

Doctoral Thesis Summary

**Factors Influencing the Business Performance of the
Pharmaceutical Companies: Contemporary
Challenges and Opportunities**

**Faktory ovlivňující obchodní výkonnost farmaceutických
společností: Současné výzvy a příležitosti**

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ABSTRACT

Pharmaceutical companies have encountered a variety of unprecedented challenges, since the beginning of the COVID-19 epidemic. It led to a record-high demand for vaccines, the suspension of numerous clinical trials, and a global shortage of medicines. It is a fact that the devastating effects of the COVID-19 epidemic led to inefficiencies in the healthcare system. In that instance, the European countries were not an exception, one side the pharmaceutical sector is a highly capital and knowledge-intensive industry in the world, which spends around 15 % of the total revenue on research and development (R&D). The study's research problem is that pharmaceutical companies invest large sums of money in their businesses, but they face numerous contemporary challenges and insufficient studies on factors that influence business performance. The research aims to identify the key factors influencing European pharmaceutical firms' business performance by highlighting their current challenges and prospects. To conduct this study, we used several techniques to find out the core variables of pharmaceutical companies' success, basically under three steps. First, we tried to find out the contemporary challenges through a systematic literature review by applying preferred reporting items for systematic reviews and meta-analyses (PRISMA) framework, and conducted an extensive literature review to find the critical determinants for pharmaceutical business success which we had used for empirical methods and Decision-making trial and evaluation laboratory (DEMATEL) in the next stages of the study. In the second stage we run the empirical analysis through the panel regression models. To get technical efficiency scores of the 10 leading pharmaceutical companies, we run data envelopment analysis (DEA). Finally, in a more practical field with primary data from pharmaceutical experts based on the DEMATEL approach was applied in third stage, also the strengths, weaknesses, opportunities, and threats (SWOT) analysis was applied. The PRISMA framework exposed by reviewing 57 papers that the weaknesses in the European pharmaceutical industry, including technological inefficiency, the patent system by default, poor R&D, disputes over the role of alliances, a lack of knowledge about the European healthcare system, and problems with pharmaceutical supply chain management. Next, in the analysis 10 leading pharmaceutical companies were applied to empirically test the research hypothesis. The results show a significant and positive relationship between technical efficiency score and return on equity of the selected large pharma companies, implies that these companies are conducting business with technical efficiently. In addition, there is a positive but statistically insignificant association between growth rate of net profit and income from alliance growth rate. The current R&D spending is positively and statistically significant to present year sales revenue of the business; while the R&D lag1 and R&D lag2 are negatively and statistically significant related to business sales revenue. The sales of the corresponding pharmaceutical businesses are positively correlated with the

human resource independent variables, such as training expenses, HCVA, and the control variable (number of employees). The study also mapped the relative relationships among the internal factors that influence the business performance of pharmaceutical companies in Europe by using the DEMATEL approach. The main elements that have the highest impact on pharmaceutical business performance in Europe are human resources competencies, the information system, technological competitiveness, and the patent system. However, financial profitability, research and development competencies, alliances with other companies, and supply chain management are the factors that are affected more by other factors. Moreover, the contemporary challenges pharma SMEs in Europe had determined through SWOT analysis, the challenges are found out, such as the financial performance of companies is continuously failing; many are still in the early stages of clinical trials, and some have already incurred significant losses as a result of clinical trial failures.

ABSTRAKT

Farmaceutické společnosti se od začátku epidemie COVID-19 potýkaly s řadou bezprecedentních výzev. To vedlo k rekordně vysoké poptávce po vakcínách, pozastavení četných klinických studií a celosvětovému nedostatku léků. Je faktem, že ničivé dopady epidemie COVID-19 vedly k neefektivitě ve zdravotnictví. V tomto případě nebyly evropské země výjimkou, na jedné straně je farmaceutický sektor ve světě vysoce kapitálově a znalostně náročným průmyslem, který vynakládá přibližně 15 % celkových příjmů na výzkum a vývoj (R&D). Výzkumný problém této studie spočívá v tom, že farmaceutické společnosti investují velké sumy peněz do svých podniků, ale čelí mnoha současným výzvám a nedostatečným studiím o faktorech, které ovlivňují výkonnost podniku. Cílem výzkumu je identifikovat klíčové faktory ovlivňující obchodní výkonnost evropských farmaceutických firem tím, že zdůrazní jejich současné výzvy a vyhlídky. K provedení této studie jsme použili několik technik, abychom zjistili klíčové proměnné úspěchu farmaceutických společností, v zásadě ve třech krocích. Nejprve jsme se pokusili zjistit současné výzvy prostřednictvím systematického přehledu literatury použitím preferovaných položek výkaznictví pro systematické přehledy a metaanalýzy (PRISMA) a provedli jsme rozsáhlý přehled literatury, abychom našli kritické determinanty úspěchu farmaceutického podnikání, které jsme použili pro empirické metody a rozhodovací zkušební a hodnotící laboratoř (DEMATEL) v dalších fázích studie. Ve druhé fázi provádíme empirickou analýzu pomocí panelových regresních modelů. Abychom získali skóre technické efektivity 10 předních farmaceutických společností, provádíme analýzu datové obálky (DEA). A konečně, v praktičtější oblasti s primárními daty od farmaceutických expertů na základě přístupu DEMATEL byla ve třetí fázi aplikována také analýza silných a slabých stránek, příležitostí a hrozeb (SWOT). Rámec PRISMA po přezkoumání 57 dokumentů odhalil slabé stránky evropského

farmaceutického průmyslu, včetně technologické neefektivnosti, standardně patentového systému, špatného výzkumu a vývoje, sporů o roli aliancí, nedostatku znalostí o evropském systému zdravotní péče a problémů s řízením farmaceutického dodavatelského řetězce. Dále bylo v analýze použito 10 předních farmaceutických společností, aby empiricky otestovaly výzkumnou hypotézu. Výsledky ukazují významný a pozitivní vztah mezi skóre technické efektivity a návratností vlastního kapitálu vybraných velkých farmaceutických společností, což naznačuje, že tyto společnosti obchodují s technickými efekty. Kromě toho existuje pozitivní, ale statisticky nevýznamná souvislost mezi tempem růstu čistého zisku a příjmem z tempa růstu aliance. Současné výdaje na výzkum a vývoj jsou pozitivně a statisticky významné pro současné roční tržby podniku; zatímco zpoždění výzkumu a vývoje¹ a zpoždění výzkumu a vývoje² negativně a statisticky významně souvisí s příjmy z obchodního prodeje. Tržby příslušných farmaceutických podniků pozitivně korelují s proměnnými nezávislými na lidských zdrojích, jako jsou náklady na školení, HCVA a kontrolní proměnná (počet zaměstnanců). Studie také mapovala relativní vztahy mezi interními faktory, které ovlivňují obchodní výkonnost farmaceutických společností v Evropě pomocí přístupu DEMATEL. Hlavními prvky, které mají největší dopad na výkonnost farmaceutických podniků v Evropě, jsou kompetence lidských zdrojů, informační systém, technologická konkurenceschopnost a patentový systém. Finanční ziskovost, kompetence v oblasti výzkumu a vývoje, spojenectví s jinými společnostmi a řízení dodavatelského řetězce jsou však faktory, které jsou více ovlivněny jinými faktory. Kromě toho byly zjištěny současné výzvy, které farmaceutické malé a střední podniky v Evropě určily pomocí analýzy SWOT, jako například finanční výkonnost společností neustále selhává; mnohé jsou stále v raných fázích klinických studií a některé již utrpěly značné ztráty v důsledku selhání klinických studií.

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LIST OF SYMBOLS AND ABBREVIATIONS USED

BMI	Business model innovation
CS	Corporate sustainability
CRS	Constant return to scale
DEA	Data Envelopment Analysis
DEMATEL	Decision-making trial and evaluation laboratory
DMU	Decision-making unit
EU	European Union
FGLS	Feasible Generalised Least Square
F1	Financial Profitability
FE	Fixed effect model
F2	Research and development competencies
F3	Human Resource Competencies
F4	Alliances with other companies
F5	Information System and Technological Companies
F6	Supply chain management

F7	Patent system and Protections
GDP	Gross Domestic Product
G20	The Group of Twenty
GLS	Generalized least squares technique
HR	Human Resource
HRM	Human Resource Management
HC	Human capital
HCVA	Human capital value addition index
HCROI	Human Capital Return on Investment
IP	Intellectual property
M&A	Merger and acquisition
NP	Net Profit
NI	Net income
NPD	New product development
OECD	Organization for Economic Co-operation and Development
OE	Organizational effectiveness
PRISMA	Preferred Reporting Items for Systematic reviews and Meta-Analyses (PRISMA)
PMS	Performance measurement systems
R&D	Research and Development
ROE	Return on Equity Ratio
SWOT	The strengths, weaknesses, opportunities, and threats
SMEs	Small and Medium Enterprises
TD	Training and development
UK	The United Kingdom
US	The United States
WIPO	The World Intellectual Property Organization
WOS	Web of Science database

1. INTRODUCTION

Following is an extensive introduction of the dissertation and the topic, "Factors Influencing the Business Performance of the Pharmaceutical Companies: Contemporary Challenges and Opportunities". In the introduction section, the research background will be discussed in current state of the issue dealt with, and the research objectives will be discussed.

1.1 Current State of the Issues Dealt With

The pharmaceutical industry is one of the most vital sectors in the world, giving millions of people access to life-saving medications and therapies, yet it faces many difficulties when carrying out its strategy. Pharmaceutical companies have

encountered a variety of unprecedented challenges, since the beginning of the COVID-19 epidemic. It led to a record-high demand for vaccines, the suspension of numerous clinical trials, and a global shortage of medicines. Following one of the most chaotic years on record, pharmaceutical businesses were expected to recover in 2022. Even while consumer confidence is increasing and the pandemic's end is in sight, the pharmaceutical industry is still in danger, there is a large prevalence of pharmaceutical fraud, increased customer expectations, a negative influence on the global supply chain, an increase in the number of diseases and patients, trouble paying for medicines, and other factors. Particularly, Europe faced increasing dependence on medicines and pharmaceutical products imported from non-European countries, (European Commission, 2021; Jerome, Saxena, Sonwaney, & Foropon, 2021). In addition, there are global challenges too, such as the rapid development of novel therapies, the adoption of new manufacturing techniques, challenges to the existing regulatory framework and product quality, the growing number of aging people, rapid increase in R&D expenditures, and patent cliffs and others, (European Commission, 2021; Weitzel et al. 2021). The following Table 1.1 has been prepared to focus on the challenges of the pharmaceutical industry.

The pharmaceutical sector is a highly capital and knowledge-intensive industry in the world, which spends around 15 % of its total revenue on research and development (R&D), (Downs & Velamuri, 2018). On the other hand, European Union (EU) has the world's second-largest market by sales account, and the increment of total investment has more than doubled during the pre-pandemic period (Azierta, 2019). For instance, the spending in the health sector was an average of 8.3% of GDP and the pharmaceutical production cost was almost one-sixth of total health expenditures in 2019. The retail pharmaceutical bill was around Euro 190 billion in 2018 (OECD, 2020) and it is a major contributor to the investment in innovation (European Commission, 2021). The complicated topic of business processes has drawn a lot of attention recently, particularly about cost reduction and productivity gains. Concurrently, the company's circumstances permit the expansion of current business procedures.

To compare the performance of scalable business processes, a performance measurement is essential (Huang et. al 2015; Fauzan, Sarno, & Yaqin, 2017). In order to effectively execute enterprise business operations and enhance company results in a global business environment, smart business management was developed. Using factor analysis and reliability analysis based on prior research, the validity and reliability of the created measurement scale are confirmed. (Yoon, 2021). Companies assess their business performance by comparing themselves to their competitors, and by planning their future endeavors. Organizations frequently implement performance measurement systems (PMS) to have their business success rate. The relevance of performance measurement has grown as

the modern business environment becomes more competitive and dynamic. To thrive, organizations must adjust to the unprecedented drastic changes what they are facing. Therefore, quick decision-making processes could guarantee processes of adaptation and response to the business environment (Kloviene, Leitoniene, & Sapkauskiene, 2013).

Table 1.1: Two major challenges of the pharmaceutical industry

The challenges due to globalization	The Challenges due to the Covid-19 crisis
<ul style="list-style-type: none"> • Competition for the rapid development of novel therapies. • The adaptation of new manufacturing techniques. • Challenges to the existing regulatory framework and product quality. • A growing number of aging people. • R&D and patent cliffs and others. 	<ul style="list-style-type: none"> • The negative impact on the global supply chain. • Rising burden of diseases and patients. • Difficulty in bearing the cost of medicines. • Europe faced increasing dependence on medicines and pharmaceutical products imported from non-European countries.

Source: Author's Own (2024).

According to (le Deu & Da Silva, 2019), the increment of total investment in Europe's biotech firms was more than double, for instance, during the seven years (2005-2011) it was \$5.1 billion but it upgraded more than twice in the next seven-year period at 11.9 billion between 2012 to 2018. That is why public expectation to get access to safe, eminent, and affordable medicines, therapies, and vaccinations is an upward demand in general, although the advantages may vary in European countries (European Commission, 2021). Moreover, there remains a scarcity of pharmaceutical products in the EU, and patients do not have access to medicines due to the shortage. This practicality has been demonstrated amid the Covid-19 pandemic in Europe and raises an important issue as to how to ensure the availability of pharmaceutical products during a crisis. European Commission's recent reports and the Global Health Summit of G20 Nations in Rome in 2021 suggest coordinating pharmaceutical and nonpharmaceutical interventions and emergency response.

In contrast, the pharmaceutical industry's prospects will undoubtedly have a wider scope. Consumers, legislators, and groups have been paying more attention to the pharmaceutical industry's long-term viability in recent years. Concerns about incorporating sustainability techniques into the development of new

delivery systems, new products that are less hazardous to the environment, waste recycling, water conservation, greener production methods, and recyclable packaging have increased interest in this area. The pharmaceutical industry's long-term viability has caught the interest of academics from a variety of fields, including chemistry, engineering, and environmental sciences. This problem is being addressed in business and management courses as well. The necessity to maintain environmental, economic, and social sustainability, as well as to limit expenses, has led to the adoption of a higher level of managerial complexity in pharmaceutical enterprises, (Milanesi, Runfola, & Guercini, 2020). Moreover, The pharmaceutical industry generates 1.2 trillion dollars in revenue worldwide. With so much money on the line and the rate at which technology is changing, the pharmaceutical business must embrace new technologies, patient design, and innovations and place a larger emphasis on prevention and digital health (Mesko, 2021).

The majority of EU nations report positive operating profits. The interesting matter is that before Brexit, the UK was a significant player in the EU's operation profit growth, particularly when it comes to the profits generated by firms like GlaxoSmithKline and AstraZeneca. In addition, Germany, France, and Denmark are the other major contributors to the UK. The three biggest pharmaceutical companies in Germany are Boehringer Sohn, Bayer, and Merck De. Particularly, Bayer experienced negative operating profit in both 2018 and 2020, which had created a detrimental impact on Germany's pharmaceutical business. However, Merck De and Boehringer Sohn's consistent operating profit performance revived the country's pharmaceutical and biotechnology sectors throughout these years. Moreover, the R&D expenditure is quite high in countries like the United Kingdom, Germany, France, Denmark, and Ireland.

Sanofi contributes about 90% of operating profit in France out of 100% over the years. The stability of Sanofi's business is also encouraging, even during pandemic periods when several large companies fail to achieve their goals, such as BAYER from Germany having a negative (-10821.0 million euro) operating profit in 2020. NOVO NORDISK is the largest contributor in Denmark, equivalent to Sanofi. There are also some new businesses there, like NOVOZYMES, CHR HANSEN, and H LUNDBECK.

1.2 Research Objectives

Table 1.2 illustrates the main and sub-objectives of the study. The steps necessary to accomplish the main purpose are known as sub-objectives. Finally, they need to identify the routes that lead to the main goal.

Table 1.2 Main and sub-objectives of the research.

Main Objective	
The research aims to identify the key factors influencing European pharmaceutical firms' business performance by highlighting their current challenges and prospects.	
Sub-Objectives	
Research objective 1	To identify the impact of technical efficiency on the business performance of the pharmaceutical companies.
Research objective 2	To identify the role of alliances on the business performance of the pharmaceutical companies.
Research objective 3	To determine the impact of patent protection and R&D investment on the business performance of the pharmaceutical companies.
Research objective 4	To identify the role of human resources on the business performance of the pharmaceutical companies.

Source: Author's Own (2024).

The research's findings would help identify the key factors influencing European pharmaceutical businesses by highlighting the current challenges and prospects of these firms. The following components will be present in the dissertation.

- Identification of main factors influencing European pharmaceutical companies' business performance.
- Determination of the role of technical efficiency on the business performance of the pharmaceutical companies.
- The role and impact of alliances or cooperation with other companies on business performance.
- R&D investments, how working on business performance of pharmaceutical companies.
- The role of human resource factors on the business performance of pharmaceutical companies in Europe.
- The contemporary challenges and potential opportunities for these firms.
- Breaking Untold Barriers by investigating Pharmaceutical SMEs' Contemporary Challenges in Europe
- The best-performed factors among them through the cause-effect analysis.

The study has been designed to interpret through data from primary and secondary sources. It will try to assist researchers, policymakers, and pharmaceutical manufacturing business planners to identify the key variables that influence pharmaceutical business performance. Particularly, the factors that perform the best among them through causality analysis, current challenges, and potential opportunities of the highly knowledge-based sector.

2. THEORETICAL FUNDAMENTALS

In the second section, the theoretical basis of using a historical overview to evaluate the determinants of business performance along with pharmaceutical companies' business performance were covered. Additionally, the determinants of pharmaceutical business performance were found out from extensive literature review.

2.1 A Historical Overview to Evaluate the Determinants of Business Performance Measurement and Pharmaceutical Business Performance Measurement

The development of performance measurement in commercial organizations during the previous 500 years was studied by (Euske, & Zander, 2005). Over the years, performance assessment was focused on giving stakeholders a picture of their company. As the business and technology models evolved in business performance measurement, therefore the need for information to understand the organization's success is crucial. Even models like return on investment, which are now seen as having significant problems, provided useful information to the businesses for which they were developed. The development of a measuring system that accurately and efficiently records organizational performance in a timely manner and it is an ongoing problem.

Luca Pacioli's contributions to accounting are perhaps what made him most famous. Many people in the accounting industry still use the concepts and procedures which were outlined in his *Summa de Arithmetica, Geometrica, Proportioni, et Proportionalita* in 1494. He is also considered a pioneer in the field of performance measurement, though. Along with internal controls like date and numbering ledgers, notebooks, and memoranda, *Summa* also discusses performance measurement. Apart from explaining the double-entry accounting method, Pacioli guided entrepreneurs through the procedures required to record every transaction. First, the endeavor needs to be justified or driven by market demand. Second, the businessman needs to be a proficient like a mathematician or an accountant. Third, the businessman's affairs need to be organized in a methodical way so that he/she can quickly grasp the business. This basically means that the businessman needs to keep a systematic record of how the business is performing (Euske, & Zander, 2005). Over the past few decades, the idea of company performance has undergone significant transformation. The managers have realized that in order to accomplish the objectives of the organization, more focus should be given on stakeholders, such as consumers, clients, workers, suppliers, and other partners, as well as local communities, rather than just the owners. Due to the introduction of numerous new performance measuring techniques and systems, the 1990s are also known as "the performance

measurement revolution." The primary function of performance measurements is to gather data regarding how well firms are doing in reaching their objectives, if intervention is required (Zsidó, 2015).

Companies have included smart business practices in their operations to improve smart business outcomes. To properly create and manage the smart business environment based on its business plan and business divisions, a firm must manage and measure the results of its smart business fulfilment. This situation calls for a measuring system that can accurately assess a company's smart business output in order to manage and improve its smart business capabilities. The measurement tool for corporate smart business success in terms of a general smart business outcome is presented by (Yoon, 2021). A high operational margin indicates that a high operating profit is made for every dollar of revenue. This is a reliable sign of a company with high-quality earnings. A profit from business operations that are made before interest and tax deductions (gross profit minus operational expenses), (Ali, & Showkat, 2022). However, historically, the definition of net income has always proven difficult for those who set accounting standards. They have also failed to provide a convincing argument for recycling and other comprehensive income (OCI). OCI is the connecting factor that reunites net income and comprehensive income, which should be viewed as two distinct components of financial statements. Therefore, the measurement basis of current value should only be used from the perspective of reporting an entity's financial performance when an asset (or a liability) is easily convertible into cash and the entity's business activity does not legally, contractually, or economically restrict the entity's ability to settle the liability or convert the asset into cash. Additionally, net income should represent the irreversible outcomes of an entity's business activities (Nishikawa, Kamiya, & Kawanishi, 2016).

Research, development, manufacturing, and distribution of pharmaceuticals are under the purview of the pharmaceutical industry. Pharma revenues globally reached 1.48 trillion U.S. dollars in 2022, reflecting the substantial growth the industry has seen over the last 20 years. However, this progress did not happen overnight; it has a significant impact on society, human health, and the drug industry, (Statista, 2024). Figure 2.1 illustrates the revenue generation from world pharmaceutical manufacturing from 2001 to 2022; which estimates that the revenue generated from the pharmaceutical sector has gradually increased. However, due to the unavailability of data, the present study focused on the last 2 decades which is the golden period of pharmaceutical revenue for a wide range of factors, such as in various works of literature, the variables affecting pharmaceutical companies' performance vary from one study to another. However, some of the most prevalent ones are R&D (Banerjee, 2012; Sahu, & Agarwal, 2017; Vihari, & Rao, 2017), innovation (Brachos, et al. 2007; Sabbir, Islam, and Das, 2020), patents, and royalties (Banerjee, 2012), technological

advancement (Bondarenko, et al. 2020), export volume (Sahu, & Agarwal, 2017; Vihari, & Rao, 2017), and profit margin (Vihari, & Rao, 2017).

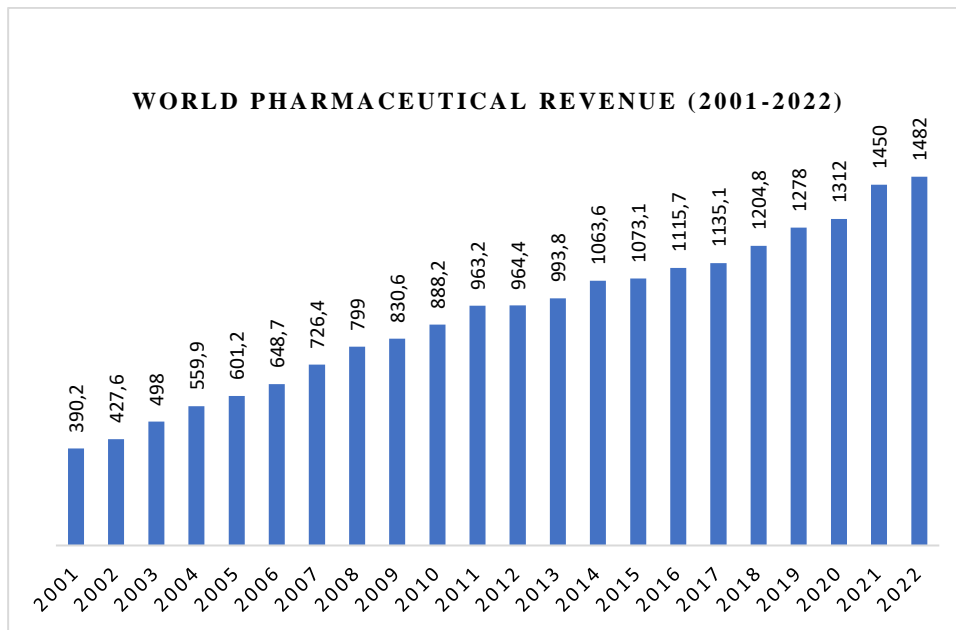


Figure 2.1: World Pharmaceutical Revenue (2001-2022) in billion U.S. dollars. Source: Estimated by Authors (2024) from Statista data.

The research on pharmaceutical companies performance ignores a few other significant aspects, like alliances and human resources. The discovery, development, and distribution of therapies and drug delivery methods are the main goals of the biotechnology and pharmaceutical value chain. Prominent companies in the biotechnology sector focus on non-drug-related operations like diagnostics and medical devices. The evolution of the biotechnology and pharmaceutical industries offers important insights into how networking and alliances formed enhanced cooperation between both sectors. Because the market believes that companies with a higher quality constellation of alliances would perform better over the long term, these companies typically enjoy higher market valuations (Gottinger & Umali, 2008).

The study by Stiller, van Witteloostuijn, & Cambré, (2021) found that three groups of determinants (leadership, managerial levers, and business processes) influences radical drug innovation. (Banerjee, 2012) investigated the factors influencing the payment structure of research contracts between large biopharmaceutical corporations and specialist research organizations. He found three different types of contracts are studied, such as royalty contracts, fixed payment contracts, and mixed contracts. Royalty contracts and patent stock how correlated in the different stages of research. Moreover, contextual elements including trust, motivation to share knowledge, managerial support, and learning

orientation are critical for facilitating knowledge transfer and innovation between pharmaceutical business actors (Brachos, et al. 2007). The export volume is also treated as a key factor of pharmaceutical business performance (Sahu, & Agarwal, 2017; Vihari, & Rao, 2017). where Sahu, & Agarwal, (2017) identify the factors that influence merger and acquisition (M&A) activity in the Indian pharmaceutical industry and find export intensity, import intensity, firm size, R&D intensity, and risk of acquisition. Additionally, Vihari, & Rao, (2017) investigated the determinants of business model innovation (BMI) and organizational mindfulness (OM) on corporate sustainability (CS) and organizational effectiveness (OE) in Indian pharmaceutical companies. They reached in conclusion with influential factors such as capital intensity, labor intensity, profit margin, technology import intensity, R&D intensity, export intensity, import intensity, firm age, dummies for the merger, dummies for acquisition, and others.

2.2 The Internal Drivers of Pharmaceutical Business Performance

The internal business environment (internal business environment) refers to the current business strategy, objectives, resources, procedures, organizational culture, and the value of the company as a whole. The company influences internal business determinants, which are elements that affect the company's performance and operational strategy. It is crucial to consider the external environment to identify prospective possibilities and risks outside of a company's operations. However, the key to a successful company is controlling the advantages of internal operations. Importantly, internal drivers have an impact on how the company's inventive process is set up (Galende, & de la Fuente, 2003; Gaol, Rahayu, & Matsuo, 2020). In pharmaceutical firms, business performance will be positively impacted by successful internal control, particularly good monitoring, knowledge, and tradition (Nguyen, 2021). Internal pharmaceutical factors, such as financial resources, R&D intensity, persistence in innovation, knowledge sharing with alliances, technology usage, and entrepreneurship, exhibit a significant influence on firm performance. Following Table 2.1 found the seven internal factors which are discussed extensively in the literature of Web of Science and Scopus data bases. Due to their direct influence on the future success of pharmaceutical companies, the seven internal criteria listed below are frequently considered significant for evaluating pharmaceutical business performance. The following subsections give a brief explanation of these criteria or factors chosen.

Financial Profitability (F1): The first factor that the owner of the pharmaceutical firm considers when making decisions about how to run or grow the business is financial performance. Management's financial choices are in line

with the shareholders' goals of maximizing wealth, which also includes the company's goal of maximizing profits. (Boldeanu & Gheorghe, 2012; Enekwe, Agu & Eziedo, 2014). When the rate of return on total assets increases, pharmaceutical companies pay more attention to both operating efficiency, corporate social responsibility, and other internal factors (Chai et al. 2020).

Research and development competencies (F2): The achievement of success in R&D activities and many characteristics of the company are having positive and statistically significant correlation. Therefore, having an R&D department, having special incentive systems for the R&D staffs, implementing innovative management practices in the R&D department, and the firm's patent policy are all variables that have a good impact on a successful and leading organization (Mendigorri, Valderrama, & Cornejo, 2016; Ling et al. 2018). As reported by (Raghavendra, Raj & Seetharaman, 2012), 72.7% of respondents, various internal issues related to the pharmaceutical sector, rather than external factors, are what are influencing how much money pharmaceutical companies spend on R&D. The performance of a pharmaceutical company's business and its inventive culture are closely correlated. Various practices, including encouraging employee creativity, accepting and partnering with alliances for the collaborative development of technologies, and employee participation in the development of new drugs or therapies, can be used to address an innovative culture (Nazari and Ghasemzadeh, 2018; Araujo et al. 2022). Additionally, pharmaceutical firms increasingly aim to produce environmentally friendly green products. To become more involved in cleaner production in the long run, the sector must foster process-orientated innovations and create an eco-friendly culture (Li & Hamblin, 2016).

Human Resource Competencies (F3): The pharmaceutical industry relies extensively on qualified personnel in a variety of positions, such as sales representatives, regulatory specialists, researchers, scientists, and clinicians. Companies can improve their R&D capabilities, ensure high-quality product development, maintain regulatory compliance, and drive effective sales and marketing strategies by having competent and motivated staff. The retention, happiness, and future performance of employees are impacted by pharmaceutical governance. Furthermore, the intrinsic factors that best describe the motivation of sales teams are personal goals and acquired abilities, (Ferreira, 2017; Ghauri, 2018; Pinto, & Rastogi, 2022; Frank, Jaeger, & Ranft, 2023). Internal capabilities of human resource teams influence positively to enlarge, uphold, or control the power of parental pharmaceutical companies (Dadfar, et al. 2010; Chai et al. 2020; Naeem et al. 2021). In addition, an internal procedure is set up whereby the employment connection is explored and negotiated so that all sides are satisfied with the outcome. For pharmaceutical businesses, it has a larger internal attribution to successful performance outcomes, but from this point of view, it also

results in an increased usage of surplus resources (Riantoputra, 2010; Luu et al. 2019; Jayamohan et al. 2022). Corporate social responsibility programs by the human resource teams address social issues, but they can also improve customer trust and foster a sense of loyalty among customers (Riantoputra, 2010; Abbasi et al. 2023). In particular, HR metrics such as employee remuneration and training can better describe how the company performed during a crisis such as the COVID-19 period, when it had a substantial and negative impact on financial performance. It offers fundamental principles for policymakers to follow, so they can gain a better understanding of how to use the characteristics of human capital to enhance the performance of their companies in times of crisis (Mahssouni, Touijer, & Makhroute, 2022).

Alliances with other companies (F4): The pharmaceutical companies may benefit strategically from alliances and collaborations with other pharmaceutical companies, research facilities, academic institutions, or healthcare organisations. Alliances increase R&D capabilities, speed up product development, increase market competitiveness, and provide access to complementary knowledge, common resources, and wider market reach (Ombrosi, Casprini, & Piccaluga, 2019; Ortiz, Donate, & Guadamillas, 2021). Whereas new entrants profit from existing players' abilities to commercialize new technologies, established firms leverage alliances with new entrants to adapt to technological change (Rothaermel, & Boeker, 2008). As the pharmaceutical industry is very information demanding and each partner can share their own skills to thrive in their business, mergers and acquisitions (M&A) are particularly typical for pharmaceutical companies (Yedidia et al. 2012).

Information system and technology of companies (F5): Technology and information systems are becoming more and more an integral internal factor for the pharmaceutical sector. The way in which technology affects collaboration in strategic business processes, such as new product development (NPD), depends on the specific characteristics of the process (Bala, Massey & Montoya, 2017).

Table 2.1: Internal Factors Influencing Pharmaceutical Business Performance.

Factors	Author (s)
Financial profitability (F1)	Boldeanu & Gheorghe (2012), Enekwe, Agu, & Eziedo (2014) Chai et al. (2020).
Research and development competencies (F2)	Raghavendra, Raj & Seetharaman (2012); Li & Hamblin (2016); Mendigorri, Valderrama, & Cornejo, (2016); Mehralian, Nazari,. and Ghasemzadeh(2018);

	Ling et al. (2018); Araujo et al. (2022).
Human Resource Competencies (F3)	Riantoputra, (2010); Dadfar, et al. (2010); Liu (2014); Ferreira (2017); Ghauri, (2018); Luu et al. (2019); Chai et al. (2020); Naeem et al. (2021); Mahssouni, Touijer, & Makhroute, (2022); Pinto, & Rastogi (2022); Jayamohan, Moss, McKelvie, & Hyman, (2022); Abbasi et al. (2023); Frank, Jaeger, & Ranft, (2023).
Alliances with other companies (F4)	Rothaermel & Boeker (2008); Yedidia et al. (2012), Ombrosi, Casprini & Piccaluga, (2019); Ortiz, Donate & Guadamillas, (2021).
Information System and Technological Companies (F5)	Estler & Ewen (2011); Bala, Massey & Montoya (2017); Alharthi, Cerotti & Far (2020); Gaol, Rahayu & Matsuo (2020).
Supply chain management (F6)	Haque & Islam (2018); Wisniewski & Tundys (2020); Zhang & Zhu (2022), Donkor, Papadopoulos & Spiegler (2022).
The patent system (F7)	Liu (2014); Asad, & Popesko (2023)

Source: Source: Author's Own (2024).

Furthermore, mismanagement of the pharmaceutical supply chain, including drug shortages, lack of coordination among healthcare stakeholders, product waste, and lack of demand information, can be resolved by integrating information between key stakeholders in the industry. Blockchain, a distributed digital ledger technology, is showing promise for resolving various supply chain management issues as it offers security, transparency and traceability (Alharthi, Cerotti, & Far, 2020). Production intelligence makes use of and closely integrates a variety of concepts and techniques currently used in drug manufacturing and therapy production (Estler, & Ewen, 2011). Therefore, to deliver the value of competence in the technology and information systems that businesses employ in their business activities, an integrated system is required (Gaol, Rahayu, & Matsuo, 2020).

Supply chain management (F6): Effective and sustainable supply chain management is essential in a pharmaceutical company to guarantee on-time drug delivery, manage inventories, and maintain quality control (Wisniewski &

Tundys, 2020; Donkor, Papadopoulos, & Spiegler, 2022). According to Haque & Islam (2018), collaboration and knowledge-sharing techniques in the supply chain have a substantial impact on customer satisfaction, which in turn increases corporate competitiveness. It guarantees a high level of product quality and new product innovation in the highly educated pharmaceutical sector. Due to the recent changes in supply chain management and the resulting complexity of the system (both offline and online), some stakeholders who act irresponsibly in the chain have faced penalties. However, if the fine is excessive, it will constrain pharmaceutical companies' financial actions (Zhang & Zhu, 2022).

The patent system (F7): To preserve the creative strategies employed by pharmaceutical companies, patent protection is crucial. Drug patents help to recover financial outlays made during the research and development phase. Since competitors can simply replicate the production of a drug, drug patents can protect against copyright claims. However, the firm's judgements on which patents to preserve or revoke are influenced by its human resources (Liu, 2014). Pharmaceutical business performance deteriorates as a result of the default patent system (Asad, & Popesko, 2023).

3. SELECTED PROCESSING METHODS

3.1 The Hypotheses

H1: Technical efficiency has a positive impact on the business performance of the pharmaceutical companies.

Technical efficiency refers to how well a particular set of inputs is utilized to produce an output. If a company is producing the most output with the fewest inputs—such as labor, capital, and technology—it is considered to be technically efficient (Kokkinou, 2021). The effectiveness of a company's activities can be measured by comparing its outcomes to those of a chosen comparable criterion. In other words, whether relatively more resources were utilized in producing the same amount of output as compared to the comparable criterion or whether relatively less output was generated with an equivalent amount of input can be used as measuring sticks in establishing the level of efficiency (Yoo, Park, & Song, 2009). Pharmaceutical companies are responding to the problems of manufacturing efficiency with more cost-cutting strategies and efforts aimed at improving operational excellence and quality (CHEM Manager, 2015). There are many efficient laboratories and many poor laboratories near the efficient border, so it is essential to define a pharma business model and needs to get the significant factors contributing a healthy business performance as efficient because the pharmaceutical industry is a highly competitive sector and firms are expected to compete with each other in case of production, cost minimization or maximizing sales (Gascón et al. 2017).

Importantly, in pharmaceutical companies, technical efficiency has a greater impact on productivity change than pure technical efficiency change¹, (Hanggraeni, 2014; Azad et al. 2018). Data envelopment analysis (DEA) has been used to quantify pharmaceutical efficiency in the vast majority of papers (Hanggraeni, 2014; Gascón et al. 2017; Azad et al. 2018; Wang, & Chen, (2021). Additionally, it is a popular method for determining the effectiveness of a business enterprise. The two-stage relational DEA approach can provide more information about the operational state of the businesses under examination, (Cheng, 2008; Yoo, Park, & Song, 2009). Pharmaceutical companies' technical efficiency improves the business performance (i.e. productivity, profitability, and market valuation) of the enterprises, (Cross, Thomas, & Light, 2009). Therefore, there is a positive relationship between technical efficiency and business performance, which means that pharmaceutical companies that are technologically more efficient will perform better in terms of business performance.

$$Y_{it} = \alpha_i + \beta X_{it} + \mu_t$$

The higher the value from the DEA technical efficiency score stimulates the higher the business performance of the company, where X denotes the cost efficiency score and Y denotes business performance indicators and β is expected to be > 0 . Therefore, the DMU cost efficiency score influences positively to the operating profit of the company.

H2: The higher the contribution from alliances, the higher will be the companies' business performance.

A strategic alliance is an agreement between two businesses to work together on a project that will benefit both parties while maintaining their individual freedom. A strategic alliance is a well-defined cooperation between two companies that have common objectives. In these corporate partnerships, each company maintains its independence while combining resources to expand into new areas, build both brands, gain market share, and achieve outcomes they might not have been able to achieve on their own (Elmuti, and Kathawala, 2001). Historically, bio-pharmaceutical business performance was dependent solely on investment; however, day by day the complexity in the business chain occurred and firms integrated each other to generate profit as well as tackle the contemporary challenges, such as including the higher cost of bringing new products to market, less costly for R&D innovation, product failure (due to devices, drugs, etc.), generic competition, pressures for managed care organizations to contain costs, and international competition, providing firms with political and regulatory influence, (Fernald et al. 2015; Jambulingam, & Saxton, 2021). The study of Jambulingam, & Saxton (2021) examined that the higher the degree of integration from alliances, the better the business performance of

¹ A technically efficient position is one in which the highest amount of outcome improvement from a given set of resource inputs is achieved.

biopharmaceutical firms. To determine the success of the alliance, three factors are used: resource dependence, transaction costs, and organizational learning. Additionally, Abuzaid (2014) examined that strategic alliance partners had a greater impact on pharmaceutical companies' incremental innovation than on their radical innovation. The formation of new products by an incumbent is positively correlated with alliances with suppliers of the new technology, and new product creation is positively correlated with firm performance, (Rothaermel, 2001). Therefore, the performance of the business profitability is positively impacted by alliance management skills (Nguyen, & Tran, 2018). However, some studies show positive but insignificant relationships, such as (Ngari, 2014), and also others illustrated the positive and statistically significant relationships between the alliance or acquisition and firm portfolio (Nielsen, 2007).

H3a: The R&D investment will impact positively on financial performance of the pharmaceutical companies.

There is a strong and positive correlation between the accomplishment of success in R&D activities and numerous firm attributes. Thus, a successful and leading organization can benefit from having an R&D department, having unique incentive programs for the R&D staff, implementing innovative management practices in the R&D department, and having a patent policy (Mendigorry, Valderrama, & Cornejo, 2016; Ling et al. 2018). We discussed already that pharmaceutical firms are knowledge intensive sector while spending money on R&D is a crucial factor. The performance of a pharmaceutical company's business and its inventive culture are closely correlated. Various practices, including encouraging employee creativity, accepting and partnering with alliances for the collaborative development of technologies, and employee participation in the development of new drugs or therapies, can be used to address an innovative culture (Nazari and Ghasemzadeh, 2018).

The investment expenditure of the previous year's R&D investment will impact the company's economic-financial performance statistically significant and concurrently. However, the background literature represents both positive and negative relationships among these variables. There is a positive relationship between R&D deployment intensity in the previous years (t-1, and t-2) and current economic returns (t) year for the technology-based entrepreneurial medical, surgical, and dental instruments industry. R&D activities had a statistically significant positive impact on the financial performance of Indian pharmaceutical companies, where both dependent and independent variables are estimated at the current period, (Nandy ,2020). Researchers accomplish R&D expenditures that are positively related to the growth of selected branches of the manufacturing industry.

H3b: Patent protection is positively related to the business performance of the pharmaceutical companies.

Patents as an output determinant of pharmaceutical innovation, a new molecular entity and new drug approvals as indicators of drug innovation, alliance firms' investment in R&D activities are examples of R&D indicators. The impact of basic research on improving the performance of innovation at the world's leading pharmaceutical companies is determined by internal and external or mixed modes of research; in these R&D programs, stakeholders such as industry, university, and alliance institutions play significant roles, which has a substantial effect on pharmaceutical business strategies and performance (Paranhos, & Hasenclever, 2011).

Doing something new that improves a product, method, or service is what innovation entails. Many innovations can be safeguarded by intellectual property (IP) rights or patent certificate. A patent certificate is a certified copy of a patent application that has been authorized by the relevant department. The owner of a patent can legally prevent others from creating, using, marketing, or selling the innovation. A patent is useful because it can help protect creation. It can safeguard any product, design, or method that meets certain criteria for originality, expediency, appropriateness, and utility. A patent can usually protect an invention for up to 20 years which has been observed in several previous studies, (Malek, 2015; WIPO2, 2021). Many organizations rely heavily on patents to develop and maintain a competitive market position. Patent strategies differ by industry and rely on the size and stage of a company. A robust patent strategy, on the other hand, can assist firms of all sizes secure their market position and avoid potentially devastating setbacks, (Gale, 2021).

H4a: Investment in human capital is positively related to the business performance of the pharmaceutical companies.

Human capital (HC) is a key factor for enterprises' performance and competitiveness. An improvement in the performance of the businesses as a result of expenditures in employee education and the use of human capital management (HCM), (Batarlienè et al. 2017; Kucharčíková et al. 2023). Therefore, the primary source of knowledge in businesses is their human resources, which are regarded as a crucial resource—possibly even the most significant one and are found to be positively correlated, meaning that investing in employee training boosts the firm's future intangible worth (Cascio, & Boudreau, 2010). In the Chinese pharmaceutical industry, the human resource management index is made up of high-performance work practices like extensive training, participation, detailed

2 World Intellectual Property Organization

job definition, result-oriented performance appraisal, internal career opportunities, and profit sharing. This index was found to be statistically significant correlation with the firm's market performance (Zhang, & Li, 2013). In Bangladesh a reputed pharmaceutical company named "Square Pharmaceutical Limited" where employee performance is developed in large part through training. For the development of both its personnel and the organization, businesses should emphasize competitive training programs (Sultana, 2013). Both recruitment and selection and the reward system had a favorable and statistically significant impact on psychological commitment, and both had a statistically positive and statistically significant impact on continuation engagement in the job in the pharmaceutical companies in Jordan (Bisharat et al. 2017).

H4b: The reward system for the employees has a positive influence on pharmaceutical firms' business performance.

An organization's incentive system, which includes both monetary and non-monetary benefits, has become crucial for monitoring employees' performance. Employee motivation can have an important impact on the success of a company (Noorazem, Sabri, & Nazir, 2021). Rewards are advantages that result from doing a task, rendering a service, or fulfilling a duty. One of the most crucial strategies for motivating employees at work is rewards. The reward system's objective is to produce successful outcomes (Salah, 2016). The indirect positive impact of the reward system is partially and sequentially mediated by the satisfying of fundamental psychological demands and contentment with changing rewards. Employers should emphasize the educational value of rewards and work to connect the goals of the compensation system with those of the workforce (Cabanas, Proença, & Carozzo-Todaro, 2020). In addition to improving performance on a financial and non-financial level, rewards also improve the likelihood that employees would apply for jobs, which strengthens teams by adding new people. As people advance with the company, self-actualization will take the place of fundamental needs satisfaction as an effective reward system (San, Theen, & Heng, 2012).

H4c: The quality of human resources is positively related to pharmaceutical firms' business performance.

The quality of human resource management (HRM) in an organization relates to how successfully and efficiently the HR function is conducted, as well as how well it contributes to the attainment of the organization's goals and objectives. It is an overall measure of the performance level of organizations and organizational components (Fox, Ellison, & Keith, 1988). Human capital accumulation and financial development are two critical variables of the economic progress of any company including pharmaceutical companies (Ha, & Ngoc, 2022). In the Indian

pharmaceutical industry valuation, the performance of a company's intellectual capital can explain profitability but not productivity (Smriti, & Das, 2017). The study by Zhang, & Li (2013) examined the association between high-performance work practices and company performance in a sample of Chinese pharmaceutical firms. Additionally, Radonić et al. (2020) found that companies with a higher level of human capital utilization have higher efficiency indices, while the DEA approach was used to assess the efficiency of the representative enterprises and compare it to the human capital value addition (HCVA) index.

3.2 The Conceptual Framework

The study is designed to the following three stages.

1st stage: In the beginning, the contemporary challenges of pharmaceutical companies have been found out from the systematic literature review, the literature are found in different resources or databases, such as Scopus, and Web of Science. Our study highlighted the complexity of European pharmaceutical industry through the systematic literature review method. It revealed the vulnerability of European pharmaceutical industry, such as default patent system, ineffective research and development (R&D), debate on the role of alliances, low level of expertise in EU health care system and others. Additionally, the determinants of pharmaceutical business performance were found out from extensive literature review.

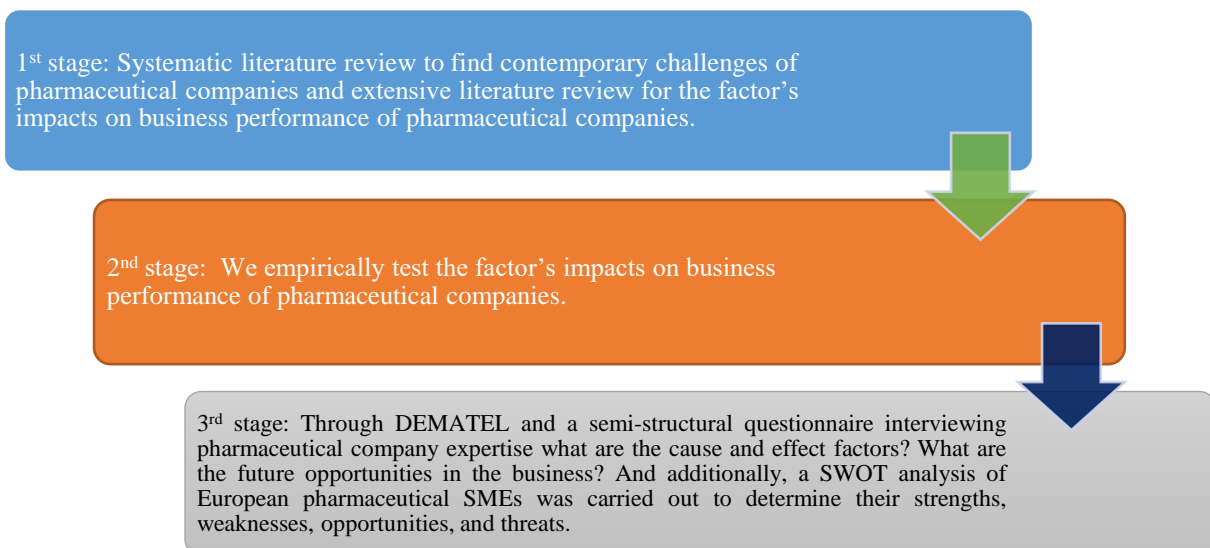


Figure 3. 1: Three stages to design study progress.

Source: Author's Own (2024)

2nd Stage: Since we know what the critical factors are in the case of pharmaceutical companies from the systematic literature review for contemporary challenges of pharmaceutical companies in Europe and an extensive literature review the critical factors for DEMATEL analysis, researcher looks through the secondary sources, such as the EU Industrial R&D Investment Scoreboard,

European Commission, and companies' annual financial reports to gather enough statistical data for testing the hypothesis. It will help to determine the impact of these critical factors on business performance. In the empirical analysis, DEA method, multiple regression models, panel fixed effect (FE), panel random effect (RE) and the generalized least squares (GLS) methodology, are applied.

3rd Stage: In the third stage, it is prepared a semi-structural questionnaire with having DEMATEL questions to interview pharma company managers, financial analysts, administrators, or other qualified and experienced professionals to learn what are the crucial factors for the cause-and-effect groups, and future opportunities of these pharmaceutical firms. Descriptive statistics will be used to analyse the primary data collected. Additionally, a SWOT analysis of European pharmaceutical SMEs was carried out to determine their strengths, weaknesses, opportunities, and threats.

Figure 3.2 illustrates that the business performance as a dependent variable which is measured by net income, operating profit, assets turnover ratio, inventory turnover ratio and sales, which is impacted by the independent variables such as technological efficiency, income from alliances, R&D expenditures and patent and human resource factors (number of employees, training cost and reward system).

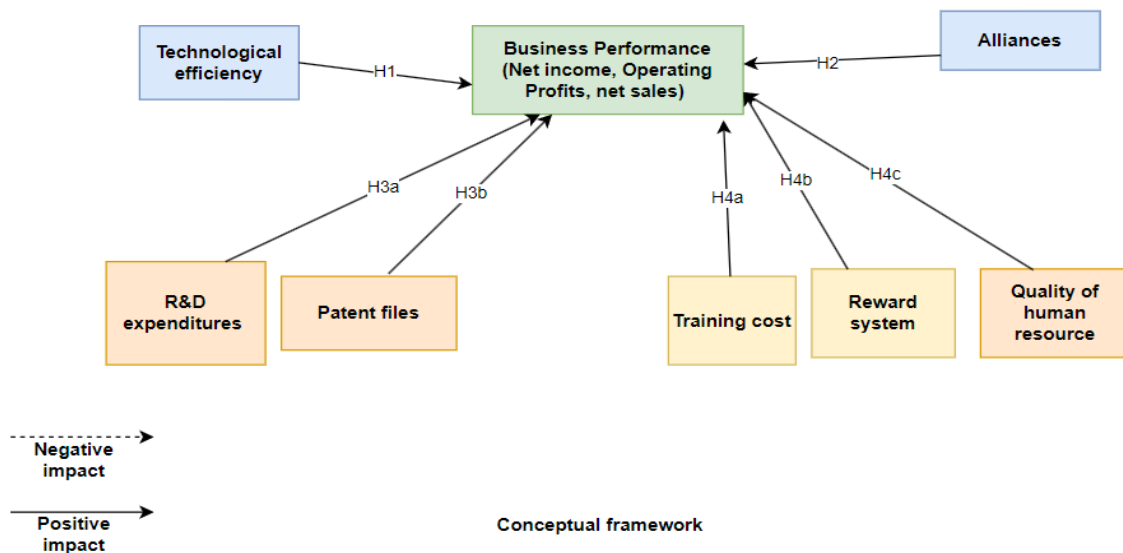


Figure 3.2: Conceptual Framework
 Author's Own (2024)

3.3 The Key Variables of the Study

The independent variables were used in the study, such as the technical efficiency score (TES) which was derived from data envelopment analysis (DEA),

income generated from alliance contribution is measured as a percentage growth rate (Alliance), research and development Expenditure (R&D), patent filed (Patent), training cost, employee cost, rewards, Human Capital Return on Investment (HCROI), and Human Capital Value Added (HCVA). On the other hand, the dependent variables were used in the analysis, such as net income, return on equity (ROE), asset turnover ratio, inventory turnover ratio, net income growth rate, and sales revenues. These were used as they accounted for business performance measurement in various steps in the study.

3.4 Methodology

This study employed a systematic literature review method. To conduct the study, the systematic literature review followed by the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) framework was applied in the present study from the databases, such as Web of Science (WOS) and Scopus with keywords “challenges in the European pharmaceutical industry”, during the period from 2011 to 2022. There had been conducted an extensive literature review to find the critical determinants for pharmaceutical business performance which had used for empirical methods.

Purposive sampling, also known as judgmental, selective, or subjective sampling, is a type of non-probability sampling in which researchers choose subject from the public to participate in their surveys based on their own judgment. The goal of this sampling is to find large companies that are confronting the mentioned contemporary challenges, such as pharmaceutical enterprises with the capacities to cope with elements such as patents, trademarks, alliances, significant R&D expenditure for innovation, and so on. As a result, companies like Roche Holding (Switzerland) - Sanofi (France), GlaxoSmithKline (UK), AstraZeneca (UK), Novo Nordisk (Denmark), Merck Group (Germany), Allergan (Ireland), UCB (Belgium), Ipsen (France), Lundbeck (Denmark) and others will be included on the sampling list. In the second stage, we run the empirical analysis through the panel regression models. The explanation of the methodological steps involved in the empirical approaches—such as the panel fixed effect model (FE), panel random effect model (RE), generalized least squares (GLS) technique, and the models' robustness checking—is imperative. To get technical efficiency scores of 10 leading companies, we run data envelopment analysis (DEA). The decision-making unit (DMU) is the year, the input variables are R&D expenditures, and Employees, and output variables are asset turnover ratio and inventory turnover ratio.

Finally, in a more practical field with primary data from pharmaceutical experts based on the DEMATEL approach was applied in third stage, also the strengths, weaknesses, opportunities, and threats (SWOT) analysis was applied.

Last but not least, the 2022 EU Industrial R&D Investment Scoreboard serves as a secondary data source for SWOT analysis, which is used to identify the obstacles encountered by pharmaceutical SMEs in Europe. We also assessed the possible prospects in the pharmaceutical industry using the DEMATEL questionnaire, which was a component of the primary data collection. Significantly, the study draws from primary as well as secondary data sources. The DEMATEL analysis was carried out through interviews with pharmaceutical stakeholders, including managers, researchers, financial analysts, and investigators. Conversely, the four central hypotheses have been tested using secondary data sources, including internet databases, annual reports, business portfolio reports, and financial statements from 10 of the top pharmaceutical companies in Europe

4. RESULTS

4.1 Results From the Systematic Literature Review

The PRISMA framework exposed by reviewing 57 papers that the weaknesses in the European pharmaceutical industry, including technological inefficiency, the patent system by default, poor R&D, disputes over the role of alliances, a lack of knowledge about the European healthcare system, and problems with pharmaceutical supply chain management. Furthermore, the COVID-19 pandemic is a recent event that results in inefficiencies in the healthcare sector, where the pharmaceutical business is a key player. This is an emerging problem that has not received enough attention in the literature yet.

4.2 The Descriptive Statistics

The descriptive statistics of technical efficiency scores was determined by constant return to scale (CRS) method. There are 20 observation or the decision-making units (DMU) years, except Boehringer Ingelheim which had only 13 observations due to the data unavailability. The DMU years included in the model, between 2003 to 2022. The technical efficiency score was calculated from the input variables, R&D expenditures, number of employees, and output variables were asset turnover ratio, and inventory turnover ratio. GSK had the highest average value 0.9025 among the 10 leading pharma companies. However, the lowest average value had Sanofi in the observations, as we can see that the minimum 0.3170 value, however all the pharma companies had maximum technical efficiency score 1.00.

The contribution from the alliance in an overall is quite low as compared to their net income. As research and development of novel treatments increasingly shift to more ambitious life science sectors in the US and Asia, Europeans are facing reduced access to new medications and the opportunity to participate in

ground-breaking clinical trials. However, the investment in R&D is quite high which is 73.25 % of overall net income and 15.17 % of overall sales during the period 2003 to 2022. The EU Industrial Research & Development (R&D) Investment Scoreboard, 2023 edition, shows that Europe's industry boosted its R&D spending significantly in 2022. Growth in EU private R&D investment has doubled from 2021 to 2022, with a 13.6% increase, and has achieved its highest rate since 2015.

Boehringer Ingelheim and Bayer had outliers with only two negative values, Boehringer Ingelheim had negative net income in 2017 and Bayer had in 2020. Which is a minor number of outliers in the analysis. The current difficult market climate and considerable negative currency effects are the main causes of the negative profit, as it led to decreased growth forecasts during this time. Many countries experienced economic slowdowns due to the coronavirus pandemic, which could cause the expansion of the pharmaceutical business to slow down.

Table 4.1: Descriptive statistics of overall variables.

Variable	Obs	Mean	Std. Dev.	Maximum	Minimum
The technical efficiency score (TES_CRS)	193	0.772932	0.184661	1	0.31709
Strategical alliances (Alliance)	71	705.338	1034.949	4084	2
Research and development expenditures (R&D)	200	6676.04	3584.873	24047	1232
Patent filed (Patent)	200	2348.235	1772.244	7821	300
Employee cost (EC)	36	11669.91429	10886.1851	36532	303
Human Capital Return on Investment (HCROI)	36	1.810963	0.373608	2.554466	1.102774
Human Capital Value Added (HCVA)	36	0.458621	0.601533	1.738706	0.092901

Net income (NI)	200	9113.91	8704.667	55525	529
Return on Equity (ROE)	200	0.782166	2.328264	31.89706	0.021609
Sales revenue (Sales)	200	43987.55276	25007.05872	176954	8157

Source: Author's Own (2024)

4.3 Empirical Results

The results shows a significant and positive relationship between standardized technical efficiency scores (Z_TES) and log of return on equity (Log_ROE) of the selected large pharma companies, implies that these companies are conducting business with technological efficiently. In addition, there is a positive but statistically insignificant association between growth rate of net profit and income from alliance growth rate. There is insufficient evidence that the contribution from alliance has a meaningful impact on business performance of the companies. According to Emami et al. (2022) showed that the financial, operational, and organizational effectiveness of partners in small, entrepreneurial enterprises is significantly and positively impacted by strategic alliances. It has been advised in that study, small business owners to focus on pre- and post-alliance factors, such as partner resemblance, alliance experience, reputation, complementary skills, industry reach, dedication to enhancing trust and expertise, and cooperation to increase performance. However, the sample of ten of the top pharmaceutical companies in Europe shows that large companies do not require the same level of assistance from alliances as small businesses do.

In our analysis 10 leading pharmaceutical companies, the current R&D spending positively and statistically significant to present year sales revenue of the business; while the R&D lag1 and R&D lag2 are negatively and statistically significant relation to business sales revenue for the leading pharmaceutical companies with control models. For-instance, the financial success of Indian pharmaceutical companies is positively impacted by research and development (R&D) efforts in current year (Nandy, 2020). Because, the current R&D is beginning to directly result in new goods and revenue, it is positively correlated with sales R&D(t) (Jaisinghani, 2016). On the other hand, it takes time for the findings of prior research to be translated into goods or sales, R&D from the past R&D(t-1) and R&D(t-2) is inversely correlated with sales. Due to the extremely high expenditures, high return uncertainty, and increased likelihood of failure, there is a negative correlation between R&D investments and firm performance. R&D is a long-term investment that takes a long time to pay dividends, particularly for pharmaceutical companies. According to earlier research, the average time lag for manufacturing metal and electrical machinery is two years,

for manufacturing pharmaceuticals it is five years, and for the other industries it is three years (Su et al., 2021).

Additionally, the relationship between a patent filed with lag2 and sales revenue is only positive but statistically insignificant, meaning that it takes two years to implement the influence of the patent filed on sales revenue. This is also consistent with the model proposed by Artz et al. (2010). The result suggests that it takes 2 years' time period to effect for patent filling to emerge in terms of sales as it takes time to have product concept introduction, product development, product advertisement, what are the conditions for market competitiveness, consumer acceptance cause a delayed impact on sales revenue.

The sales of the corresponding pharmaceutical businesses are positively correlated with the human resource independent variables, such as training cost, HCVA, and the control variable (number of employees). On the other hand, rewards, employee or personnel costs, HCROI are negatively correlated with sales revenue. Among the human resource independent variables, training cost, personnel cost, number of employees and HCVA are statistically significant correlation to the business sales. The independent variables, like rewards and HCROI are negatively and statistically insignificantly related to sales revenue of these 10 leading pharmaceutical companies. This implies that higher spending on the factors above will encourage higher sales income. For instance, higher training expenses result in more capable workers who can use their skills to advance the business.

4.4 Results from the DEMATEL Analysis

The study also mapped the relative relationships among the internal factors that influence the business performance of pharmaceutical companies in Europe by using the DEMATEL approach. The extensive literature review from the Web of Science and Scopus databases found that seven internal factors are very demanding in the case of European pharmaceutical business performance. The main elements that have the highest impact on pharmaceutical business performance in Europe are human resources competencies, the information system, technological competitiveness, and the patent system. However, financial profitability, research and development competencies, alliances with other companies, and supply chain management are the factors that are affected more by other factors.

4.5 Results from the SWOT Analysis

Moreover, the contemporary challenges pharma SMEs in Europe encounter through SWOT analysis. The contemporary challenges are the financial

performance of companies is continuously failing; many are still in the early stages of clinical trials, and some have already incurred significant losses as a result of clinical trial failures. Legal actions against the research tax credit, repayment of government grant loans, and the usefulness of specific research programs may all be impacted by the concerns posed by shifting competitive and regulatory contexts. However, according to the output from the SWOT analysis, the majority of businesses benefit from factors including advantageous locations, innovative advanced therapies, the adoption of novel, specialized technologies, and higher R&D and training expenses. Additional opportunities include securing sustainable development, enormous opportunities through alliances, patent protection by SMEs, a focus on improving overall human health, and the ability of SMEs to profit from the marketing of therapeutic and diagnostic solutions as opposed to large pharmaceutical companies, which are financed by drug sales revenues.

5 CONCLUSIONS

5.1 Contribution of the Study

The contribution of the study has been categorized as a contribution to the theory and a contribution to the practice.

5.1.1 Contribution to the Theory

The process of developing and advancing an existing theory with some logic and data is known as theoretical contribution. Through a narrative analysis of the literature, this study has concentrated on theoretical contribution-related questions and their responses. The study on the factors influencing the business performance in pharmaceutical companies in Europe is the first attempt in this dissertation, even there are not significant studies conducted on it as well as the contemporary challenges of pharmaceutical companies in Europe. There are not such comprehensive studies to identify in one study with factors contributing pharmaceutical business and what challenges these companies are encountering over the period of time. In addition to providing an overview of the EU pharmaceutical market, Boldeanu, & Pugna, (2014) synthesize the evolution of the Romanian pharmaceutical market into a SWOT analysis. The paper's conclusions centre on the estimation of the Return on Equity (ROE) ratio, which is the primary performance metric deemed important for the pharmaceutical sector. however, our study not only confined of on financial parameter like ROE, it focused technological factors, R&D, intangible asset like Patent file, partnership asset like strategic alliances, human resource factors and so on.

From a comprehensive and broader perspective, our study makes the case that previous research overlooked the current problems affecting the European

pharmaceutical business. The current study is distinctive in that it examines a number of factors of internal pharmaceutical companies - a comprehensive investigation that the researchers have not yet completed - and concentrates on all European pharmaceutical companies due to the fact that the European pharmaceutical industry is currently facing a number of challenges. Moreover, some recent studies ought to focus the pharmaceutical companies after Covid-19 pandemic as an important research field to be focused for the betterment of the contemporary challenges, for-instance, Kwon, Kim, and Lee's research (2020) examined the ways in which the factor moderates the relationship between the pharmaceutical industry's cost advantage and differentiation tactics and the performance of mergers and acquisitions (M&A). Our study, also adds value in the perspective with the impact of strategical alliances from certain leading pharmaceutical companies in Europe on their net income.

From the perspective of methodology (empirical findings, the cause-effect relationship among internal factors, SWOT analysis for finding strength, weakness, opportunities and threats for pharmaceutical SMEs in Europe) also illustrate insightful interpretation to contributing the theories.

5.1.2 Contribution to Practice

The pharmaceutical industry relies heavily on knowledge and human resources for pharmaceutical research and business development, policymakers should be able to identify this important internal factor and give it more priority. This is because the more resourceful a company is with its human resources, the more likely it is to succeed in the future. The present study of internal drivers of pharmaceutical company performance is very insightful, as it has the potential to boost further competitiveness, the health authority personnel can have guidelines to make strategic decisions, inspire investor confidence, ensure regulatory compliance and performance benchmarking, and support talent acquisition and retention. The social consequences of examining the internal performance drivers of pharmaceutical companies in Europe include increased access to healthcare care, advances in medical research, improved patient safety, and quality assurance.

The SWOT analysis revealed significant issues, such as the continuous decrease in pharma SMEs' business profit, failure in R&D, and others, which will offer informative guidelines for policymakers, investors, and management bodies in European pharmaceutical SMEs to recognize and eventually overcome the challenges. Pharmaceutical SMEs are fundamentally concerned with human health, well-being, the development of clinical trials, and the sustainability of the social, economic, and environmental systems. The present study is directly interlinked with these noble issues..

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LIST OF PUBLICATIONS OF THE AUTHOR

Publications in Book Chapter

- (i) Asad, A.I., Sabary, G.S. (2025). Key Elements of Financing in Female Digital Entrepreneurship: A Causal Analysis Using Delphi-DEMATEL Approach for Bangladesh. In: Arora, R., Sarker, T. (eds) *Financing of Sustainable Development Goals (SDGs)*. Palgrave Macmillan, Cham. https://doi.org/10.1007/978-3-031-80478-6_4

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- (i) Sabary, G.S., Ključnikov, A., Asad, A.I., Kloudová, J. and Ferraris, A. (2025). Unveiling opportunities and obstacles in emerging markets: analysis of women's home-based enterprises using Delphi-DEMATEL approach", *Journal of Asia Business Studies*, Vol. ahead-of-print No. ahead-of-print. <https://doi.org/10.1108/JABS-05-2024-0242>
- (ii) Asad, A. I., Popesko, B., & Damborský, M. (2024). The nexus between economic policy uncertainty and innovation performance in Visegrad group countries. *Oeconomia Copernicana*, 15(3), 1067-1100. DOI: <https://doi.org/10.24136/oc.2804>.
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 - (viii) **Asad, A. I.**, Pavelková, D., Pham, T. P., & Quddus (2022). Impact of export and import on value addition of ready-made garments sector in Bangladesh. *Journal of International Studies*, 15 (2), 23-39. DOI: 10.14254/2071-8330.2022/15-2/2.
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- (x) Asad, A. I., Sufyan, A. & Popesko, B. (2023). BAFA – 2024. Accounting and Finance in Emerging Economies (AFEE) Breaking Untold Barriers: Investigating Pharmaceutical SMEs' Contemporary Challenges in Europe. The Accounting & Finance in Emerging Economies SIG is holding its 25th Workshop at the University of Economics in Katowice, Poland on 1-2 July 2024.
- (xi) Asad, A. I. (2024). Exploring the Relationship between Economic Policy Uncertainty and Industrial Business Performance in Visegrad Economies, presented the core results at 46th EBES Conference – Rome.
- (xii) Asad, A. I., Sufyan, A. & Popesko, B. (2023). Title of research: The Factors Influencing the Growth of SMEs in the EU Pharmaceutical Industry: An Empirical Analysis, IFKAD-2023, University of Basilicata, Matera, Italy. (conference paper, published).
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- (xiv) Asad, A. I. et al. (2022). Impact of export and import on value addition of ready-made garments sector in Bangladesh. EMF, International Scientific Conference 2022, Faculty of Management and Economics, Tomas Bata University in Zlín. Czech Republic.
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- (xvi) Asad, A. I., Rahman, S., & Akter, S. (2021). Households' Waste Material Management and Recycling: How Much Conceivable to Support A Zero-Waste Management. 10th International Conference on Management Zero Waste Management and Circular Economy, Mendel University of Brno, Czech Republic. 91-99.
- (xvii) Asad, A. I., Drahomíra, P., & Tuong Vy, N. T. (2021). Contemporary Challenges in the EU Pharmaceutical Industry: A Systematic Literature Review. Proceedings IFKAD 2022: Managing Knowledge in Uncertain Times, Rome, Italy, 717-730
- (xviii) Rahman, S. & Asad, A. I. (2021). The Impact of Macroeconomic Determinants of Export Earnings in South Asia: A Study on Bangladesh, India, and Pakistan. Proceedings of the 15th International Conference Liberec Economic Forum 2021, 325-334, Liberec, Czech Republic.
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- (xx) Tien, P. P.; Abdul, Q.; Asad, A. I., Popesko, B, & Hussain, S. The Factors of Fintech: A Literature Review, Conference Proceedings 17th Annual International Bata Conference for Ph.D. Students and Young Researchers, Czech Republic, 395-405.
- (xxi) Abdul, Q., Pavelková, D., Hussain, S.; Tien; P.P. & Asad, A.I. (2021). Investment Decisions and Firm Performance Under Economic Policy Uncertainty. Conference Proceedings 17th Annual International Bata Conference for Ph.D. Students and Young Researchers, Czech Republic, 442-453.

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- **Erasmus Study stay** at Faculty of Economics, Matej Bel University in Banská Bystrica, Slovakia. (01.07.2024-31.08.2024).
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