of Resources	The success factors mentioned are in line with the values of S1 that are found in literature.	“It is a cross-functional team that is preparing the launch transfer. To make the launch happen you need the collaboration from the warehouse, from production, from packaging, supply chain.” (Technical Expert)	The aspects mentioned can be clearly assigned to at least one value in S1.

	S2: Market Analysis & Pricing Strategies	The success factors mentioned are in line with the values of S2 that are found in literature.	“First, we have to estimate the timing to market. It's one of the variables that you should take into account.” (Product Expert)	The aspects mentioned can be clearly assigned to at least one value in S2.
	S3: Positive Relationships to External Stakeholders	The success factors mentioned are in line with the values of S3 that are found in literature.	“Getting stakeholders on board with whatever scenario that you are pushing for is absolutely important.” (Strategy Expert)	The aspects mentioned can be clearly assigned to at least one value in S3.
	S4: Production and Supply Chain Management	The success factors mentioned are in line with the values of S4 that are found in literature.	“The success factors in the end are to keep with the growing of the company, our sales, our products getting to the market, so to have no disruption in the day-to-day activities and the supply chain.” (CDMO Expert)	The aspects mentioned can be clearly assigned to at least one value in S4.
	S5: Complementary	Additional success factors that are not represented in S1-S4 but fit the overall context are mentioned.	“The sweet spot with scenario planning is you need to develop scenarios that are both technically robust and data driven.” (Project Expert)	The aspects mentioned are not equivalent to S1-S4 but fit the overall context.
Effectiveness	E1: High	Conviction that there is a direct and positive connection between scenario planning and NPL success.	“We always have scenario planning in my experience. [...] For me it is a success and you need to have it to be successful.” (Technical Expert)	All aspects mentioned point to high.
	E2: Medium	Conviction that scenario planning is beneficial in understanding present decision options but incomplete as it lacks a direct connection to actions.	“Scenario planning by itself, I don't think will prevent, enhance or rather predict the success of a product launch. Instead, what it does is it helps you identify things that can go wrong and it helps you identify your mitigation plans and strategies” (Project Expert)	Some aspects mentioned point to high, others to low.

	E3: Low	Conviction that there is no direct impact, positive or negative, between scenario planning and NPL success.	“Scenario planning as it is, I don't think will contribute to successful product launches.” (Digital Expert)	All aspects mentioned point to low.
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4.2 Qualitative Content Analysis Results

This section represents the results of the deductive coding of the interviews in regards to the coding agenda presented in the previous section. The findings show that each category established from literature finds relevance in practice by interviewees giving statements that allow assignment to the variables and values. Table 3 represents an overview on the quantitative analysis of collected quotes by stating points of discovery, as well as providing reasons for the assignment of the codes. Interestingly, all values are represented in the interviews although clear trends are apparent and indicate that some values are more present in practice than others are. The following sections further analyze each variable and value with the goal of explaining the results.

Table 3 Deductive Coding of Interviews

Variable	Value	Points of Discovery	Reasons for Code
Scenario Planning Characteristic	C1: Narrative	3	Clear description of scenarios, story-telling or similar aspects
	C2: Numerical	3	Forecasting activities, statistical elements
	C3: Mixed	6	Key words such as “hybrid”, “mixed”, “both”
Primary Drivers of Risk and Uncertainty	P1: Regulatory Hurdles, Austerity Measures and Authority Approvals	11	Diversity of regulations between countries, local regulatory burden, authority decisions, requirements by authorities, approvals, timing of approval
	P2: Competition, Demand and Expectations	6	Market positioning, competitors, first to market, volumes, demands, first orders, forecasts
	P3: Supply Chain Risks	7	Procurement of raw material, internal delays, external delays, unplanned events, interruptions, supply resilience, lead time
	P4: Complementary	6	Development phase, commercialization, timing to launch, country diversity, funding, labelling and packaging, robust manufacturing processes

Success Factors	S1: Cross-functional Collaboration and Allocation of Resources	15	Human resources and activity plans, have teams prepared, skills and knowledge, collaboration, team constellation, leadership, responsibilities, diversity, communication, group size
	S2: Market Analysis & Pricing Strategies	3	Timing to market, knowing your patient and patient needs, segment selection
	S3: Positive Relationships to External Stakeholders	2	Stakeholder expectations, get stakeholders on board
	S4: Production and Supply Chain Management	4	Prevent supply chain interruptions, keep productivity, keep lead times, flexibility and agility, good supply chain management
	S5: Complementary	12	Aspects that cannot be categorized as S1-S4: implement at management level, cultural transformation, choice of systems and tools, use from the beginning, quality of information / quality of scenarios, iterative improvement, shared philosophy, derivation of actions and strategies
Effectiveness	E1: High	12	Efficiency enhancement, prevention of uncertainties, effective decisions derived, contribution to success, indispensable for success, applicability, proven effective in past experience
	E2: Medium	10	Likely to be effective, other tools might be more suitable depending on context, questionable benefit if scenarios don't occur, only a plan, challenging to utilize
	E3: Low	1	Clear doubts

4.2.1 Overview of Scenario Planning Utilization in Practice

To identify whether the interviewees are utilizing scenario planning as defined in this thesis, questions related to scenario planning characteristics, scope areas and real-life examples are emphasized in all interviews.

The deductive coding shows a clear tendency towards a hybrid utilization of scenario planning, combining narrative and numerical elements, with six points of discovery in value C3, and three points each in C1 and C2, respectively. In this context, it needs to be clarified that most interviewees stating to use either numbers only or a mixed style, explain doing so. The Product Expert, for instance explains that scenario planning as utilized in their function is viewed as forecasting. The interviewee shows a clear awareness of scenario planning as per literature being narrative, and a likewise clear decision to include data nevertheless. Further, several interviewees describe that in order to create solid scenarios, in their specific function numbers are more sufficient, for instance when dealing with supply and demand, while other functions involved in NPL would take those numbers and create descriptive stories at a later stage. One example is the Network Expert predominantly using numerical scenarios, but mentioning to work closely with the commercial marketing department of the company, which is then creating narratives out of the numbers. The Strategy Expert underlines this statement by explaining that to them scenario planning as well refers to statistics and forecasts, but that ultimately descriptive mitigations are derived.

Ultimately, a clear trend towards mixed methods is seen in the interviews. Companies are mainly aware of scenario planning technically being narrative, but their experience seems to show that in practice, numbers are inevitable. The results of the primary drivers of risk and uncertainty give further explanations for this discovery.

4.2.2 Drivers of Risk and Uncertainty in NPL

The pharmaceutical industry undoubtedly is characterized by high uncertainty and volatility. Based on the literature review, three main categories of risk and uncertainty were established and are represented as values P1 to P3 in Table 2.

The evaluation of the interviews shows that 24 out of 30 discoveries for variable P lie within those three categories, validating the importance of the risks and uncertainties in practice. Most frequent aspects mentioned by the experts relate to P1 with eleven findings for this value. The Launch Expert, for instance, refers to an increasing number and diversity of requirements between countries. The Supply Chain Expert adds the challenge of timely

approval and therefore adherence to launch schedules. Interestingly, aspects related to austerity measures are only stated once, namely by the Strategy Expert explaining how macroeconomics as well as governmental budget-decisions are playing an increasing role in NPL, further risking launch success.

In regards to competition, demand and expectations, most experts state that the usual strategy for launches is to be first to market, which is making competition an important value to assess risk and uncertainty in NPL. Out of the six discoveries in P2, some experts such as the Technical Expert mention time constraints in relation to competition, while others such as the Project Expert are putting emphasis on the impact on future sales. To assess demand, the Product Expert adds the importance of positioning research, while the Supply Chain Expert states estimating demand for different countries as one of the main aspects.

Value P3, on the other hand, is discovered seven times, with most interviewees stressing the relevance of preventing supply interruptions, for instance the Strategy Expert describing difficulties in manufacturing steps or the CDMO Expert mentioning access to raw material as main challenges. Further, the Technical and Planning Experts underline the length of supply chains that is putting adherence to planned lead times at risk.

Besides the values found in literature, five complementary discoveries are made, represented in value P4. One example that exceeds the findings from literature is the risk of relabeling and packaging, mentioned by the Network Expert, which again leads to major delays in supplying the market.

4.2.3 Success Factors of Scenario Planning in Practice

One of the main goals of the interviews was to gain understanding for the participants' perception of what would make scenario planning a successful tool in mitigating risk and uncertainty in NPL. Therefore, interviewees repeatedly were asked to offer examples on practical experiences where scenario planning enhanced launch performance, as well as to state the concrete aspects contributing to that success.

Results show a clear tendency towards cross-functional collaboration and allocation of resources being the most important success factors, accumulating 15 points of discovery. The answers unanimously include the significance of choosing the right people, with the right knowledge and skills, from the right functions across a company while reducing the number of participants to a minimum required, stated by the CDMO, Technical, Launch and Project

Expert. Besides, other aspects of S1 refer to a clear allocation of tasks and activities as well as good communication management, according to the Product and Network Expert. The Launch Lead adds the importance of having a tool for doing so. Interestingly, eight out of the ten interviewees involved in this research offered answers that can be assigned to S1, further underlining the importance of the specific success factor.

Value S2 to S4, on the other hand, are discovered much less frequently. For instance, S2 is identified three times, whereas it is necessary to explain that this observation is made with only one interview partner. The Product Expert explains the importance of the correct timing to market as well as detecting the right segment and knowing your patient and patients' needs, referring to market analysis as an important success factor in NPL. However, pricing strategies as part of S2 are not mentioned at any point in this or another interview, although this may be outside the scope of the experts' expertise.

Moving on, value S3 is discovered twice. First, the Strategy Expert is expanding the importance of communication with stakeholders by stating that they as well need to be informed about the scenarios that are being planned. The Digital Expert adds expectations management both internal and external as another crucial factor.

In regards to S4, four findings are made including agility and flexibility of supply chains mentioned by the Launch Expert or the need to prevent disruptions added by the CDMO Expert. The Technical Expert again adds the significance of implementing tools for doing so.

Lastly, 12 complementary success factors are mentioned throughout the interviews, the most frequent one being to view scenario planning as a cultural transformation and not just a strategic tool. In those regards, the Product, Technical and Planning experts are highlighting the importance of establishing a shared vision and understanding of benefits and goals among participants as requirements to create the right mindset for successful scenario planning. To get from talking to doing, the Planning Expert adds the derivation of clear strategies and mitigations. Further, the CDMO Expert points out the importance of involving higher management levels from the beginning since without doing so, lower levels will not be willing to cooperate.

4.2.4 Best Practices and Recommendations

In order to answer RQ3 all interviewees are explicitly asked to describe their best practices with scenario planning as well as giving recommendations to other companies implementing and using the tool.

Almost all interviewees mention offering training programs as one of the main recommendations. This is complemented by aspects such as choosing the right people, systems and tools that is especially emphasized by the Technical Expert as well as establishing a framework with clear governance and decision-making processes, added by the Supply Chain and Planning Experts. Further aspects relate to the involvement of leaders and change management practices, added by the Network Expert stating that those are mandatory to enable teams to successfully utilize the tool and see the benefit in it. Lastly, establishing a knowledge management and spreading lessons learned is recommended by the Supply Chain and Network Expert, by describing how many companies are losing knowledge that would enhance future launches by providing best practices from experiences made.

4.2.5 Effectiveness of Scenario Planning in NPL

The last factor represented in the coding agenda aims at understanding whether participants view scenario planning as being effective. The success factor is represented in variable E and the values “High”, “Medium”, and “Low” respectively. During the interviews, it is not directly asked whether the experts view the tool as being effective, rather, the aim is to interpret experiences made and draw a conclusion from that. As a result, most interview partners positively refer to the utilization of scenario planning in launches, leading to twelve points of discovery in E1. Additionally, ten findings related to a medium effect of scenario planning are made where experts perceive the tool effective, but mention doubts, difficulties or constraints in that context. Only one finding of E3 is made due to severe doubts being expressed by the Digital Expert.

Analyzing E1, one of the most frequently mentioned aspects is scenario planning effectively preparing companies for unexpected situations instead of leaving them solely reacting upon occurrence. The Launch Expert for instance explains how in a previous launch, having solutions for every scenario proved to be of highest value since especially in fast changing environments, situations can change any time and preparation is the only way to succeed. This is underlined by the Network Expert describing how the FDA unexpectedly approved them much earlier than planned due to enormous demand from the market and an immediate need

for the medication. Without having planned the launch scenario, they potentially would not have been able to supply patients in time. Even though, most interviewees have made positive experiences with scenario planning, several concerns and difficulties are expressed.

With ten out of 24 discoveries appointed to a medium effectiveness of scenario planning, the value is almost as often represented as E1. Mainly two types of constraints are mentioned. First, some interviewees describe how depending on the context, other tools are perceived more suitable, for instance when making simple decisions in the daily business. The CDMO Expert indicates that in those situations other tools can be faster, which is further underlined by the Supply Chain Expert explaining that scenario planning is time consuming and should therefore be utilized sensibly. Second, several experts express their concern that in the end scenarios are not more than a plan that may never become reality. Specifically the Project Expert highlights this by stating that scenarios are based on a limited set of variables, leaving a high risk of misjudgment. Other indicators for a medium effectiveness of scenario planning are detected when interviewees use formulations of uncertainty in this context, such as the Launch Expert explicitly saying that he is not sure whether it is effective in his current project, or the Strategy Expert stating that it does help but not without challenges.

Finally, only one sign of low effectiveness is expressed throughout the interviews. The Digital Expert leaves the impression of not being convinced by scenario planning as being an effective tool in NPL. The expert does concede that it might be helpful, but clearly explains that solely scenario planning is not enough to make a difference.

4.3 Research Conclusion

The qualitative content analysis was designed to complement the findings from the literature review. Previously, it was observed that literature on scenario planning is abundant while the conjunction to NPL is rare. By conducting ten interviews with industry experts offering years of experience in pharmaceutical product launch, this research gap is closed. The aspects found in literature are completed as follows.

First, most risks and uncertainties mentioned by the interviewees are in line with literature. The experts lay special emphasis on regulatory hurdles and authority approvals, which might be because those values fall beyond a company's control while approvals are inevitable for launching the product before any evaluation of success or non-success takes place.

Competition, demand and expectations as well as supply chain risks are mentioned equally often and are therefore interpreted as moderately important to the interviewees. The full

answer to RQ1 is as follows, whereas the aspects found in literature as well represent the main aspects mentioned by the interviewees:

- Regulatory Hurdles, Austerity Measures and Authority Approvals
- Competition, Demand and Expectations
- Supply Chain Risks
- Timing to Market
- Funding
- Relabeling and Packaging

In regards to success factors, the interviewees show a clear tendency towards team constellation, including cross-functional collaboration and allocation of resources. It seems predominantly important to include the right people, with the right knowledge and set of skills, as well as providing them with the right systems and tools to proceed. Besides, special emphasis is laid on establishing the right mindset, making scenario planning a cultural transformation instead of a working tool only. In fact, all other aspects found in literature are not mentioned as frequently as people-related aspects in that context, but many more instead. The full answer to RQ2 is:

- Cross-functional Collaboration and Allocation of Resources
- Market Analysis & Pricing Strategies
- Positive Relationships to External Stakeholders
- Production and Supply Chain Management
- Cultural Transformation
- Derivation of Mitigation Strategies and Actions
- Involvement of Management Levels

Since best practices and recommendations are not found abundantly in literature, RQ3 is mainly answered by the interviews. Summarizing the recommendations given by the experts, it is clear to say that to use scenario planning successfully, sufficient preparatory work as well as clear structures are required. In total, the experts give seven recommendations:

- Offer training on scenario planning
- Implement a clear governance and decision-making process
- Choose the right people, and minimize the number of participants
- Minimize the amount of scenarios

- Involve leadership-personalities and change management practices to enhance a cultural transformation
- Choose the right systems and tools, and train people accordingly
- Establish a knowledge management and spread lessons learned

Summarizing the findings on effectiveness, a strong tendency towards high and medium effectiveness of scenario planning as a strategic tool in NPL is observed, with almost equal points of discovery for E1 and E2. Nevertheless, it is important to emphasize that despite the assessment that scenario planning is an effective tool, a non-negligible number of concerns and difficulties is mentioned. This leaves the overall impression that in order to make the tool succeed, it is important to be aware of the risks and uncertainties related to NPL as well as internalizing the success factors and realizing them in practice. Ultimately, H1 is affirmed and scenario planning perceived as effectively enhancing pharmaceutical product launch.

5 General Discussion

5.1.1 Introduction

This study was conducted to investigate whether scenario planning as a strategic tool effectively enhances pharmaceutical product launch. This was done by first, analyzing existing literature on the topic and second, conducting interviews with industry experts to understand their perception and experience with the tool and therefore complement theoretical findings by practical results. The theoretical part provides an initial overview of the tool characteristics as well as the risks, uncertainties and success factors in the pharmaceutical industry and product launch. The qualitative content analysis successfully complements those findings and allows conclusions to be drawn about applicability and practical implementation. Resulting, differences and similarities are observed. The findings of the study have the following implications.

5.1.2 Theoretical and Practical Implications

Although the results of the theoretical and practical analysis in the main parts coincide, it should be emphasized that minor deviations are observed.

In the realm of literature, scholars and researchers delineate foresight, strategic planning, and scenario planning as distinct concepts, despite acknowledging their interconnectedness as per the established definitions. Comparing this perception to the interviewees' experience it is seen that in practice scenario planning is used in far less specific ways, and experts relate to the tool as anything related to foresight and strategic planning. The distinction between the terminologies is not seen in practice, although, it might be useful to reduce difficulties and enhance success factors mentioned by the experts themselves. For instance, a shared understanding as well as pre-defined guidelines on how to realize scenario planning as well as the desired outcome is likely to enhance a cultural transformation that is aimed by many of the experts. Further, this would include defining systems and tools that are being used throughout the process, and might as well include training on those exact resources.

Moreover, while the experts generally identify similar risks, uncertainties, and success factors, a slight disparity in their prioritization compared to the literature is observed. For instance, literature emphasizes that a significant portion of risk and uncertainty in the pharmaceutical industry yields from production and supply disruptions. While the experts mainly support this, the success factors mentioned in the interviews do not entirely align with this perception. In regards to success factors, SCM is not perceived the main success

factor, and they instead focus on the importance of cross-functional collaboration and resource allocation to enhance launch success. Additionally, pricing strategies, market analysis, and fostering positive relationships with external stakeholders are not given significant consideration and are infrequently mentioned during the interviews.

Furthermore, industry experts have highlighted various limitations and challenges associated with scenario planning, raising valid concerns regarding its efficacy in mitigating risk and uncertainty during pharmaceutical product launch, thus casting doubt on the validity of H1. However, an in-depth examination of the existing literature on the subject, coupled with insights gained from experts' practical experiences, leads to the conclusion that scenario planning can indeed be effective when implemented diligently. This entails defining scenario planning clearly to align with the company's objectives, as well as establishing robust processes for its implementation and execution. The experts' seven recommendations are considered vital for achieving success in this regard.

5.1.3 Limitations and Further Research

Like any study, this research implies certain limitations and provides opportunities for future research. For instance, a broader range of experts from various functions involved in pharmaceutical product launch could have been included. While the experts involved in this study have extensive knowledge in their respective fields, it is possible that their focus on their specific functions and related risks, uncertainties, and success factors may offer limited perspectives. Additionally, the interviewees naturally confined their statements to the pre-launch phase. While this emphasizes the significance of the pre-launch phase in overall launch success, it restricts the discussion to that specific stage and only allows for assumptions regarding the similarities or differences in subsequent post-launch phases. Moreover, it suggests the necessity of knowledge management, as highlighted by the experts themselves. By solely focusing on the pre-launch phase, the experts miss the opportunity to reflect upon and learn from past experiences. It is evident that the post-launch phase also presents potential challenges and valuable lessons that should have been considered by the experts. This limitation may be attributed to the fact that their functions are primarily focused on the pre-launch stage. Nevertheless, this gap in the study highlights the potential for further investigation on this topic.

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Appendix A

Interview guideline for semi-structured interviews conducted with experts in the pharmaceutical industry.

Background Information: Profile Analysis

- What is the main business of your company? What products or services does it cover?
- Please describe your role in the organisation.
- Does your company follow a specific strategy in regards to the launch of new products?
- What experience have you already gained with scenario planning?
- Could you please describe the characteristics of scenario planning, the way you use it?

Research Question 1: Addressing Risks and Uncertainties

- What are some of the primary drivers of risk and uncertainty in the industry?
- What specific drivers has your company faced during pharmaceutical product launch?
- Can you provide an example of how you have successfully used scenario planning to mitigate risk and uncertainty during new product launch?
- If never used before, can you imagine implementing scenario planning as a strategic tool during new product launch?

Research Question 2: Scenario Planning and Product Launch

- In your experience, how has scenario planning contributed to successful product launches in the pharmaceutical industry?
- What specific aspects of scenario planning do you consider “success factors”? What is needed to make the tool successful?
- In your opinion, what are possible limitations and downsides of scenario planning?
- Can you provide an example of when scenario planning enhanced the success of a new product launch in your company or could have done so?

Research Question 3: Best Practices and Recommendations

- What can pharmaceutical companies actively do to improve the utilization of scenario planning and enhance employees to use it successfully?
- How can companies effectively implement and integrate scenario planning into their strategic planning processes in regards to new product launches?

Conclusion

- Do you have other strategic recommendations to reduce uncertainty and mitigate risks?
- Do you have other recommendations for companies or industry experts to successfully implement and use scenario planning?
- Would you like to add anything else?

Appendix B

Summary of all quotes collected from the interviews, assigned to variables and values from the coding agenda.

Table 4 Summary of Deductive Coding of Interviews

Variable	Value	Reference Quotes	Interview Code
Scenario Planning Characteristic	C1: Narrative	“We then described scenarios for every quadrant.”	CDMO Expert
		“To me it is rather narrative than numbers. Of course numbers do play a role in terms of the content. But the stories are narratives ythat describe possible future outcomes that we need to consider.”	Digital Expert
		“In the last months, I would say, the decision making process has been more formalized and more structured. When there is a financial relevance, we need to formalize the decision that we need to take. Here, we also need to describe the scenarios and the options.”	Supply Chain Expert
	C2: Numerical	“Yes, I would say except for this product it is that way with scenario planning [...]. It’s more about numbers, and making sure I have what I need at the time I need it.”	Technical Expert
		“The other scenario planning is in terms of volume and supply chain.[...] That scenario plan goes more into the supply chain forecasting statistical world.”	Strategy Expert
		“That is also, where the numbers really come in. Earlier, you asked me about the narrative versus the numbers and when you are really trying to influence a business case for a particular scenario that you’re planning for, the numbers are very important.”	Strategy Expert
	C3: Mixed	“We usually do not use scenario planning as it technically is. It would need to be written in narratives, but we do kind of scenario planning and forecasting.”	Product Expert
		“It’s more like tables and figures that show different values. Hybrid. It is written and of course with numbers.”	Launch Expert
		“We play with both.”	Supply Chain Expert

		<p>“It is a bit of both. There I work within supply chain, people are generally more number focused and interested in some data around it. But we work really closely with the commercial marketing teams when we're preparing for one of these launches. They do it more as a story.”</p>	Network Expert
		<p>“To me, it's a combination. We use numbers to come up with a score and a rating, but at the end of the day, it is the content of what would drive those down that is important. The numbers do not matter at the end. It is about the right mitigation action.”</p>	Strategy Expert
		<p>“I think it's mostly numbers. In order to generate a quality scenario plan, the quantification is ultimately really how you get to decision. I think the qualitative stuff is important as an input because obviously in order to generate your assumptions, you need to have qualitative assessments and qualitative assumptions. I think it's both.”</p>	Planning Expert
Primary Drivers of Risk and Uncertainty	P1: Regulatory Hurdles, Austerity Measures and Authority Approvals	<p>“Also during the development phase there are a lot of products that fail even before reaching the market because regulatory authorities would find the product would be unsafe or some of the safety issues are felt and assessed as more important than the efficacy and the benefits that the product brings to the market.”</p>	Product Expert
		<p>“There's a lot of uncertainties in terms of access and lots of diversity especially in Europe where regulatory institutions and departments in states usually have different approaches to the same kind of information.”</p>	Product Expert
		<p>“Then the pharmaceutical industry has a lot of regulatory burden.”</p>	CDMO Expert
		<p>“We always face new requirements. The requirements by authorities are getting higher and higher, and this brings many risks.”</p>	Launch Expert
		<p>“From my experience, regulations and authorities are mainly putting launch success at risk. When you launch, you usually launch in different countries, where different regulations exist and different authorities need to give their approval.”</p>	Digital Expert

		“In terms of product launch, we play with two types of variables. One is the date of the approval being the most uncertain one because that is not in our control and we have a big variety of timelines.”	Supply Chain Expert
		“It depends on what is approved by the authority.”	Network Expert
		“Therefore, because of the local regulatory requirements, it delays the timeline a bit and that changes.”	Network Expert
		“It is not only the fact that there is the uncertainty around the molecule, but it's also the fact that we work in a very, if not the most highly regulated environment or industry. Why? Because we have a direct impact on patient's health.”	Project Expert
		“Then, there's also, and this we have seen more often recently, the influence of macroeconomic factors on the industry and on the way governments decide what to pay for and what not to pay for that affect the company's business case.”	Project Expert
		“In that case, the scenario planning was, do we get approval on time? Do we get delayed? Do we get a rejection? That one was a very difficult scenario because the last thing we wanted was to get rejected from a regulatory approvability side.”	Strategy Expert
	P2: Competition, Demand and Expectations	“We do a lot of marketing research in terms of positioning, in terms of awareness and intention to prescribe, but sometimes these perceptions do not really happen in the field when we launch the product.”	Product Expert
		“And of course then you have the external factors, like competitors, which usually we are always running against the clock, against competitors.”	Technical Expert
		“The other one, are the competition. Our strategy is to be first to market and if competitors are on it as well, we need to be fast.”	Digital Expert
		“The other one is the volume or the first order. For instance, if there is an increase in demand of a certain country, and we need to commit volumes with CMOs or even with the internal site, or we need to order material to support that, or we need to anticipate a certain risk.”	Supply Chain Expert

		“Also, whether you're first or second to market has a huge impact and a direct correlation on the potential sales that you have of a molecule in its lifetime.”	Project Expert
		“Then, you have uncertainties in the demand landscape and bad forecast. You need to figure out how to have processes that is agile enough to dynamic demand.”	Strategy Expert
	P3: Supply Chain Risks	“Our main risks are the supply chain, so the access to raw materials, for instance.”	CDMO Expert
		“The first, of course, is the internal. You may have delays at every step. So, when you're transferring, when you're launching, you can face delay at any time and you have to plan for it.”	Technical Expert
		“Let's imagine that something unplanned happens like you lose the facility for whatever reason. It is a fire, an earthquake, a bomb, you name it. That will immediately put a stop on our launch process and there's nothing we can do about it because then we need to start over from the beginning, almost from the clinical manufacturing with a different vendor or whatever.”	Project Expert
		“The other scenario planning is in terms of volume and supply chain. It is looking for the things that could go over what it's forecasted, which means then you could potentially run out of supply at launch, because there's maybe more demand than you expected, or under demand, which then you have write -off risk products.”	Strategy Expert
		“The majority of supply interruptions and issues that happen are in manufacturing, and a huge amount of them come from the direct materials that go into the production, in terms of materials that are required for making the products.”	Strategy Expert
		“Nowadays, it is also the lack of supply resilience in the device landscape. [...] It is not just about making the actual product, it's about the devices required to administer that product where it's as crucial in terms of availability, in terms of quality, supply.”	Strategy Expert
		“Another area is issues during manufacturing and not having robust manufacturing processes.”	Strategy Expert

		“For me, the main complexity here is lead time, because supply chains are long, in some cases we're talking about three years at an extreme example, there is a need to commit forecasts well in advance of having perfect information.”	Planning Expert
	P4: Complementary	“Sometimes, because development of pharmaceutical products takes so long, 12 years to reach the market and then they have a very short commercialization period compared to the development days, the main risk is that when we reach the market the product will no longer be relevant.”	Product Expert
		“There's a lot of uncertainties in terms of the timing to launch. One of the areas that are most important for industry at the moment is oncology and we have a very diverse timing to launch. There are countries that launch the day after the approval from the EMA. Some countries like Portugal will launch 700 days after the approval of the EMA.”	Product Expert
		The third one in our position is the funding, or at least the funding that our clients may have to do to investigate and develop new drugs. Because if they stop developing, then they don't come to us to produce.”	CDMO Expert
		“One of the biggest risks is needing to reprint because there's a change in what we expect the final wording to be that would impact the timing of things.”	Network Expert
Success Factors	S1: Cross-functional Collaboration and Allocation of Resources	“Because sometimes when the environment changes and it changes very quickly, you don't really have time to adapt. And if you have plans in terms of human resources and activities, that's for sure one of the great advantages that scenario planning would bring to the companies when the uncertainties happen.”	Product Expert
		“If you want to use scenario planning you have to have teams prepared to use that tool, and teams that are knowledgeable with that tool, and that sometimes takes time and requires commitments and resource allocation that sometimes we are so short of.”	Product Expert
		“It would require knowledge from collaborators and time discussing the	Product Expert

		certainties, writing the scenarios, writing the strategic options and selecting them.”	
		“I think it's most important that this is done properly by people who have the knowledge, because scenario planning that is done badly can be even worse, because in the end you might take actions that are not good.”	CDMO Expert
		“It is a cross-functional team that is preparing the launch transfer. To make the launch happen you need the collaboration from the warehouse, from production, from packaging, supply chain.”	Technical Expert
		“Yes, that's one major thing in our company. It is so big and responsibilities are sometimes not clear and sometimes 10 people are responsible for one thing and that leads to problems. You need clear resource allocation.”	Launch Expert
		“It is about forming the right, or discussing within the right functions, it's about defining accountability to the makers formalize the decisions, and describe the rational, document it, and being able to look back.”	Launch Expert
		“I think the most important part is having a tool where people can see: what are the tasks, when should it be done and who is the action owner.“	Launch Expert
		“. It is not only supply chain but also finance, and sometimes commercial or regulatory. It tends to be cross functional and you need to pick up working like silos to do that. It is necessary to put people from different functions together.”	Supply Chain Expert
		“What's important in doing scenario planning is making sure that you have a diversity of viewpoints in something so complex as producing our products and getting them to patients. There is quality aspects, there's financial aspects, there's regulatory aspects. If only one or two functions sits together to try to come up with all of the possible scenarios we might face, I think you don't have a diversity of thoughts and experiences there.”	Network Expert
		“There's a lot of work from a lot of different functions to enable that, and it was that planning, what could we do	Network Expert

		and how could we think about it in advance that helped in the end.”	
		“One of my big learnings for the 10 plus years I've been in supply chain is that communication across product teams is so very important. [...] And it's important that they create a community of communication, even to the point of maybe over-sharing. That kind of communication and sharing is really important to the success of teams.”	Network Expert
		“The one critical element is that you need to have the right people involved in the exercise. By the right people, I mean people who actually know technically or empirically what is the potential effect of this or that choice. These people need to be able to put forth their opinion or their experience or run the analysis that they need to run. Without any sort of obstacles hindering them, any sort of political alignments, or agendas, or anything in order to make the best and most objective scenario analysis.”	Project Expert
		“The important thing is to make sure a scenario plan is the best it can be. You need unbiased, technically minded, experienced people planning out the effects of each decision on the plan.”	Project Expert
		“I think that scenario planning is always going to be best served by a very small group of experts using professional software to do that.”	Planning Expert
	S2: Market Analysis & Pricing Strategies	“First, we have to estimate the timing to market. It's one of the variables that you should take into account especially for countries where you have national approvals, but then you have hospital by hospital clearance, and this is more common than we thought of.”	Product Expert
		“But then we revealed that some of the patients, especially older patients, have a lot of difficulties and we kind of knew this due to the reports from other countries. You need to know those things.”	Product Expert
		“And I think the segments that we select to launch the product in the initial phase is also an important topic and an important aspect to look after because that will then be important to	Product Expert

		develop campaigns, develop materials, develop communication tools.”	
S3: Positive Relationships to External Stakeholders		“To be successful, it is equally important to manage stakeholder expectations, both internal and external of course.”	Digital Expert
		“Getting stakeholders on board with whatever scenario that you are pushing for is absolutely important.”	Strategy Expert
S4: Production and Supply Chain Management		“The success factors in the end are to keep with the growing of the company, our sales, our products getting to the market, so to have no disruption in the day-to-day activities and the supply chain.”	CDMO Expert
		“We really have to have an IT tool to be able to see what happens if the drug product will be delivered later, what happens if the line is not ready when we need it or if other process steps are not coming in time.”	Technical Expert
		“And that's the next thing, to be very, very fast, you have to be flexible and agile.”	Launch Expert
		“What we see know is that a lot of it is related to keeping your lead times, so that means a good supply chain management is inevitable to succeed.”	Digital Expert
S5: Complementary		“I think writing those on the paper and having the team aligned on which are the scenarios and how important they are, they will help the companies to react more quickly to changes but also trying to experiment.”	Product Expert
		“I think the approach to scenario planning is a cultural transformation. It would require that all the employees actually see the benefit of it and to imbed that in the culture and their daily work.”	Product Expert
		“It is important to implement it at highest level, because if the bottom of the organization is doing it, no one will care.”	CDMO Expert
		“I think many people have difficulties looking at scenarios and thinking about what may go wrong. To make the launch successful, you have to bring them to this thinking. This is a big challenge, because it is not easy for everyone to do that.”	Technical Expert
		“A recommendation is to use scenario planning from the beginning on. By	Launch Expert

		doing scenario planning, you are thinking about what can happen, what might happen, and you can start as early as possible to work on the different plans that are needed for successful launch.”	
		“There is to be very good work in defining those scenarios, and even if it sometimes means that it's not meeting business objectives, or maybe not expectations, but it should be very much related to what you see in reality.”	Supply Chain Expert
		“Also, when you do a scenario plan, you're planning for certain things to happen, but life is life. Those things don't necessarily happen as per the plan, so a very important thing is to actually come back to your scenario, update your scenario and then see if the rest of the plan still makes sense. A scenario plan is not a static thing. You always need to have this feedback loop at the end and then iteratively feedback into your scenarios.”	Project Expert
		“The sweet spot with scenario planning is you need to develop scenarios that are both technically robust and data driven. You need a lot of data that they can be considered robust and help us make better decisions.”	Project Expert
		“But the scenario planning process should also be quick and agile that we're able to respond to business requests and needs in a short timeframe. Very often the decision needs to be made in a couple of days, so we need to hit that balance.”	Project Expert
		”Scenario planning requires some serious influencing and inspiring because you need to be very clear and focus on what is it either bringing to the company, what is it bringing to patients, what is it bringing to the healthcare system versus what it costs. It is always this kind of balance of investment versus reward and benefit.”	Strategy Expert
		“Honestly, I think that the most important thing is a clear philosophy. I think that's tremendously powerful to align teams so that they know what it looks like.”	Planning Expert

		<p>“The important step is to generate options from your scenarios. And that's where the magic happens and where you drive action. Otherwise, it's just a paper exercise. You need to decide what scenarios are most relevant to convert into options. [...] The art is really how to converge on a set of no more than five options that you can then use to drive decision making.”</p>	<p>Planning Expert</p>
<p>Effectiveness</p>	<p>E1: High</p>	<p>“I think scenario planning on this topic would help companies to be more effective to operate better and to prevent uncertainties to break their operational model.”</p>	<p>Product Expert</p>
		<p>“I believe the direct reports of the CEO are using these tools to come up with scenarios. And we saw that some decisions already have changed in the company, for instance, we have several different sites worldwide.</p>	<p>CDMO Expert</p>
		<p>“I believe it can contribute to a successful launch and production flow.”</p>	<p>CDMO Expert</p>
		<p>“For me it is a success and you need to have it to be successful. If you don't have these different scenarios, everything you are doing is just to constantly react to situations.”</p>	<p>Technical Expert</p>
		<p>“If someone tells me we have this, then out of my mind, I can already imagine what is going to be the impact because we have worked on many, many, many scenarios for all the project parts.”</p>	<p>Technical Expert</p>
		<p>“When I was in another role, we were setting up new drug products in the facility and of course the demand was changing a lot. We had a solution for every scenario and because we did the scenario planning, we were able to react to the market. We cannot influence what will happen in a certain way but we can have plans on how we react to those quick changes that can happen anytime.”</p>	<p>Launch Expert</p>
		<p>“Without having a scenario, you don't easily get to that type of conversations and discussions:”</p>	<p>Supply Chain Expert</p>
		<p>“All that costs money and that qualifies for our formal decision and then building the most likely scenarios.”</p>	<p>Supply Chain Expert</p>

		“If we hadn't started planning in advance, we would have potentially gotten an approval from the FDA and then been waiting months and months to be able to actually supply the product to the market. That was a bit of a success, I would say, in terms of teams continuing to analyze what's possible and the creativity.”	Network Expert
		“That is where you start getting into things like building up safety stock, for example, or validating a second line for either one of the molecules so that you have more capacity. That is the outcome of doing a proper scenario plan and then taking measures in function of what you find.”	Project Expert
		“The business case was negative, it was too costly for such a small volume of product, and so we decided again to stop the program right there and then. Again, it's not a positive outcome, but it is a perfectly valid outcome of scenario planning that you actually stop something before you throw good money into a bad option. That is actually what you want to get out of these type of exercises.”	Project Expert
		“In that case scenario planning worked and we're in the process now of implementing this.”	Strategy Expert
	E2: Medium	“Probably, if we had applied it, we may have been quicker to have an alternative solution.”	CDMO Expert
		“On a day-to-day we use other tools that are more like checklists or that we evaluate much faster.”	CDMO Expert
		“It may never be used and some people might ask why we are wasting our time. In the end, when it happens, it will benefit you but there is an uncertainty to that.”	CDMO Expert
		“We are now reacting and doing some planning because we did not have a plan for that but you don't really know what is happening in this phase, so the scenario in this case can always be completely different.”	Technical Expert
		“As I said, we are using scenario planning right now. I have to think about whether it is successful because our scenarios now are changing very often.”	Launch Expert

		“I think for simple decisions, maybe it's better to be pragmatic. Building scenarios is also a bit time consuming for several functions so it should be related to somehow impactful decisions or complex decisions.”	Supply Chain
		“The biggest limitation to scenario planning is that it's only that, it's a plan. You cannot plan with all of the variables that are out there in the world. You have to take a very limited set of variables and you have to make your best guess, informed guess, technical guess, but at the end of the day, it's all a guess.”	Project Expert
		“It helped and it worked out, but it is still quite a challenge.”	Strategy Expert
		“I think whilst we have some great examples around launch, I mean, the service levels being the major outcome measure, it is also important to look at how scenarios don't work on the other side of the equation as well.”	Planning Expert
		“I think the limitations in scenario planning are that it doesn't answer anything in itself. And the real magic is conversion of scenarios to options and then options to decisions.”	Planning Expert
	E3: Low	“Scenario planning as it is, I don't think will contribute to successful product launches.”	Digital Expert

Appendix C

Overview on recommendations on how to successfully use or implement scenario planning in NPL processes, stated by experts.

Table 5 Overview of Expert Recommendations

Recommendation Category	Reference Quotes	Interview Code
Training	“I think one of the key things that management should do is actually to invest in training for their managers, people managers, team managers, and also directors of departments that can convene and create a culture of planning.”	Product Expert
	“I think first you need to train the people at least at a certain level because at the end, this is a framework.”	CDMO Expert
	“You need do train people.”	Technical Expert
	“The people need to be trained, at least to use the tools. It should be maybe three, four people with the knowledge and the accountability to decide what is the scenario, not more.”	Launch Expert
	“You need to have a process, you need to have a governance, and you need to have the functions trained to do that.”	Supply Chain Expert
	“The trend is to train people a bit more on that within the group, but that's just starting, let's say, in the last 12 to 18 months, that's occurring in a bit more formal fashion.”	Network Expert
	“The first thing a company can do is to actually train people in what scenario planning actually is, as a discipline and as a tool. You teach people how to do proper do simulations, you teach them how to do statistical models, you teach them to do design of experiments, and teach them when it actually makes sense to use those tools.”	Project Expert
	“I actually think that if there was an area to kind of train out and get more widespread adoption, it's helping people to be really good at framing options and driving decisions.”	Planning Expert
Governance & Decision Making Processes	“The other point that was not obvious to us is that until a year ago we did not have a decision-lock, proper decision-lock in our supply chain organizations.	Supply Chain Expert
	“This made me think about how we actually communicate this to our teams. Because I think nothing happens without a decision. And decisions need clear options. And scenarios are just the input.”	Planning Expert

People Selection	“But if leaders just ask for it and the people below have no idea about what scenario planning is, they will never be able to give it to them. There's nothing better than the training and awareness and having the right people.”	Technical Expert
	“We are not the best I have to say. Because there are too many people working on the scenarios, too many opinions, and we need to streamline this more. I would say as few people as possible should be involved.”	Launch Expert
	“All I would say is you need people with influence to be champions of whatever scenario you're really pushing for.”	Strategy Expert
Minimize Scenarios	“The greatest risk is to build just too many scenarios. It is mandatory to identify the most critical risks.”	Technical Expert
	“My advice is that you at least plan the delay scenarios, and then the production schedule. And you need to see what your capacity is, and how fast you can react and produce.”	Technical Expert
	“Don't look in every scenario, only the most likely ones, and focus then on two or three scenarios where you can drive the outcome to that scenario.”	Launch Expert
Leadership & Change Management	“It's not only a single approach or a workshop where everybody will be very happy and satisfied because they learned a new thing. It's something that should be adapted in the culture of the company.”	Product Expert
	“If you go to a technician in the production, they will never think about scenarios. You need to make them aware of this. And from a leader perspective, leaders can bring that to them. Leaders should ask for scenarios. [...] This is also about the company culture and about change management.”	Technical Expert
	“Further, you need to consider how can leaders help teams deal with those situations in a constructive way when they occur. The people in a product team, for example, that are trying to launch a product and the leaders around them sometimes don't always prepare themselves for that.”	Network Expert
	“It would definitely need to be a very straightforward, easy to use and show that it adds benefit. Because what you do not want to do is just add another step to everything we do, but really drive with the value it brings.”	Strategy Expert
Systems & Tools	“What is not good is that there is no single list there about maybe 20 lists about that and they have to be streamlined as well. [...] There is not the single tool and you need licenses. Some of the tools you cannot learn by yourself. You always need some help by	Technical Expert

	somebody. It would be helpful to have one tool that is understood and used by everyone.”	
	“One thing that is always a struggle is to have a good system to do scenario planning. It is very easy to end up with having a spreadsheet. Nothing bad to have a spreadsheet, but you can easily make mistakes with that.”	Supply Chain Expert
	The other thing is to invest in data gathering tools. [...]If you give your scenario planning teams access to this sort of information, it gives them a big number of data points that they can actually use to build better scenarios.”	Project Expert
	“If we can find the right tool that's easy to use and maybe can be rolled into the technical development teams and then eventually the technical product teams and commercial could see that as a potential option.”	Strategy Expert
Knowledge Management and Lessons Learned	“There should be more learnings, or at least more taking that into consideration for future decisions or scenario planning. It would be good to incorporate that into the system making process, all the scenarios, all the decisions, all the cases to improve in the future. That is a help.”	Supply Chain Expert
	“I think we can also, from that group of launch experts, just share knowledge a bit more because they have these experiences. It is a knowledge management topic. [...] Knowledge management can be a powerful piece of that as well.”	Network Expert

Appendix D

Excerpts from semi-structured interviews conducted with experts in the pharmaceutical industry.

Interview 1: Product

00:01 **Interviewer:**

What is the main business of your company and what products or services does it cover?

00:40 **Interviewee:**

We have mainly an investigational company that researches in the field of virology and oncology. We have some other products, e.g., on the fungal and cystic fibrosis, but mainly two areas. In oncology, we have solid tumors and we have products with the CAR T-cell technology.

01:07 **Interviewer:**

How would you describe your role in the organization.

01:10 **Interviewee:**

Currently, I'm a brand manager for HIV in Portugal and I'm also currently on an assignment for a lung cancer launch in the Middle East region, so accumulating both roles, mainly marketing.

01:29 **Interviewer:**

What strategy does your company follow in regards to the launch of new products?

01:31 **Interviewee:**

That's a complex question, because the strategy is not well defined on paper as a single word. But basically we follow a differentiation position trying to be first on the market and to cover unmet medical needs and diseases bringing transformative products to the market that actually will tackle the most relevant and severe diseases in the field that we operate, either virology or oncology. For this, you can take the example of HIV where we were pioneers in bringing single-tablet regimens to the market, the first single-tablet regimens was launched by us. Also in virology, we were the ones that launched the first antiviral drug for COVID-19. Now we are entering the space of solid tumors, so actually speaking, we tend to try to be the first to launch for severe diseases in the market.

03:12 **Interviewer:**

I can imagine especially in a situation where you try to be first in market, you're facing a lot of uncertainty and risks. Have you ever considered using scenario planning as a strategic tool?

03:16 Interviewee:

Sure, in regards to the scenario planning, we all do our planning and provide the plans for the launches. I think what you should take into account for my example is that we usually do not try the scenario planning that the scenario is the way, technically, the scenario planning is. We usually do not use scenario planning as it technically is. It would need to be written in narratives, but we do kind of scenario planning and forecasting. We are trying to imagine which options should we take if some of the scenarios would effectively happen, but not on the formal way as scenario planning should be used.

04:26 Interviewer:

Before we move on with the scenario planning what in your opinion are some of the main risks and uncertainties related to new product launch in the pharmaceutical industry?

04:47 Interviewee:

Good question. Sometimes, because development of pharmaceutical products takes so long, 12 years to reach the market and then they have a very short commercialization period compared to the development days, the main risk is that when we reach the market the product will no longer be relevant. That's a huge uncertainty and that's a huge risk that all the companies take during the development phase. Also during the development phase there are a lot of products that fail even before reaching the market because regulatory authorities would find the product would be unsafe or some of the safety issues are felt and assessed as more important than the efficacy and the benefits that the product brings to the market. So, the risk management balance is something that worries us the most and it can be changed from one day to another due to reports or the things that will happen in the real world usage that were not supposed to happen or were not expected to happen as we have captured those clinical trials in a very strict and limited field and limited space. So, when we launch the product, and the product begins to be used by a larger population this is where the safety issues might arise. That's one of the greatest uncertainties. We do a lot of marketing research in terms of positioning, in terms of awareness and intention to prescribe, but sometimes these perceptions do not really happen in the field when we launch the product. There's a lot of uncertainties in terms of access and lots of diversity especially in Europe where regulatory institutions and departments in states usually have different approaches to the same kind of information. So, some of the more restricted countries in Europe might evaluate the cost effectiveness of a drug in a way and others that are more open to innovation and evaluated it in another way. There's a lot of uncertainties in terms of the timing to launch. One of the areas that are most important for industry at the moment is oncology and we have a very diverse timing to launch. There are countries that launch the day after the approval from the EMA. Some countries

like Portugal will launch 700 days after the approval of the EMA. There's a huge uncertainty for this analysis as well.

08:10 Interviewer:

Those are a lot of different risks and uncertainties. When you use scenarios to mitigate those risks, where do you start and how many scenarios would you consider?

08:30 Interviewee:

I do not say that there will be an exact number. It will depend from project to another. And it will depend if you work on the European Global Department or on an affiliate. First, we have to estimate the timing to market. It's one of the variables that you should take into account especially for countries where you have national approvals, but then you have hospital by hospital clearance, and this is more common than we thought of. I got a lot of countries in Europe that after the national approval of the financing, there will be a phase where I have to approve it hospital by hospital, so timing to approval hospital by hospital is one of the key aspects when we watch the problem. And I think the segments that we select to launch the product in the initial phase is also an important topic and an important aspect to look after because that will then be important to develop campaigns, develop materials, develop communication tools. So I would say the uncertainty is how's the financial health of the national health systems in the countries that will for sure impact the timing for marketing terms of access. Also always a product when to be approved by the authorities in terms of indications and populations would be key to then select the segments and the targets that we would like to have.

10:52 Interviewer:

In your opinion, what specific aspects of scenario planning itself can especially be helpful to improve successful launch?

11:05 Interviewee:

I think besides the selection of the uncertainties, writing a correct narrative with the strategic options that we have for each scenario is very relevant. Because sometimes when the environment changes and it changes very quickly, you don't really have time to adapt. And if you have plans in terms of human resources and activities, that's for sure one of the great advantages that scenario planning would bring to the companies when the uncertainties happen. I think writing those on the paper and having the team aligned on which are the scenarios and how important they are, they will help the companies to react more quickly to changes but also trying to experiment and try small things, even those that are not the most strategically relevant, to simulate what would happen if that kind of scenario would happen, and then be more close to what the real life

experience would be. Let's say we don't know currently that whether digital or omni-channel is that relevant and strategically key for pharmaceutical companies. That's something that we're still looking for because we know in Portugal that face-to-face interaction is absolutely key. We know that by market research data, but we also know that the trend to a more digital approach is there, and it might change from one day to another with the new generations coming in and you have to be prepared. So, if you plan for a scenario where all the doctors don't want to be called on a face-to-face meeting, I have to be prepared for alternative ways of reaching that. So, we should eventually try a lot in order to be prepared for that. And that, I think, is the most relevant advantage and beneficial aspect of the scenarios.

13:56 Interviewer:

Can you provide a specific example of how scenario planning helped with a specific issue in your experience?

14:11 Interviewee:

When we changed the packaging of one of our products from bottles to blisters, this was something that was planned, of course, but not all the countries have launched. We as Portugal affiliate were kind of isolated in Europe launching this new packaging formulation. And this actually gave us a lot of marketing hype and marketing conversations about how important the blister is and how important the new packaging is for the patients or the portability of the product, the easiness of usage, and also the compliance. We knew that this blister will have a technical issue in terms of openness. For some people it could be very difficult to take out the pill from the pocket because they have this resistance for and to prevent the children to open it. But then we revealed that some of the patients, especially older patients, have a lot of difficulties and we kind of knew this due to the reports from other countries. And anyway, we had to launch, and we launched it as this new packaging, but we planned already a technical change to another type of reason. So, we launched it, and we assessed the number of complaints. But we have planned that we will have a 2.0 blister version that would prevent these issues to occur. I think we planned to have a scenario where the number of claims would be high and then we planned the change one year after to prevent those claims, if those claims would be high enough to justify the change. So, that's what is really happening in the market. It's a small example, but I think it's useful to understand what the risks are, what are the uncertainties, how we can plan ahead, and how we can go after what the market values the most, and the trends, and also the needs from the patients which are the most important things for our industry.

17:24 Interviewer:

So overall, you would say that scenario planning can be effectively used to mitigate risks and

uncertainties. Do you think it is better in a way than other strategic tools or do you have any other tools that pop up in your mind?

17:35 Interviewee:

I cannot say whether it is better than other tools or not, but what I know is that if you want to use scenario planning you have to have teams prepared to use that tool, and teams that are knowledgeable with that tool, and that sometimes takes time and requires commitments and resource allocation that sometimes we are so short of, that management would not be motivated to use this tool as one of the primary tools to plan ahead. I think forecasting brand plans or strategic discussions are all used. I think scenario planning as a formal approach to planning ahead, sometimes and most of the times people don't invest that much at the moment, at least from my experience, and it would require knowledge from collaborators and time discussing the certainties, writing the scenarios, writing the strategic options and selecting them. I think it's a good tool. I don't have the data to say it is a better tool or not. And I would say that this would require an investment on time and resources from the companies that would bring this tool to life and to make that more effective.

19:28 Interviewer:

What would you specifically say can help organizations when implementing scenario planning as a strategic tool? What are the success factors and what needs to be put in place in order to make it work effectively?

19:45 Interviewee:

Because the operational margin in the pharmaceutical industry are reducing, at least in Europe, we have price cuts and we have approved maximum prices across Europe and our expenses are growing up on salaries, on direct costs and indirect costs. Everything is growing and the operational margin is becoming reduced, so we are operating in an uncertain environment with lower operational margins, so we have to be very efficient in terms of management. So, I think scenario planning on this topic would help companies to be more effective to operate better and to prevent uncertainties to break their operational model. I think one of the key things that management should do is actually to invest in training for their managers, people managers, team managers, and also directors of departments that can convene and create a culture of planning. It's not only a single approach or a workshop where everybody will be very happy and satisfied because they learned a new thing. It's something that should be adapted in the culture of the company, that should be talked about, that should be communicated across the company, should be communicated with good examples across the industry but also on our company. All this has been implemented and how successful it was in order to create this culture of using scenario

planning as a tool to make this more successful in a very, at the moment restricted environment and very difficult economic environments for all the companies that don't have the chance to charge higher prices at least in Europe.

22:14 Interviewer:

Do you have any strategic recommendations you would give organizations when dealing with those topics?

22:50 Interviewee:

I think we're all fast moving companies that want to make things very powerful. We are all looking and pursuing the new trends and sometimes management becomes a bit passionate about the new trends of digital or artificial intelligence, data mining, big data, whatever, like these big words and they sometimes don't realize that companies have to do the basics first and scenario planning for sure is one of the basic things. Either if they use a formal approach into scenario planning like academia would say that we should or any other forms of planning. Because the management cycles are so short and if you can see like a typical CEO run for three or four years in their jobs and roles, they don't have the enough time to transform organization. It's one of the things that I have seen in the industry, either global CEOs, or general managers don't really have the time to implement transformational changes into the organization. Some of them would say that they are going to change the organization, but in the end of the day what they will do is to try to make the company more efficient, of course, and to increase the revenue, of course, but cultural transformations don't happen for one day to another or in three years. I think the approach to scenario planning is a cultural transformation. It would require that all the employees actually see the benefit of it and to imbed that in the culture and their daily work. Because it requires time, it requires efforts. Efforts in learning how to do it, but also efforts on a day-to-day basis how to implement it. And because as you know, scenario planning can be changed and can be adjusted along the time, it would require people to meet and to be committed to the project. I think also the fact that the management cycles are so short, the objectives of the top management sometimes are not aligned with the cultural transformation of the company on a 10-year, 20-year timeline. This could prevent some of the companies to adopt these kind of tools more quickly. And that's for me, that's the most relevant part in this. I think it's why sometimes this kind of approach is important. We can see, from the example that I have, Portugal, you see a lot of this happening in family-owned companies where we know that they will try to run the company for centuries. They are here to stay and they are eager and more open to implement those kind of things, of strategic and relevant ways of making sure the company is adapted and prepared to face the uncertainties of the future. If I know that I'm being in charge, the company for three years, why am I worried with the

changes that will happen in 20 years' time? Or even that I don't know if they will happen? It is a divergent view on a business, where people want to be successful, but in the same way they know that they will not be here to see what success will look like in 20 years' time. So why should they make the effort to transform the organization in that sense?

27:12 **Interviewer:**

So, you would say that scenario planning has a lot to do with change management and in general, how an organization works?

27:29 **Interviewee:**

Yes. You even have to create new roles. You have to take a lot of courage in terms of management to do that, so. And sometimes the CEOs are not even allowed to do that by chairmen and investors. And if we speak about life cycle management and the resource allocation, everybody said that pre-launch and launch phase are the most relevant phases of the life cycle. That's where we should put all our resources if you have to. And launch phase is absolutely determined for the success, the long-term success of the product, so if you know that this is the most relevant part of the life cycle, and if you know that products in pharmaceutical companies, product success is the thing that fuels the pipeline and that fuels the money to invest in the pipeline. That is absolutely critical to make sure that product launches are as effective as possible. If you know scenario planning tool is such a relevant tool to avoid uncertainties and to be prepared for any kind of turmoil in the markets or that product launch, it could be absolutely mandatory. For me, from my experience, it's not what we see. We see a lot of planning, of course. We see a lot of discussions, but you don't see a formal process of establishing the select option.

Interview 6: Network

00:00 **Interviewer:**

Could you please explain the main business of your company and your role in the organization?

00:04 **Interviewee:**

We are a global pharmaceutical company. We have two divisions, pharmaceuticals and diagnostics, all in the exploration of improving healthcare for people around the world. I work in the pharmaceutical division and within the pharmaceutical division we have a group called TechOps manufacturing and I work in the supply chain area within that. So within supply chain we are kind of, I think of us a little bit as the conductors of the orchestra. All of PT is a bit of an orchestra that is delivering medicine to patients and quality and regulatory. Our manufacturing

sites are all key part of that and supply chain plays a little bit of roles, a bit of conductor orchestrating across the PT space.

01:24 Interviewer:

Since I am focusing on the launch of new products within this study, in your opinion, does your company follow a specific strategy when it comes to the launch of new products?

01:28 Interviewee:

I've spent over 10 years now in supply chain and when I was part of our local US planning team, launched several products within at least the local US market and one of the norms or best practices we have is that we invest a lot of time obviously in developing the products and getting it ready for launch across the organization, whether it's in the commercial or the manufacturing space. So an important element for us is when that comes together to the final approval in a given country from the health authorities, we try to launch very quickly after. We want to have product on the market and available to patients very soon after we get those health authority approvals. Typically what we try to do here within the US, we try to have product available within one to three business days after a health authority approval. Occasionally because of different constraints, it can be longer, but that's a norm that we have and we similarly operate that way in many of our bigger markets in the EU, Japan, and I think we're trying to close that gap now for China as well.

02:52 Interviewee:

If you're saying ready to launch, does that mean that you would produce at risk before that?

02:55 Interviewee:

So for sure, because of the lead times for our products, the drugs, the API manufacturing, the drug product manufacturing is all done at risk, where it's regulatory allowed. The discussion that we have per product team is then if we do the packaging at risk as well too. And that, as I'm sure you've uncovered in your research, has to do with what the final labeling looks like and what's approved by the health authority, whether there are any last minute changes that could change the wording, meaning that our physical leaflets that go with them there might have to be changed after the final feedback. I have seen products that do even package at risk before approval so that we can shorten that timeline. I have seen other products that choose to wait, but they come up with special expedited timelines with the suppliers, for example, printing the leaflets so we can shorten that.

04:05 Interviewer:

In that process and in your experience, have you already used scenario planning as a strategic tool?

04:08 Interviewee:

I look at scenario planning in terms of what I've been doing the last four years has been launching OMP, which is our new supply chain planning platform within PT. That is new. We haven't used that formally within the system as a way to create scenarios for this, but there are many folks who are adept at offline simulations using older tools like Excel and such things to model what would be the financial cost, for example, of doing that sort of thing and also looking at then what would be the impacts to timing, right? If we make decision A versus B, those are the options we look at and analyze then what would be the impact to first patient being able to receive a dose of this product or the risk of inventory we'd have to write off because there had to be a change and we had to throw something out. We are using scenario planning, I would say that we do it manually offline using these older tools and we hope to in the coming years bring it more into a systematic approach in some of our new planning tools.

05:47 Interviewer:

And if you say scenario planning, would that be written out stories or is it more in terms of numbers?

05:50 Interviewee:

It is a bit of both. Where I work within supply chain, people are generally more number focused and interested in some data around it. But we work really closely with the commercial marketing teams when we're preparing for one of these launches. They do it more as a story, especially since I have only launched directly a product within the US, much of what our sales and marketing colleagues and commercial do is about the story of the benefits of our products. That is the job of a marketing professional. They are sometimes even looking to pre-identify patients who could benefit. With many of our oncology and cancer medications, our first indication when we launch a product is potentially in the third or fourth line setting. So, patients who have not been successful on one, two, maybe three different therapies, but maybe this product that we want to launch will help them when they're kind of at the end of the road for their options. That is where I think our sales and marketing colleagues look at putting together the story of who are the folks that will benefit. It as well provides the motivation for people in manufacturing to say, this is the benefit for why we are working these extra hours or we have added an extra shift to do something so that we can get the product out there for patients. At the end it is a little bit of both, I would say, at least the way we do marketing here in the US that plays on the word side of things a bit more.

08:01 Interviewer:

Before we move on with the scenario planning, what are some of the primary drivers of uncertainty and risk during product launch?

08:05 Interviewee:

Obviously, one of the biggest ones we talked about was the wording that goes on the label. So we generally need for launch products, not always, but many times we're doing the actual packaging operation in-house, but the printing of the leaflets, the folding cartons is generally done by a provider. One of the biggest risks is needing to reprint because there's a change in what we expect the final wording to be that would impact the timing of things. The other thing we find is, for example, in China, they require the manufacturing date to be after the health authority issues their approval letter. Therefore, because of the local regulatory requirements, it delays the timeline a bit and that changes, you know, we're not talking about a one to three day lead time like we are in some of the US and EU countries, I would say. At least those laws are stable now, so we know to factor them into our scenarios and consider them, but it is a big factor that we have to consider for the local market.

09:38 Interviewer:

Could you provide an example of how you have used scenario planning when one of those uncertainties or risks occurred?

09:42 Interviewee:

In my experience, we prepare our scenarios in advance. That way we know what we would do in different options, but when we have an uncertainty that arises and becomes true, what we are better at is what I call in English, firefighting. We are better at understanding the problem and kind of everybody coming together around the problem and trying to resolve it quickly. Because we know the target, we know what we are trying to achieve, it is launching the product, and it is getting it to our patients. Now, because of an uncertainty that's come up, either we plan for it and then we execute that plan to make option B, for example, go forward, or if it isn't, we try to get everyone together and say, okay, how are we going to tackle this problem in an unplanned way? This can go two ways. I would say, it happens the letter that we are all rushing to just resolve the uncertainty and the problem. And this is where we need to improve, like, could we have thought of that option before and come up with a plan in advance rather than dealing with it when it comes up, if that makes sense.

11:36 Interviewer:

What aspects do you think make scenario planning successful?

11:42 Interviewee:

It's funny, we talk about this right now in a decision making process, I'm responsible for it. I do not know how you define it in your research, but for us, a scenario is something that we do not control or cannot control, but we need to be aware of and plan for it. Then, the options are what we would do to mitigate that scenario, right? And so I think what's important in doing scenario planning is making sure that you have a diversity of viewpoints in something so complex as producing our products and getting them to patients. There is quality aspects, there's financial aspects, there's regulatory aspects. If only one or two functions sits together to try to come up with all of the possible scenarios we might face, I think you don't have a diversity of thoughts and experiences there. One really important thing is to make sure you have a lot of different functions involved in doing that scenario preparation so that you can consider all the different things you might encounter or get a broader view of that. If you do it in isolation or with a smaller group, you do not get the diversity of opinion that I think could help you in doing the scenario planning.

13:14 Interviewer:

Have you received any training of scenario planning or how did you get to use it?

13:42 Interviewee:

No, I never received any sort of formal training. I used to, very early in my career, work in quality. In that point we did root cause analysis a lot when you would have an investigation and unknown event occur. Sometimes I use some of those principles around root cause analysis and those concepts to also create scenarios, to think about what could go wrong. But in terms of a formal training, I haven't experienced one myself. It is something we're doing now a bit more, not in the context of launch, but our decision -making processes within supply chain. I just give you a brief example. The decision of whether we're going to produce a certain amount of product at an external manufacturer at a CMO can be a large financial commitment. We asked teams to more formally document these types of decisions. We are putting together a framework around that and we ask them to create options within that scenario. The scenario is two or three major markets are increasing their demand. We cannot supply from our current internal site. We want to go to a CMO, for example, and bring them on line as an additional source. There are regulatory constraints. There are financial things to consider in doing that. And so we ask teams to more formally document that. The trend is to train people a bit more on that within the group, but that's just starting, let's say, in the last 12 to 18 months, that's occurring in a bit more formal fashion.

15:55 Interviewer:

Besides some training, can you think of anything a company can do to enhance the scenario planning process and help the employees use it?

16:02 Interviewee:

It's a good question. I am sure there have to be frameworks out there that probably I have not been exposed to, or we could offer trainings on that. The other thing we do, and the way we're set up today, so I'm part of a community of global product planners. It is about 40 people, and they are divided up into different segments. We have a team of launch experts within the global planning community. We also have people who work with more established products, and things are a bit more stable, but they're trying to maximize efficiency and cost optimization at that point. I think we can also, from that group of launch experts, just share knowledge a bit more because they have these experiences. It is a knowledge management topic. How do we share that within an organization? I think a lot of organizations struggle with that actually, is how do you disseminate, spread knowledge amongst people in an inefficient way? It happens when I sit down with this person in San Francisco for a coffee and I say, oh, what happened? I learned that, but there are 38 other colleagues who do not get to hear what we say over a coffee. Knowledge management can be a powerful piece of that as well.

17:43 Interviewer:

We have talked about some positive aspects about scenario planning. Can you also think about limitations or downsides of the tool?

17:48 Interviewee:

There is something to be said about expectations management. If you aren't broad enough in your thinking around scenario planning, especially amongst leaders in the organization, for them to understand that scenarios the team did not consider may come up. Further, you need to consider how can leaders help teams deal with those situations in a constructive way when they occur. The people in a product team, for example, that are trying to launch a product and the leaders around them sometimes don't always prepare themselves for that. How do you prepare for uncertainty? How do you coach people through uncertainty? Because what I see is that many of our leaders need to do is coach people through that. What I fear is that if you think, if you are a leader who thinks that the team considered all possible scenarios, it is a bit foolish to assume that. You can't assume that everything was perfect with the scenario analysis and that other situations may not come up.

19:20 Interviewer:

We touched upon that question in the beginning, but can you think about one specific example where scenario planning did help?

19:25 Interviewee:

There is one example where I was not directly the leader of the team, but I was part of it and eventually became the leader of the product later. The product was a medication for blood cancers, leukemia and other blood cancer conditions. It was so successful at the time in its clinical trials. We had not even started commercial production, and it was around the time when the breakthrough therapy designation framework started with the FDA. And they actually approached us to say, there's a high unmet need. The question was, how do we get this product to patients sooner? At that point, we were only producing product for clinical trials. We had not started any sort of commercial production. The team analyzed different scenarios, also the capacity within our network on how we could get more vials of product produced on our commercial assets. It wasn't possible. One of the scenarios we came up with that we analyzed was relabeling clinical vials and selling them for commercial use when we launched first in the US. Ultimately, we took that path, but it took some creative thinking that in the scenario space to say, scenarios A through C were not going to be feasible. Therefore, how do we come up with a creative other option to support this idea of launching earlier? There's a lot of work from a lot of different functions to enable that, but it was that planning, what could we do and how could we think about it in advance that helped in the end. Because this team started planning on the options in parallel to the regulatory discussions with the FDA. If we hadn't started planning in advance, we would have potentially gotten an approval from the FDA and then been waiting months and months to be able to actually supply the product to the market. That was a bit of a success, I would say, in terms of teams continuing to analyze what's possible and the creativity. How do we do something that we've never done before in a product launch, which I don't think we have, at least as long as I've been around, and make it successful?

22:16 Interviewer:

Do you have any other strategic recommendations when it comes to mitigating risk and uncertainty in product launch?

22:37 Interviewee:

One of my big learnings for the 10 plus years I've been in supply chain is that communication across product teams is so very important. What people do not realize is they are in their functional silos. They are thinking about their function and maybe what is important to them. They may come across information that they do not even realize may be helpful to other functions. And it's important that they create a community of communication, even to the point of maybe over-sharing. Because you never know when you might spark that realization. When someone from quality shares something, the people at supply chain might say, oh, well, we can

leverage that to overcome this situation, for example. That kind of communication and sharing is really important to the success of teams. It is hard to make that happen in an organic way, but I think it also helps the business and it helps what we are trying to do in doing that. A bit more high level, the challenge is how do you implement that and how do you foster that within a product team? That is not easy, but there is great benefit to it.

24:07 **Interviewer:**

Is there anything you would like to add?

24:23 **Interviewee:**

Right now, we are a bit on an adventure as we try to figure out how do we do this more systematically from a tools perspective. It is a trial. We're going to try it out and see how we can leverage some of our planning tools to do this, to get better views of the data side of it. But I think pushing our group on how you handle the other non -data related things, coming up with those scenarios you want to analyze, the options you want to analyze is really important. It is an interesting space.