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MASTER'S THESIS

CREATING A SUPPORTIVE BUSINESS ENVIRONMENT FOR RESEARCH-BASED PHARMACEUTICAL COMPANIES IN SLOVENIA

Ljubljana, September 2025 NIK KOVAČ

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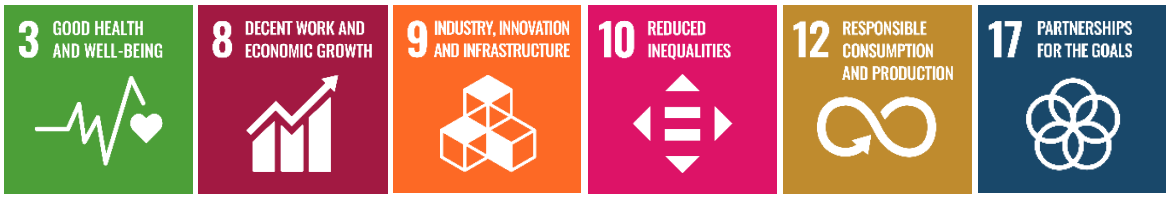
ABSTRACT

The thesis explores the role of a supportive business environment for research-based pharmaceutical companies. It examines key challenges faced by various stakeholders within the research-based pharmaceutical ecosystem, including policymakers, industry leaders and academia. The research incorporates a qualitative analysis of multi-stakeholder perceptions, gathered through in-depth interviews of relevant stakeholders, to evaluate the strengths and weaknesses of Slovenia's local business environment. Based on these insights, the thesis provides a set of targeted recommendations to address the specific needs of stakeholders, with the goal of enhancing the effectiveness and global competitiveness of the country's pharmaceutical sector.

KEY WORDS: research-based pharmaceutical companies, supportive business environment, multi-stakeholder perceptions, stakeholder challenges, targeted stakeholder recommendations

SUSTAINABLE DEVELOPMENT GOALS



POVZETEK

Magistrsko delo raziskuje vlogo spodbudnega poslovnega okolja za znanstvenoraziskovalne farmacevtske družbe. Preučuje ključne izzive, s katerimi se soočajo različni deležniki v ekosistemu znanstvenoraziskovalne farmacevstke industrije, vključno z oblikovalci politik, vodilnimi v farmacevtski dejavnosti in akademskimi krogi. Raziskava vključuje kvalitativno analizo zaznav več relevantnih deležnikov, zbranih s poglobljenimi intervjuji, da bi ocenili prednosti in slabosti slovenskega poslovnega okolja v Sloveniji. Na podlagi teh spoznanj delo ponuja nabor usmerjenih priporočil za obravnavo specifičnih potreb deležnikov, s ciljem, da poveča učinkovitost in globalno konkurenčnost farmacevtskega sektorja v državi.

KLJUČNE BESEDE: znanstvenoraziskovalne farmacevstke družbe, spodbudno poslovno okolje, zaznave več deležnikov, deležniški izzivi, ciljna priporočila za deležnike

CILJI TRAJNOSTNEGA RAZVOJA

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LIST OF ABBREVIATIONS

sl. – Slovene
AI – (sl. umetna inteligenca); Artificial Intelligence
AMPMD – (sl. Javna agencija Republike Slovenije za zdravila in medicinske pripomočke); Agency for Medicinal Products and Medical Devices of the Republic of Slovenia
ATMP – (sl. zdravila za napredno zdravljenje); Advanced Therapy Medicinal Product

CEE – (sl. Srednja in Vzhodna Evropa), Central and Eastern Europe
CMR – (sl. Center za raziskave zdravil); Centre for Medicines Research
COVID-19 – (sl. koronavirusna bolezen); Coronavirus Disease
EFPIA – (sl. Evropska zveza farmacevtske industrije in združenj); European Federation of Pharmaceutical Industries and Associations
EMA – (sl. Evropska agencija za zdravila); European Medicines Agency
EU – (sl. Evropska unija); European Union
FDA – (sl. Uprava za hrano in zdravila); Food and Drug Administration
GDP – (sl. bruto domači proizvod); Gross Domestic Product
GHIT – (sl. inovativna tehnologija za globalno zdravje); Global Health Innovative Technology
HIIS – (sl. Zavod za zdravstveno zavarovanje Slovenije); Health Insurance Institute of Slovenia
HTA – (sl. vrednotenje zdravstvenih tehnologij); Health Technology Assessment
IP – (sl. intelektualna lastnina); Intellectual property
IT – (sl. informacijska tehnologija); Information Technology
JCA – (sl. skupna klinična ocena); Joint Clinical Assessment
M&A – (sl. združitev in prevzem); Mergers and acquisitions
MSD – (sl. Merck Sharp in Dohme); Merck Sharp and Dohme
NIPH – (sl. Nacionalni inštitut za javno zdravje); National Institute of Public Health of the Republic of Slovenia
NME – (sl. nova molekularna entiteta); New Molecular Entity
OECD – (sl. Organizacija za gospodarsko sodelovanje in razvoj); Organisation for Economic Co-operation and Development
R&D – (sl. raziskave in razvoj); Research and Development
RWE – (sl. dokazi iz vsakodnevne klinične prakse); Real-World Evidence
U.S. – (sl. Združene države); United States
UMC – (sl. Univerzitetni klinični center Ljubljana); University Medical Centre Ljubljana
W.A.I.T. – (sl. čakanje na dostop do inovativnih terapij); Waiting to Access Innovative Therapies

1 INTRODUCTION

In a world characterised by rising life expectancy and the associated ageing of the population, personalized healthcare and fast-paced advancements in technology are transforming the global healthcare landscape (IESE, 2024). The Slovenian healthcare system, like many other European systems, was designed more than half a century ago. Despite its adaptability and dedicated workforce, it faces major challenges. The growing pressures of the modern healthcare needs of an ageing population coupled with rapidly evolving medical technology necessitate a comprehensive reassessment and upgrade of the system (Bernik et al., 2023). According to a report, the Organisation for Economic Co-operation and Development (OECD) countries are estimated to mismanage up to one-fifth of health spending due to inefficiencies such as over-treatment and unnecessary procedures, pointing to a major opportunity for improvement. Prioritising prevention and early treatment are crucial for improving medical results and minimizing burden of disease (OECD, 2017). Slovenia's pharmaceutical industry is characterised by a blend of local and multinational companies, with significant investments in Research and Development (R&D). One example is Novartis, which has made high investments in digitalization and innovation, and its dissemination in Slovenia (Zavrtanik, 2024). The commitment to innovation and its dissemination is further demonstrated by the increasing collaboration between industry players and research institutions, fostering a culture of continuous development and knowledge sharing (Roche, n.d.).

Patient-focused healthcare systems, involving all stakeholders, face mounting pressure to continuously enhance patient care while addressing the increasing economic burden of diseases. This burden includes direct, indirect, and intangible costs from a societal perspective, encompassing expenses borne by patients, their families, the healthcare system, employers, and other relevant parties (Jo, 2014). This is a problem that has to be addressed by multi-stakeholders' involvement in order to mitigate its effects, and one of those stakeholders are also the research-based pharmaceutical industry.

Research-based pharmaceutical companies alongside all other relevant stakeholders have the responsibility to contribute to the financial stability of healthcare systems. Managing this issue remains one of the most significant challenges for all healthcare stakeholders. According to 2020 data from the Institute for Health Metrics and Evaluation, nearly 30 per cent of the global disease burden could be avoided through preventive measures, early interventions, or greater patient accountability. This highlights the need to emphasise prevention and early treatment, both of which can enhance health outcomes while helping to control costs (Remes et al., 2020). Furthermore, analysis by the OECD in 2017 revealed that, as previously mentioned, as much as 20 per cent of global healthcare expenditures are wasted due to factors such as late diagnoses, overtreatment and inefficiencies within healthcare organisations. These inefficiencies often result in providing treatments that are

either unnecessary or of low value, ultimately having little to no impact on their health outcomes. These insights emphasise the pressing need for systemic reforms in healthcare delivery to reduce inefficiencies, improve efficiency and allocate resources more effectively, ensuring better patient care and improved health outcomes (OECD, 2017).

In order for research-based pharmaceutical companies to thrive and make meaningful contributions, they must operate within a stable, long-term-oriented business environment that supports innovation and facilitates the development and dissemination of pharmaceutical advancements. This environment should be characterized by clear and effective regulatory frameworks, easy market access and attractive incentives for investment (Jeck et al., 2021).

The purpose of this thesis is to contribute to creating a more favourable business environment for research-based pharmaceutical companies in Slovenia by analysing the key characteristics of such an environment, identifying challenges faced by stakeholders, and assessing Slovenia's potential to position itself as a regional hub for pharmaceutical research and innovation. By providing a comprehensive analysis of the current landscape and formulating targeted recommendations, the thesis seeks to support policymakers, industry leaders, and other relevant stakeholders in fostering a more competitive and sustainable pharmaceutical sector, in order to improve patient access to medicines in Slovenia.

To achieve the purpose of fostering a more favourable business environment for research-based pharmaceutical companies in Slovenia, this thesis sets out to accomplish five key goals, each addressing a critical aspect of the industry's development and potential.

The first goal of this thesis is to define the key characteristics of an optimal business environment for research-based pharmaceutical companies. A well-functioning environment should foster innovation, encourage investment in R&D and provide regulatory and financial support to facilitate the growth of the industry. This thesis examines factors such as access to funding, clinical trial infrastructure, and the role of government policies in shaping a competitive and innovation-friendly ecosystem.

The second goal is to identify the key challenges faced by stakeholders within the research-based pharmaceutical ecosystem. Various stakeholders, including government bodies, regulatory agencies, healthcare providers, nonprofit organisations and pharmaceutical companies all contribute to and are influenced by the business environment. This thesis explores the barriers they encounter such as regulatory inefficiencies, talent shortages and limitations in research funding, to gain a deeper understanding of the obstacles that hinder industry growth.

Another crucial goal is to analyse and critically evaluate the current business environment for research-based pharmaceutical companies in Slovenia. This involves assessing Slovenia's regulatory framework, economic landscape and available infrastructure to determine the extent to which it supports research-driven pharmaceutical innovation. The

thesis also compares Slovenia's position with other countries to identify potential competitive advantages and areas that require improvement.

Additionally, this thesis aims to assess Slovenia's potential to become a regional hub for research-based pharmaceutical companies. Given Slovenia's strategic location in Central Europe and its existing pharmaceutical sector, there is an opportunity for the country to position itself as a leading destination for pharmaceutical R&D. This thesis evaluates factors such as talent availability, collaboration between academia and industry, access to international markets and the overall attractiveness of Slovenia for pharmaceutical investments.

Finally, based on the findings, the thesis develops a set of targeted recommendations for specific stakeholders within the research-based pharmaceutical ecosystem. These recommendations provide actionable insights for policymakers, industry leaders, research institutions and regulators to create a more favourable environment for research-based pharmaceutical companies. The focus is on enhancing regulatory efficiency, improving incentives for innovation, strengthening collaboration among stakeholders and positioning Slovenia as a competitive player in the global pharmaceutical research landscape.

To accomplish the purpose and goals of this thesis, four research questions have been posed:

1. What is the added value of research-based pharmaceutical companies in Slovenia?
2. What are the key characteristics of the current business environment for research-based pharmaceutical companies in Slovenia?
3. What is the nature of collaboration among stakeholders in ensuring access to innovative pharmaceuticals for patients in Slovenia?
4. Could Slovenia become a regional hub for research-based pharmaceutical companies?

The answers to these research questions provide a comprehensive understanding of the current landscape for research-based pharmaceutical companies in Slovenia, highlight the challenges and opportunities within the ecosystem and offer insights into the country's potential to become a regional hub for pharmaceutical innovation. These findings serve as the foundation for the development of targeted recommendations to foster a more favourable business environment for the sector.

Research questions are answered based on existing published research and the analysis of stakeholders' viewpoints, allowing for a comprehensive analysis that integrates both theoretical and practical insights from all key decision-makers within the ecosystem.

This thesis begins with a comprehensive review of existing literature addressing the role of a supportive business environment for research-based pharmaceutical companies, as well as the key challenges faced by various stakeholders within this ecosystem, both globally and with a particular emphasis on the European Union (EU). Building on this foundation, the thesis proceeds with an in-depth analysis of how multiple stakeholders perceive the business

environment for research-based pharmaceutical companies in Slovenia, based on insights gathered through interviews with relevant stakeholders. The thesis concludes by presenting a set of targeted recommendations for specific stakeholder groups, developed in light of the findings from both the literature review and empirical analysis.

It's important to note that research-based pharmaceutical companies can operate within a country in various capacities, ranging from selling through intermediaries to establishing subsidiaries, setting up production facilities, or even serving as regional hubs. This thesis concentrates on companies with subsidiaries in Slovenia, as their presence demonstrates recognition of the country's advantageous environment.

In conducting the literature review, generative Artificial Intelligence (AI) programmes are used alongside traditional academic database searches to assist in identifying relevant sources, as well as for language editing, as well as for language editing (Elicit, ScholarGPT, ChatGPT and Google Gemini).

2 THE ROLE OF A SUPPORTIVE BUSINESS ENVIRONMENT FOR RESEARCH-BASED PHARMACEUTICAL COMPANIES

Creating an encouraging environment for pharmaceutical innovation and access to effective products depends on multiple key components. A well-structured regulatory framework at the EU level can streamline drug approval processes and safeguard intellectual property (IP), thereby promoting investment in R&D (EFPIA, 2022b). Effective regulations can support the development and commercialization of new drugs by lowering barriers and providing incentives for innovation and its dissemination. For instance, the United States (U.S.) Food and Drug Administration's (FDA) Breakthrough Therapy Designation has substantially boosted innovation and its dissemination by accelerating the approval process for drugs that show significant improvement over existing treatments (Chandra et al., 2022).

Protecting IP rights is essential for securing the outcomes of pharmaceutical R&D investments and encouraging companies to pursue innovative and high-risk research. A robust IP framework, particularly through patents, provides temporary exclusivity that allows firms to recover the substantial costs associated with drug discovery and development, which often take over a decade and involve considerable financial risk (DiMasi et al., 2016). These legal protections not only incentivize innovation but also promote transparency and cumulative progress by requiring the public disclosure of inventions (Gambardella et al., 2008). The European Federation of Pharmaceutical Industries and Associations (EFPIA) highlights the critical role of IP incentives in driving both R&D and commercial investment within the sector (EFPIA, 2024b). Moreover, effective patent enforcement and alignment with international IP standards strengthen legal certainty and attract domestic and international investment, contributing to a more

favourable business environment for research-based pharmaceutical companies (OECD, 2018).

Ensuring fair competition and addressing profit shifting among multinational corporations are crucial for maintaining market equilibrium (Garcia-Bernardo & Janský, 2024). Profit shifting involves tactics used by Multinational Enterprises to transfer earnings from countries with higher tax rates to those with minimal or no taxation. The OECD highlights that tax revenue losses due to base erosion and profit shifting range between 90 and 220 billion euros per year, accounting for approximately 4-10 per cent of global corporate income tax revenues (OECD, n.d.). Similarly, a study indicates that in 2017, multinational corporations transferred more than 780 billion euros in profits, mainly to countries where effective tax rates were under 10 per cent. This substantial profit shifting undermines fair competition by enabling certain corporations to gain tax advantages over competitors operating in higher-tax jurisdictions (Garcia-Bernardo & Janský, 2024). In other words, it's putting a massive disadvantage on research-based companies that want to keep the profits within high-tax countries, including Slovenia. These companies must allocate a larger portion of their revenue to taxes rather than reinvesting in R&D, potentially slowing innovation and weakening their global competitiveness. High-tax countries may also struggle to attract and retain research-driven firms if their tax policies are uncompetitive.

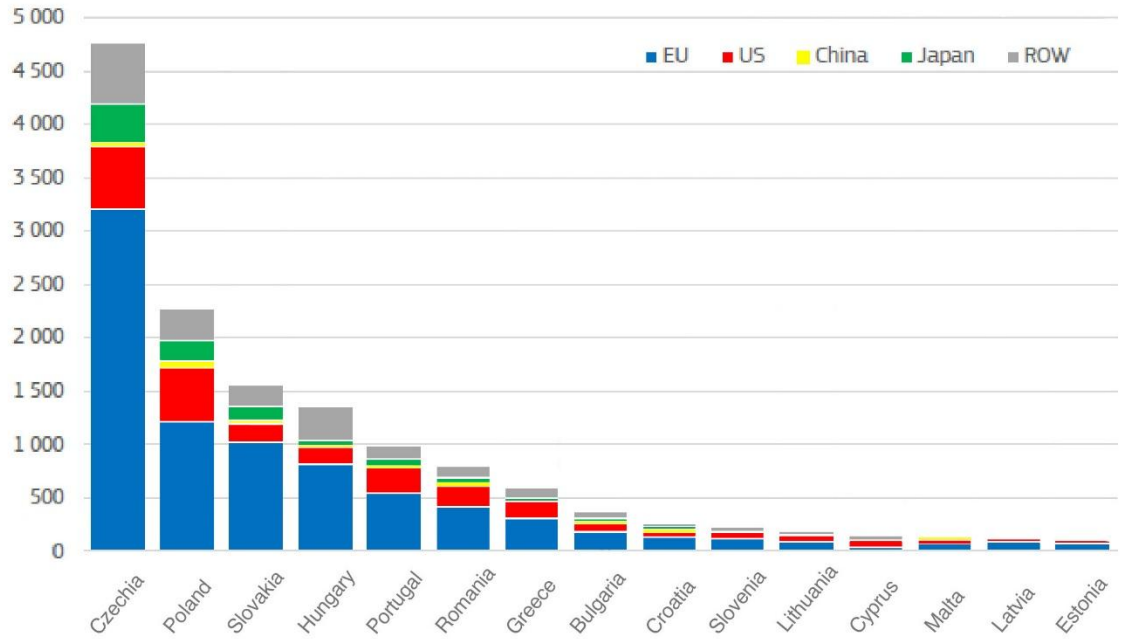
Ballreich et al. (2019) from Johns Hopkins school of public health contributes to the topic by stating that transparent and inclusive decision-making processes are essential for integrating innovative medicines into public funding systems. A lack of clarity in pricing and access mechanisms can result in inefficiencies that hinder patient access to critical treatments. Establishing a transparent environment with clear frameworks helps ensure equitable access, prioritizing patient needs while enhancing the effectiveness of healthcare systems (Ballreich et al., 2019). For instance, the EU's EU4Health program emphasises the need for transparent decision-making in healthcare to strengthen healthcare systems across Europe and improve overall health outcomes. By focusing on enhancing healthcare resilience, preparedness, and access to services, EU4Health underscores the role of clear and inclusive processes in integrating innovative medicines into public funding systems (European Commission, 2021). Additionally, transparent and predictable reimbursement processes can incentivize companies to launch new therapies in a particular market, thereby improving patient access and fostering a sustainable innovation ecosystem. A study on the reimbursement of innovative pharmaceuticals in hospitals highlighted the significance of efficient reimbursement pathways. Establishing clear mechanisms for reimbursement can help balance the need for affordability with the command to reward innovation, thus ensuring a sustainable market for new therapies (Jeck et al., 2021).

Adequate funding and investment opportunities are also key to driving pharmaceutical innovation and its dissemination. One report highlights the importance of balancing public and private investment in biopharmaceutical R&D to foster a dynamic ecosystem (Fowler et al., 2024). Collaboration between public and private investment plays complementary roles

but is only allowed in the R&D phase and, later on, in ensuring accessibility of therapies or medicine to patients. Public funding can support fundamental research, while private investment can drive the development and commercialization of new therapies. The EFPIA notes that the pharmaceutical industry is a significant contributor to the Gross Value Added in the EU, with innovative companies accounting for a substantial portion of this economic impact (EFPIA, 2021). A country aiming to foster pharmaceutical innovation and its dissemination could leverage this by promoting foreign direct investment. Creating innovation hubs, strengthening end-to-end capabilities, and funding disruptive pharmaceutical innovation are all strategies that have been shown to attract investment (EFPIA, 2022b). Additionally, the European Commission's report suggests that targeted financial policies and incentives can help mitigate investment risks and encourage long-term R&D commitments, particularly in the face of increasing regulatory and economic challenges (Nindl et al., 2024).

A competitive business environment is essential for attracting pharmaceutical R&D investments. As seen in Figure 1, Slovenia has fewer foreign-owned research-based subsidiaries compared to neighbouring countries such as Poland, Hungary and Czechia, suggesting that improved investment policies and regulatory efficiencies could enhance Slovenia's attractiveness to multinational companies (Nindl et al., 2024).

Figure 1: Number of pharmaceutical subsidiaries located in each widening country, by country of the mother company, 2023.



Notes: ROW = rest of world; The list of widening countries is available at https://rea.ec.europa.eu/horizon-europe-widening-who-should-apply_en

Source: Nindl et al. (2024).

The presence of a skilled workforce is another crucial element for creating a supportive environment for research-based pharmaceutical companies. One study emphasises the importance of personnel training in linking innovation with performance in the pharmaceutical industry (Castillo Apraiz & Matey de Antonio, 2020). Investing in Science, Technology, Engineering and Mathematics education, promoting specialised training programmes, and attracting top talent can help build a knowledge-rich environment beneficial to innovation and its dissemination. The European Commission also emphasises the need for developing digital skills and competencies as part of a broader industrial strategy (European Commission, 2023b). Enhancing digital capabilities is particularly important, as digital transformation is becoming a decisive factor for pharmaceutical companies when considering where to invest (Grom, 2023). Digital competitiveness influences R&D and manufacturing investment decisions, especially in the context of virtual clinical trials and data management (EFPIA, 2022b).

Effective collaboration among academic institutions, the research-based pharmaceutical industry and research organisations plays a crucial role in turning scientific breakthroughs into commercially viable treatments. According to Olk and West (2019), cooperative value creation within industry conglomerates plays a critical role in advancing pharmaceutical innovation and its dissemination. Namely, public-private partnerships that include academia, research organisations and private pharmaceutical companies could drive collaborative innovation efforts, especially in emerging fields such as advanced therapy medicinal products (ATMP) and gene and cell therapy. The importance of collaboration is further highlighted by the potential for spillover effects, where partnerships with local universities or international entities can enhance knowledge exchange and foster innovation and its dissemination (EFPIA, 2022b).

A supportive business environment plays a crucial role in enabling innovative pharmaceutical R&D, particularly when it encourages collaborative approaches that mitigate financial and scientific risk. In this context, public-private partnerships and alternative incentive models have gained importance as strategies that address market failures in areas such as neglected diseases, rare conditions, and antimicrobial resistance. These approaches combine public funding and policy support with private sector capabilities to accelerate the development of needed therapies. For instance, push incentives like research grants and tax credits help subsidise early-stage R&D, while pull mechanisms such as market entry rewards, milestone prizes, and transferable exclusivity vouchers offer financial returns upon successful product development (Renwick et al., 2016). The Global Health Innovative Technology (GHIT) Fund exemplifies this model by bringing together the Japanese government, industry, and global health stakeholders to fund treatments for infectious diseases in low-income settings (GHIT Fund, 2023). In Europe, the Innovative Medicines Initiative, a joint undertaking between the European Commission and EFPIA, supports large-scale collaborative research projects that tackle scientific bottlenecks and promote data sharing across the R&D ecosystem (Innovative Medicines Initiative, 2023). These initiatives

illustrate how cross-sector partnerships can increase efficiency and share risk. However, without complementary reforms to improve IP transparency, streamline regulatory processes, and reduce administrative burden, the full potential of these collaborative models may remain untapped (Outterson et al., 2016; Scannell, 2023).

Lastly, national culture and effective governance play a pivotal role in shaping a business environment that supports pharmaceutical innovation. One study indicates that factors such as board gender diversity and national culture significantly impact corporate innovation. A culture of inclusivity, diversity, and sound governance can promote openness to innovation by encouraging different perspectives and approaches to problem-solving. Effective governance structures can also ensure that regulatory frameworks, investment policies, and market access strategies are aligned with the broader goal of supporting pharmaceutical innovation (Attah-Boakye et al., 2020). In EU countries, this requires well-defined national health policies, strategic frameworks and planning, along with transparent healthcare legislation. Additionally, an effective EU-wide pharmaceutical regulatory system ensures patient safety and treatment efficacy, complemented by regulations governing Health Technology Assessment (HTA) that is essential in improving decision-making on public funding of research-based pharmaceuticals (European Commission, 2023b, 2024).

In conclusion, a supportive business environment for innovative pharmaceutical companies includes several interrelated factors: effective regulatory and IP frameworks, transparent decision-making, adequate funding and investment opportunities, a skilled workforce, collaborative ecosystems, favourable market access and clear reimbursement policies, and a supportive national culture and governance. By focusing on these aspects, a country can establish an environment that enables the expansion and innovation of their research-based pharmaceutical sector, while also strengthening the broader pharmaceutical sector. This, in turn, can drive advancements in healthcare and contribute to overall economic growth and stability. As a result, patients gain improved access to innovative medicines, as research-based pharmaceutical companies play a crucial role in increasing the availability of treatments within a country. These companies lead advancements in drug development while also investing in local manufacturing, distribution channels, and healthcare infrastructure, helping to expand access to both new and existing therapies (Hazel et al., 2022).

3 KEY CHALLENGES OF VARIOUS STAKEHOLDERS WITHIN THE RESEARCH-BASED PHARMACEUTICAL ECOSYSTEM

The research-based pharmaceutical ecosystem is a highly complex and interdependent network, involving multiple stakeholders, including pharmaceutical companies, investors, regulatory agencies, public payers, healthcare providers, policymakers, researchers, and patients. Each stakeholder plays a critical role in advancing pharmaceutical innovation while simultaneously facing unique challenges that influence drug discovery, regulatory

compliance, market access, financial sustainability and healthcare outcomes. Despite pharmaceutical R&D being one of the most heavily invested sectors globally, the industry continues to struggle with low research efficiency, financial constraints, regulatory complexities, and ethical dilemmas (Schuhmacher et al., 2016).

The traditional pharmaceutical R&D model, historically dominated by vertically integrated firms that manage the entire drug development process, has evolved into a fragmented "relay race" system where various stakeholders, including academia, biotech firms, and large pharmaceutical companies, contribute at different stages, offering greater specialisation (Moon et al., 2022). While this multi-stakeholder approach has allowed for more diverse expertise, it has also introduced inefficiencies due to misaligned incentives, IP restrictions, exclusivity agreements and lack of transparency, which have made collaboration more difficult and increased the cost of innovation (Munos, 2009).

The self-regulatory nature of the pharmaceutical industry further complicates this landscape, as firms restrict data sharing, leading to duplication of research efforts and slower drug development (Scannell et al., 2012). Pharmaceutical companies often refrain from sharing preclinical and clinical trial data due to concerns over IP protection and competitive advantage. However, this reluctance hinders scientific progress and reduces trust in the industry. Regulatory bodies like the European Medicines Agency (EMA) and the U.S. FDA have emphasised the need for greater transparency to ensure data integrity and reproducibility (Alemayehu et al., 2014). Research suggests that open access to clinical trial data facilitates better decision-making in drug approvals and post-market surveillance, improving overall healthcare outcomes (Orsini et al., 2020). Despite commitments to enhance clinical trial transparency, many pharmaceutical companies selectively disclose positive findings while withholding negative results, contributing to publication bias and research inefficiencies (Doshi & Jefferson, 2013). The AllTrials initiative has pushed for mandatory registration and full reporting of all past and present clinical trials, yet compliance remains inconsistent, with many companies failing to disclose complete data sets (Goldacre, 2012). These practices distort regulatory decision-making, delay patient access to reliable treatments, and create barriers to effective collaboration among stakeholders (Alemayehu et al., 2014).

Beyond clinical trials, pricing and cost transparency remain significant concerns. Many pharmaceutical companies employ opaque pricing strategies, making it difficult for regulators, healthcare systems, and patients to assess the true value of therapies. Scannell has highlighted that undisclosed R&D costs further contribute to the lack of transparency, ultimately eroding trust between pharmaceutical firms and healthcare stakeholders (Scannell, 2023). To address this issue, experts have called for mandatory R&D disclosures, which would provide a clearer picture of the financial investments required for drug development and justify pricing models (Rathee et al., 2025).

While public-private partnerships, collaborative research initiatives, and industry-led transparency efforts aim to address these inefficiencies, self-regulation alone has proven insufficient. Regulatory intervention is often necessary to enforce compliance with transparency standards, for example; standardise data-sharing, ensure financial accountability and promote fair access to research findings (Britain's Health Data Initiative, 2025). Expanding mandatory disclosure frameworks and adopting blockchain-based tracking systems in pharmaceutical supply chains could improve transparency while ensuring compliance with industry standards (Alemayehu et al., 2014).

Different stakeholders hold diverse opinions on transparency in pharmaceutical R&D. Research on web-based pharmaceutical knowledge platforms suggests that independent third-party validation of industry data helps improve credibility. Most respondents favoured regulatory oversight of industry-reported environmental and clinical data, as it helps reduce bias and strengthen trust in the research process (Linder et al., 2023). Transparency initiatives such as data registries, third-party audits, and mandatory disclosure of clinical trial results have been proposed to strengthen stakeholder confidence. While some pharmaceutical companies have voluntarily adopted transparency measures, such as publishing detailed trial results in open-access repositories, systemic changes are still needed to align industry practices with stakeholder expectations (Cobey et al., 2024). Building trust in the pharmaceutical industry requires a multi-faceted approach, including clinical trial transparency, pricing clarity, data-sharing agreements, and independent validation of reported findings. Regulatory frameworks and industry-wide transparency initiatives play a crucial role in fostering public trust and collaboration. However, to ensure lasting improvements, a culture shift toward openness and accountability among all stakeholders is necessary (Prinz et al., 2011).

A key barrier in this fragmented system is the issue of trust and transparency. Many pharmaceutical firms refrain from openly sharing preclinical and clinical data, fearing that competitors might gain a market advantage. This lack of transparency discourages cross-sector collaboration and reduces the efficiency of public-private partnerships (Scannell et al., 2012). Research on self-regulation in the pharmaceutical industry highlights that opaque pricing strategies and undisclosed R&D costs further reduce trust among stakeholders, making collaborative drug development less efficient (Scannell, 2023).

While IP protection is essential for incentivising innovation, it also introduces notable challenges within the research-based pharmaceutical ecosystem. Patents, in particular, are intended to reward risk-taking by granting temporary market exclusivity; however, they can also act as barriers when overly broad claims or strategic "evergreening" tactics, such as patenting minor changes to existing drugs to extend exclusivity, are used to delay generic competition entry (Gambardella et al., 2008; OECD, 2018). These practices contribute to growing patent complexity and the formation of patent thickets, which are dense collections of overlapping patents surrounding a single product, and can hinder drug development and increase the risk of unintentional infringement, even for leading firms (Gurgula, 2017). Managing expansive patent portfolios also demands considerable legal and administrative

resources, diverting attention from core R&D activities (WIPO, 2022). For Small to Medium-sized Enterprises and academic institutions, the high cost and complexity of navigating patent systems can limit their ability to protect and commercialise innovations (WIPO, 2022). Additionally, an overemphasis on IP protection may discourage open collaboration, reducing access to shared knowledge and lowering the overall efficiency of innovation ecosystems (Linder et al., 2023; Scannell et al., 2012). These issues highlight the need for a more balanced and transparent IP framework, one that protects innovators' rights while supporting fair competition and fostering collaboration across sectors (EFPIA, 2024b).

Moreover, the high-risk nature of pharmaceutical R&D, combined with investor pressure for short-term financial returns, has driven pharmaceutical firms toward Mergers and Acquisitions (M&A) rather than investing in long-term, high-risk drug development (Moon et al., 2022). A study on M&A trends in the pharmaceutical sector found that between 2000 and 2020, over 60 per cent of large pharmaceutical firms opted for acquisitions over internal R&D expansion, largely due to the uncertainty of early-stage drug development (Danzon, 2007). While M&A strategies allow companies to quickly expand their drug pipelines, they often disrupt long-term research and shift focus away from breakthrough innovations (LaMattina, 2011).

Despite these challenges, public-private partnerships and alternative incentive models have emerged as potential solutions to counteract R&D inefficiencies. Organisations such as the GHIT Fund and the Innovative Medicines Initiative have demonstrated that collaborative models can reduce R&D risks while ensuring innovation remains financially viable (Munos, 2009). However, without policy reforms to address IP barriers and improve transparency, the full potential of multi-stakeholder collaboration remains unrealized (Scannell, 2023).

One of the primary challenges for the companies and investors in the research-based pharmaceutical ecosystem is the sustainability of the industry's R&D model due to rising investor expectations for a fair return on investment. While pharmaceutical companies allocate substantial financial resources to R&D, the number of New Molecular Entities (NMEs) approved and commercialised often fails to justify these enormous expenditures (Schuhmacher et al., 2016). The pharmaceutical industry, as a whole, has struggled to achieve the expected output of 2 to 3 NMEs per year per company, a benchmark necessary to sustain innovation-driven growth. This imbalance between R&D spending and drug approvals raises concerns regarding the long-term viability of traditional R&D models, compelling companies to explore alternative strategies such as M&As, external partnerships, and cost-cutting measures such as divesting from non-profitable or insignificant markets to maintain competitiveness (Schuhmacher et al., 2016).

The research-based pharmaceutical industry faces notoriously low success rates in drug development, with only a small fraction of drug candidates successfully progressing from early research to market approval. According to Centre for Medicines Research (CMR) International's Pharmaceutical R&D Factbook, the overall success rate from initial testing

to market approval in 2014 was only 4.9 per cent (CMR International, 2014), reflecting significant attrition at various development stages. Similarly, Paul et al. (2010) estimated the probability of technical and regulatory success at just 4.1 per cent, reinforcing the high-risk nature of pharmaceutical R&D. Recent analyses of 14 leading research-based pharmaceutical companies from 2018 to 2022 indicate that average success rates increased to 10.8 per cent (Roland et al., 2024), while a broader study of 18 companies from 2006 to 2022 found that the average likelihood of first approval rate increased to 14.3 per cent by 2022 (Schuhmacher et al., 2025). Even though these figures are higher than a decade ago, they still highlight the significant financial and scientific risks involved in bringing a new drug to market.

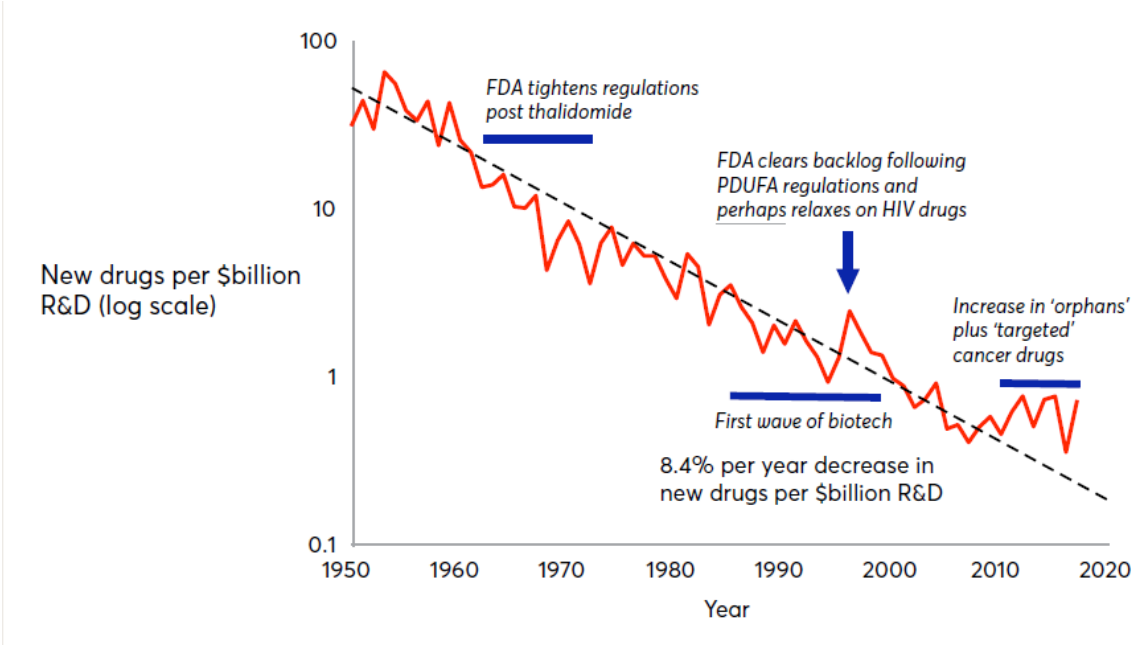
Among the factors driving these high attrition rates, one of the most pressing concerns is the questionable reliability of published preclinical data. Research suggests that a significant portion of preclinical drug discovery data is not reproducible, with only 20 to 25 per cent of published drug targets being fully validated when tested in an industrial setting. Up to two-thirds of drug development projects were terminated solely due to inconsistencies between published and in-house data. The research believes that academic findings tend to favour positive outcomes, as they are more likely to be accepted by high-impact journals. This selective publication potentially contributes to scepticism toward the reliability of academic research (Prinz et al., 2011). Another large-scale study confirms the reproducibility crisis, reporting that 72 per cent of biomedical researchers believe there is a reproducibility crisis in their field, with 27 per cent of them consider it a critical issue (Cobey et al., 2024). Many researchers attribute this crisis to the "publish or perish" culture, which prioritizes publishing novel, positive findings over replicating existing research. A journalist found that 62 per cent of surveyed scientists identified pressure to publish as a key driver of poor reproducibility, arguing that career advancement incentives encourage selective reporting, data manipulation, and a lack of rigorous replication studies. This ongoing crisis raises concerns for pharmaceutical R&D, as unreliable preclinical data can lead to costly failures in later clinical development stages (Coddington, 2025).

Since the year 2010 the pharmaceutical industry has observed a notable increase in the number of new drug approvals. For instance, between 2010 and 2019, the average annual approval rate was 38 new drugs, marking a 60 per cent rise compared to the previous decade (Congressional Budget Office, 2021). However, this uptick may not signify a genuine improvement in R&D efficiency. A comprehensive study by Fernand et al. (2024) argues that such increases are transient, influenced by factors like reduced regulatory thresholds and a strategic pivot towards high-risk, high-reward projects. Namely, despite implementing strategies such as public-private partnerships, open innovation and the integration of advanced technologies like AI, the industry continues to experience a decline in R&D efficiency. Consequently, the aforementioned surge in drug approvals may be a temporary anomaly rather than an indication of sustained R&D efficiency.

This persistent downturn aligns with Eroom's Law, which describes the long-term decline in pharmaceutical R&D efficiency. It talks about how despite significant technological advancements, the cost and time required to develop new drugs have continued to rise while success rates have steadily declined (Scannell et al., 2012). Named as the reverse of Moore's Law, which predicts exponential improvements in computational power, Eroom's Law states that the number of new drugs approved per billion dollars of inflation-adjusted R&D spending halves approximately every nine years since 1950, reflecting an 80-fold decrease in inflation-adjusted terms (Van Norman, 2017).

Figure 2 visually represents this decline, showing the consistent downward trend in R&D efficiency over the decades. The graph highlights how fewer new drugs are being produced per billion dollars spent, despite ongoing investments in drug development and higher approval rates. Key regulatory changes, such as FDA tightening regulations post-thalidomide and the first wave of biotech innovations, are marked along the timeline, demonstrating how policy shifts and scientific advancements have influenced, but not reversed, the overall decline. The temporary rise in approvals following Prescription Drug User Fee Act regulations and Human Immunodeficiency Virus drug policies suggests that short-term regulatory relaxations can momentarily improve efficiency, but the overarching trend remains downward (Jones & Wilsdon, 2018).

Figure 2: Eroom's law: Declining efficiency in pharmaceutical R&D from 1950 to 2020.



Source: Jones & Wilsdon (2018, p.27).

This decline is attributed to several structural challenges, including regulatory burdens, target exhaustion, and the shift toward high-risk, high-reward therapies (Scannell, 2023).

Industry efforts to counteract Eroom's Law have included public-private partnerships, biotech collaborations, and adaptive clinical trials, yet these strategies have not fundamentally reversed the downward trend (Scannell, 2023). The growing focus on specialty drugs and precision medicine has further increased R&D costs, as these therapies require more extensive clinical validation and targeted patient populations, limiting their scalability (Van Norman, 2017). Ultimately, unless systemic changes are made to optimize drug discovery, reform regulatory pathways, and improve investment strategies, Eroom's Law is expected to continue shaping the pharmaceutical landscape for years to come.

Additionally, regulatory approval itself poses additional challenges that affect a broad spectrum of stakeholders. Fragmented cooperation between national and European regulatory bodies introduces procedural redundancies and legal uncertainties, particularly for complex products such as ATMPs. Stakeholders involved in development face administrative burdens tied to inconsistencies across jurisdictions, especially in areas requiring additional oversight, such as those involving genetically modified organisms. The limited and often non-continuous involvement of stakeholders throughout the product lifecycle further complicates regulatory navigation. These issues delay market entry, reduce predictability, and constrain the efficient delivery of therapies to patients (Hines et al., 2020).

Beyond regulatory approval, HTA has emerged as a significant bottleneck within the research-based pharmaceutical ecosystem, particularly in the European context. The lack of coordination in HTA and pricing procedures across EU Member States creates major barriers to equitable patient access and introduces inefficiencies for pharmaceutical stakeholders. Misalignment between national systems leads to redundancies in evaluation processes and delays in the adoption of advanced therapies. There is a recognised need for harmonised HTA approaches and innovative payment models that can support equal access to novel treatments across Member States. At the same time, existing assessment frameworks are described as conservative and underdeveloped, particularly in the context of ATMPs, limiting their diffusion and uptake (Fischer et al., 2023)

As HTAs grow in importance across healthcare systems, outcomes research has become a central requirement for demonstrating the broader value of new pharmaceutical products. Rather than focusing solely on efficacy and safety, HTA bodies increasingly rely on evidence that captures therapeutic benefits, side effects, patient-reported outcomes and the broader economic impact on healthcare systems. For research-based pharmaceutical companies, this creates a significant challenge: they must not only develop innovative treatments but also produce diverse forms of data that meet the expectations of national payers and regulatory authorities. These demands influence both market access strategies and reimbursement prospects (Rosenkranz, 2024).

However, the complexity and fragmentation of HTA processes continue to contribute to substantial delays in patient access to innovative treatments. Pharmaceutical companies must meet diverse national criteria to demonstrate added value over existing therapies, often under

inconsistent and time-consuming review systems. While Real-World Evidence (RWE) holds promise for bridging data gaps and enabling more patient-centred and cost-effective decisions, HTA bodies remain hesitant to accept RWE due to methodological concerns. This disconnect not only slows access for patients but also undermines efficiency across the system. Recent EU-level initiatives, such as the Joint Clinical Assessment (JCA), seek to harmonise HTA processes, reduce duplication, and improve coordination among stakeholders, thereby accelerating access to innovative therapies across Europe (Pugeat et al., 2025), although some phases of HTA are still being handled within the national domain (European Commission, 2023a).

In parallel to these HTA-related barriers, stakeholders encounter additional complexities during the pricing and reimbursement phase. Manufacturers face strategic delays in launching products in lower-priced markets due to the influence of external price referencing, which can discourage early entry. While value-based pricing has been promoted as a tool to balance innovation and affordability, its implementation remains difficult, creating uncertainty for both industry and payers. Managed-entry agreements are increasingly adopted to manage risks and expedite market access for high-cost medicines, especially where clinical evidence is limited. However, their confidential nature undermines transparency and trust, particularly for regulators and patients. The absence of comprehensive impact assessments and the opacity surrounding negotiated discounts further limit the system's accountability. As a result, both public authorities and pharmaceutical developers operate within a fragmented and often inefficient reimbursement environment, affecting timely access to therapies and sustainable pricing models (Vogler et al., 2017).

4 ANALYSIS OF MULTI-STAKEHOLDER PERCEPTIONS ABOUT THE BUSINESS ENVIRONMENT OF RESEARCH-BASED PHARMACEUTICAL COMPANIES IN SLOVENIA

4.1 Data and methodology

4.1.1 Data collection

The research questions have been developed through a combination of the literature review presented in Chapters Two and Three, expert consultations and industry discussions. These research questions call for an in-depth description and evaluation of the landscape, stakeholder opinions, and underlying reasoning, thus requiring a qualitative approach. A qualitative method is more suitable than a quantitative approach for researching complex, context-driven topics like the one in this thesis, or when participants' personal viewpoints are crucial, because it allows for a deeper exploration of individual experiences, opinions, and motivations. Interviews are selected because they provide rich, nuanced data that

uncover underlying issues, such as challenges faced by stakeholders, which might not be captured through structured, quantitative surveys (Corbin & Strauss, 2008).

The thesis employed semi-structured in-depth interviews. Semi-structured in-depth interviews are guided conversations with open-ended questions, which enable investigation of the perceptions of multiple stakeholders about the posed research questions, while at the same time allowing flexibility and adaptability in questioning in order to explore topics in detail while maintaining a focused framework (Salomão, 2023). Therefore, semi-structured interviews offer a balance between structured and open-ended questioning, enabling the researcher to delve deeper into the participants' responses and explore unexpected topics or nuances that arise during the conversation (Salomão, 2023).

To develop interview questions, initial interview topics have been identified based on existing research and refined through input from academic experts. The final set of interview questions is shaped through several rounds of feedback from representatives of research-based pharmaceutical companies, including a structured round table session. This process ensures alignment of topics with both academic priorities and real-world industry concerns. The finalised interview questions, including potential sub-questions, are tailored to each stakeholder group and are provided in Appendix 1 for company representatives and Appendix 2 for other relevant stakeholders.

To select interview participants, a purposive sampling technique was employed, specifically the maximum variation sampling method. This technique is designed to ensure inclusion of individuals with diverse perspectives relevant to the research topic. Maximum variation sampling focuses on selecting participants who differ in key attributes, in our case their roles within the research-based pharmaceutical ecosystem. In doing so, it ensures the collection of rich and comprehensive data, which enables identification of common themes across a variety of perspectives, revealing patterns. Lastly, it enhances the credibility of the findings through a wide range of experiences and viewpoints. By employing maximum variation sampling, this thesis aims to capture a comprehensive understanding of the multifaceted landscape of pharmaceutical and healthcare sector (Rai & Thapa, 2015).

The research-based pharmaceutical ecosystem in Slovenia encompasses a wide range of stakeholders whose roles collectively shape the environment in which innovative medicines are developed, assessed and delivered. These stakeholders include research-based pharmaceutical companies, healthcare providers, patients and public institutions involved in the organisation, regulation, evaluation, and financing of the healthcare system. While all these actors contribute to the broader system, this thesis focuses more narrowly on those directly involved in shaping the regulatory and policy environment for research-based pharmaceutical companies.

Accordingly, the interview sample is purposefully limited to two stakeholder groups with direct influence on or engagement with policy and regulatory decisions related to the

research-based pharmaceutical ecosystem. The first stakeholder group includes representatives from research-based pharmaceutical companies, all of whom held leadership positions at various levels within their organisations. These individuals are chosen for their direct involvement in the strategic decision-making and operations of the company. In cases where the company's presence in Slovenia extends beyond research-based activities, interviewees are explicitly instructed to focus solely on the research aspect of the business, disregarding other areas such as production.

The second stakeholder group includes other key stakeholders, namely regulators, payers, and representatives from relevant agencies and associations The selected interviewees provide diverse insights into the regulatory, policy and financial landscapes that shape the business environment for research-based pharmaceutical companies in Slovenia.

The decision to concentrate on these particular stakeholder groups was made to ensure the thesis remained closely aligned with the regulatory and institutional dynamics affecting the business environment. As a result, stakeholders such as hospitals, healthcare providers, and patients are intentionally excluded. While their perspectives are important within the broader healthcare system, this thesis prioritises the relationships and interactions between research-based pharmaceutical companies and the institutions that influence their operational landscape in Slovenia.

The number of interviewees was guided by the principle of thematic saturation, the point at which additional interviews no longer yield new insights. In this case, after approximately four to five interviews within each stakeholder group, recurring patterns began to emerge, and the responses became increasingly consistent. This indicated that the sample was sufficient to capture the key themes relevant to the research questions.

In total, 16 semi-structured interviews were conducted. These included nine research-based pharmaceutical companies and five other relevant stakeholders, with two of the companies having two interviewees each, as seen in Table 1. To ensure the integrity of the responses and protect participants from any potential repercussions, the identities of the companies, stakeholder organisations, and individual interviewees remain confidential. For confidentiality reasons, the sizes of stakeholder organisations are not disclosed, as this information could compromise their anonymity. This approach allows participants to express their views openly without fear of negative consequences arising from their involvement or the opinions they have shared. To further control disclosure, each interviewee has been assigned a unique code or identifier, which is used to reference them and mark their quotes throughout the thesis.

The duration of these interviews varied between 40 and 75 minutes and took place over a two-week period, from August 28 to September 10, 2024. The interviews were held either in person or through online platforms, depending on the availability and preferences of the

participants. All interview transcripts and participant authorisations are in the possession of the author and available upon request for legitimate purposes.

Table 1: Interviewees from research-based pharmaceutical subsidiaries and other stakeholder organisations

Organisation	Type	Size*	Code
Company 1	Multinational enterprise subsidiary	Medium & Large	CR1-1
			CR1-2
Company 2	Multinational enterprise subsidiary	Micro & Small	CR2
Company 3	Multinational enterprise subsidiary	Medium & Large	CR3
Company 4	Multinational enterprise subsidiary	Micro & Small	CR4
Company 5	Multinational enterprise subsidiary	Medium & Large	CR5-1
			CR5-2
Company 6	Multinational enterprise subsidiary	Micro & Small	CR6
Company 7	Multinational enterprise subsidiary	Medium & Large	CR7
Company 8	Multinational enterprise subsidiary	Medium & Large	CR8
Company 9	Multinational enterprise subsidiary	Micro & Small	CR9
Stakeholder 1	Public body		SH1
Stakeholder 2	Government sector		SH2
Stakeholder 3	Nonprofit Association		SH3
Stakeholder 4	Public body		SH4
Stakeholder 5	Government sector		SH5

**Micro & Small: less than 50 employees in Slovenia, Medium & Large: 50 or more employees in Slovenia.*
Source: Own work.

4.1.2 Data analysis

A preliminary study[1] on this topic has already been conducted and published, offering an initial overview of stakeholder perspectives (Kovač et al., 2024). This thesis builds on that foundation by expanding and deepening the literature review, providing detailed argumentation for methodological decisions and applying a more comprehensive and in-depth analysis of the full data.

The analysis of the interview data follows a combined deductive–inductive approach. An initial set of codes is developed based on the literature review, presented in the previous chapters, and used to inform the structure of the interview guide. This deductive foundation helps ensure alignment between the research questions and the data collection process. However, as the analysis progresses, new insights emerging from the interview material led

[1] The preliminary study was a collaborative effort by three students and two mentors, conducted as part of the broader project Engineering the Industrial Transformation (Domadenik Muren, et al., 2024). The interviews and their transcription were carried out during this study. Its findings provide a broad orientation but are limited in scope compared to the more comprehensive analysis developed in this thesis.

to the refinement of the coding structure, incorporating inductive elements and allowing the final set of codes to better reflect the lived experiences and perspectives of participants.

All 16 semi-structured interviews are transcribed by the author. Given the bilingual nature of the data, certain transcripts require slight modifications to ensure clarity and consistency, particularly in cases where participants use slang, dialect or jargon in Slovenian or English. The transcripts are analysed using QDA Miner Lite, a computer-assisted qualitative data analysis tool, in combination with Microsoft Word. Although generative AI tools are considered during the early stages of the project, they are ultimately not used due to concerns regarding reliability, interpretability and control over the coding process.

The analysis begins with multiple rounds of close reading and coding. The coding process involves assigning short, descriptive codes to manually identify meaningful excerpts in the transcripts. These codes are then reviewed across all interviews to identify recurring patterns and divergent viewpoints across stakeholder groups. Where recurring ideas are identified, related codes are grouped into broader categories that capture common topics or issues. These categories are then aligned with the thesis' research questions and structured into thematic areas, which form the basis for presenting the findings. This layered process enables the transition from individual quotations to generalisable insights while preserving the nuances of stakeholder perspectives.

To ensure consistency and transparency, each transcript is reviewed multiple times and is applied the coding structure systematically across interviews. Codes and categories are refined iteratively during the analysis, allowing for gradual adjustment as patterns and themes become clearer. This ongoing process helps maintain analytical rigour while ensuring that the findings remain grounded in the data.

To explore stakeholder perceptions of the value-added of the presence of research-based pharmaceutical companies in Slovenia, the analysis is based on codes such as access to medicines, early market access, patient care quality, medical innovation and public health outcomes. Economic and systemic contributions are captured through codes such as tax contributions, community investment and employment multiplier, while broader impacts on knowledge and talent development are reflected in codes such as academic collaboration, career development and knowledge transfer to the public sector. These codes serve as the analytical foundation for identifying how stakeholders perceive the multifaceted contributions of these companies to the healthcare system, economy and broader society.

To examine how stakeholders perceive the current business environment and operational conditions for research-based pharmaceutical companies in Slovenia, the analysis incorporates codes such as bureaucratic barriers, regulatory inefficiencies, market access barriers and lengthy drug approvals, which highlight systemic challenges affecting day-to-day operations. Economic and workforce-related constraints are reflected in codes such as labour cost challenges, specialised talent shortage and recruitment challenges. The analysis

also considers strategic and structural concerns, including misaligned financial incentives, commitment to Slovenia and long-term presence concerns, as well as barriers related to digital transformation and the limited use of health data. Together, these codes provide a foundation for understanding the complex interplay between regulatory, economic and organisational factors shaping the business environment for research-based pharmaceutical companies in Slovenia. National Institute of Public Health of the Republic of Slovenia (NIPH)

To analyse stakeholder perceptions of collaboration within Slovenia's research-based pharmaceutical ecosystem, the analysis applies a range of codes reflecting both positive and challenging aspects of interaction. Examples of cooperation are captured through codes such as positive academic collaboration and Pharma Forum collaboration. At the same time, several codes address institutional and procedural aspects, including public sector disengagement, limited direct ministry engagement, and lengthy HIIS-related processes. Issues related to information flows are coded under lengthy National Institute of Public Health of the Republic of Slovenia (NIPH) data access and one-sided communication. Relational aspects are reflected in codes such as reduced industry policy influence, collaboration limitations due to trust, and public perception as barrier to collaboration, while industry perceived as profit-driven highlights reputational elements raised by participants. These codes provide the structure for examining different dimensions of stakeholder collaboration.

To assess stakeholder views on Slovenia's potential to develop into a regional hub for research-based pharmaceutical activity, the analysis incorporates codes such as clinical trial expansion, investment incentive improvement and stable business environment, which point to conditions considered important for growth. Other codes, such as small market size as obstacle and transport infrastructure gaps, reflect potential structural limitations. Further codes capture suggestions related to cross-border public–private initiatives, simplified hiring procedures and structured stakeholder collaboration, as well as company inclusion in decision-making. Digital and data-related aspects are also coded, including data structure enhancement, disease-specific digital registries and medicine value assessment improvement. In addition, codes such as perception of foreign companies highlight reputational factors relevant to stakeholder views.

4.2 Results

In this section, the results are presented according to the four research questions guiding the thesis. Each addresses a distinct element of the research-based pharmaceutical ecosystem in Slovenia.

4.2.1 Value-added of the presence of research-based pharmaceutical companies in Slovenia

The presence of research-based pharmaceutical companies in Slovenia has the potential to generate value across several areas of national interest, while also creating positive spill-over effects that benefit adjacent sectors. One interviewee speaks about the broad impact of these companies, describing them as *"an essential part of Slovenia's healthcare system, development, progress, and accessibility of medicines and information. It ensures that Slovenian patients receive better care"* (CR7).

Several others emphasise that the presence of research-based pharmaceutical subsidiaries in Slovenia plays a key role in enhancing the national healthcare system and improving patients' quality of life. This is achieved in part through improved access to medicines. One respondent illustrates this impact by stating, *"We bring better access to medicines in this country, earlier entry of medicines to the market and greater stability in terms of avoiding shortages"* (CR6). This perception reflects broader trends in the pharmaceutical sector, where companies with strong local infrastructures and regulatory expertise are better positioned to navigate approval procedures efficiently (Scannell, 2023). Moreover, research-based companies contribute to earlier patient access through ongoing innovation and accelerated clinical development pathways, particularly when operating in favourable regulatory and business environments (DiMasi et al., 2016). There is some disagreement between non-industry stakeholders whether the physical presence of research-based pharmaceutical company's branches in Slovenia contributes to early access to new medicine. Some argue that local presence does not necessarily expedite drug availability. As one notes, *"It's not necessarily the case that medicines arrive earlier in Slovenia just because companies have subsidiaries here; I don't believe there's a strong direct correlation"* (SH4). Another adds that *"local subsidiaries do not directly accelerate the entry of a medicine to the market, but they do help emphasise Slovenia's importance to the company's headquarters"* (SH3). On the other hand, some believe that having these branches present directly enhances Slovenia's access to important medicines. One interviewee states that *"their presence is a positive thing for Slovenia so that we get access to important medicines more quickly. It is beneficial in the sense that a small country like ours doesn't rely solely on generics, but also has access to innovative medicines"* (SH5). Although stakeholder perceptions vary, evidence suggests that the physical presence of a company subsidiary in a country like Slovenia does not directly lead to faster market access for new medicines, as delays are more often driven by systemic factors such as national pricing negotiations, HTA timelines, and budget limitations rather than company location (Vogler et al., 2017). Nonetheless, subsidiaries may play an indirect role by facilitating communication with national authorities, improving the alignment of local market needs with corporate strategies, and signalling strategic relevance to the company's global headquarters (EFPIA, 2022a).

Furthermore, this previously mentioned indirect role of the local physical presence of companies was also touched upon by the interviewees. One non-industry stakeholder

explains that such a presence signals the country's relevance to the global pharmaceutical industry, stating that *"Their presence is a guarantee that the manufacturer recognises Slovenia as a market"* (SH3). Another highlights the reputational value this brings, noting that *"It says something about Slovenia's reputation that such companies are present here. It is extremely important to us that Slovenia remains attractive to global innovation leaders"* (SH2).

Another way research-based pharmaceutical companies are perceived to enhance Slovenia's healthcare system is through the early introduction of new, innovative treatments and technologies. Their presence in the country is seen as a key contributor in ensuring that patients gain faster access to the latest therapies, particularly for conditions that previously lacked adequate treatment options. As a company representative explains, they *"aim to provide Slovenian patients with innovative medicines as early as possible for diseases that still lack treatment options, thereby extending and improving lives"* (CR5-1). Access to medicine is considered as well-developed, particularly in terms of early access to new medicines and preventive care, with one interviewee noting that Slovenia currently ranks among the top ten European countries in early access to medicines (CR1-1) at the time of the interviews. While this reflects a positive perception of Slovenia's performance in medicine access, data from the 2023 EFPIA Patients Waiting to Access Innovative Therapies (W.A.I.T.) Indicator shows a more nuanced picture. According to the report, Slovenia had an average time of 563 days from central EMA approval to patient availability for newly authorised medicines, placing it just below the European average of 531 days. Although Slovenia remains in a competitive position relative to some nearby Central and Eastern Europe (CEE) countries, such as Romania (778 days), Poland (804 days) and Serbia (615 days), this figure suggests that access timelines may not be as advanced as perceived and continue to vary across therapeutic areas and products (EFPIA, 2024a). This highlights the important role that research-based pharmaceutical companies can play in supporting earlier access through timely market entry, transparent pricing practices, and transparent collaboration with health authorities, thereby contributing to improving Slovenia's position in future access benchmarks (Access to Medicine Foundation, 2020). Another respondent emphasises that these companies *"offer solutions for problems that don't yet have solutions, extending life, making innovative treatments accessible and addressing unmet medical needs"* (CR9). This is further supported by examples such as Ozempic, a Glucagon Like Peptide (GLP-1) receptor agonist developed by Novo Nordisk, which is available in Slovenia and addresses unmet medical needs in the treatment of type 2 diabetes by improving glycaemic control and offering additional benefits such as weight reduction, particularly important for patients with limited therapeutic options (Stević et al., 2024).

Non-industry stakeholders express varied opinions on the value and pricing of innovations brought by research-based pharmaceutical companies. Some believe that these companies are essential for developing treatments, especially for rare and genetic diseases where generic alternatives are not possible. This view is reflected in one non-industry stakeholder's

comment, *"They are crucial for treating the population, especially in the case of rare and genetic diseases, where generics cannot even exist. Without innovative pharmaceutical companies, the population could not survive"* (SH5). This perspective is supported by research, which highlights that innovative therapies for rare diseases would not be possible without sustained investment in research (Runge et al., 2024). Opposingly, others argue that the innovations introduced by the research-based pharmaceutical industry are mostly incremental and do not always justify their high prices. As one non-industry stakeholder observes, *"I believe these companies make small improvements to existing medicines on the market, but they demand prices that are 10 per cent higher"* (SH4). This concern is reflected in research that questions the relationship between small improvements in medicines and the rising cost of drugs. For example, one study discusses the potential benefits of incremental pharmaceutical innovations, such as better quality or convenience for patients, but also notes that the higher prices are not always supported by the actual added value (Yin, 2023).

Additionally, interviewees from non-industry stakeholder organisations emphasise the substantial impact that research-based pharma companies have had on medical advancements in Slovenia over the past few decades. One notes, *"The contribution of research-based pharmaceuticals to medical progress over the past 40 years has been enormous; they are an irreplaceable part of that progress"* (SH3). This perspective aligns with data from the EFPIA, which highlights that the innovative pharmaceutical industry has significantly driven medical progress, leading to notable improvements in patient well-being across Europe (EFPIA, 2021). The same interviewee further elaborates that these companies advance science through both academic collaboration and their own research efforts, resulting in medicine products and therapies (SH3). This collaborative approach is evident in Slovenia, where institutions like University of Ljubljana engage in joint development of knowledge and innovation with pharmaceutical companies, contributing to the research of new medical technologies and thus medical progress (University of Ljubljana, 2024). However, some correspondents point out that a significant portion of medical research is conducted within public institutions, such as universities (SH4). This observation suggests that while research-based pharmaceutical companies contribute significantly to medical advancements, they are not the solely responsible for these developments.

Lastly, research-based pharmaceutical companies also contribute to the improvement of Slovenia's healthcare system through their active involvement in delivering comprehensive, high-quality care across the entire patient journey. From the initial diagnosis to final therapy and ongoing follow-up, these companies are perceived as key contributors to the continuity and effectiveness of treatment. As one respondent explains, *"We treat patients throughout the entire treatment path, from the first diagnosis to the final therapy and further monitoring"* (CR1-1), highlighting their long-term engagement in patient outcomes. One example of this approach in practice can be seen with Merck Sharp and Dohme (MSD), which has established a global model of organising expert input forums. These forums bring together healthcare professionals, including doctors, researchers, and clinical specialists, to share

practical insights and help shape the development and implementation of treatment strategies across the full care continuum. While public information about such forums specifically in Slovenia is limited, the presence of MSD's medical and regulatory experts in the country suggests a strong foundation for such collaborative efforts (MSD, 2024). Others stress the importance of the expertise and resources these companies bring, with one interviewee noting that *"we provide the best information and therapies; if research-based companies leave Slovenia, it would be a major setback for the country"* (CR7). An example of this is Bayer's Calantic Digital Solutions, a cloud-based platform that supports radiologists with AI-powered tools for faster diagnosis and workflow efficiency. By helping prioritise cases and automate key tasks, it contributes to shortening the patient journey and improving access to timely treatment (Bayer, 2022). Another interviewee reinforces the critical role of pharmaceutical innovation by stating that *"without innovative medicines, the generics industry wouldn't exist either… without innovation, we'd be left treating everything with aspirin or similar treatments. New therapies help us save lives faster and more efficiently"* (CR4). Collectively, these perspectives underline the belief that the presence of innovative pharmaceutical companies contributes not only to the availability of advanced treatments, but also to the broader infrastructure of care delivery in Slovenia.

Furthermore, analysis by the OECD in 2022 revealed that Slovenia had the highest proportion of adults aged between 25 to 64 holding a doctoral degree, with approximately 4 per cent of its population achieving this level of education (OECD, 2023a). This highly educated talent pool underscores the importance of knowledge-intensive industries, such as the research-based pharmaceutical sector, which can offer suitable employment opportunities and effectively make use of the country's highly educated human capital, as one company representative states, *"we employ only highly educated workforce"* (CR6).

The interviewees from research-based pharmaceutical companies emphasise that the industry not only offers stable and competitive job opportunities for highly educated professionals but also fosters an environment that supports continued learning and career growth. As one company representative states, *"Each employee has a personal development plan, a dedicated budget and yearly skill assessments to clearly map out what they already know and what they will need to learn in the next 5 to 10 years"* (CR1-1). Another adds, *"We offer hands-on experience, virtual learning opportunities and career development support, which includes personalised growth plans aligned with each employee's goals and aspirations"* (CR5-1). This aligns with broader research showing that research-intensive pharmaceutical companies are key drivers of knowledge-based employment and contribute significantly to the upskilling of national workforces (World Trade Organisation et al., 2013). Non-industry stakeholders, just like company representatives, also believe that the presence of these multinationals contributes to the development of Slovenia's human capital. As one non-industry stakeholder explains, *"The advantage of having large corporations here is that they invest heavily in human capital through various workshops and additional training. As a result, experts who have the opportunity to work in these companies in*

Slovenia can later pass on this knowledge to students or become involved in public institutions" (SH5).

Additionally, company representatives highlight the sector's ability to offer dynamic career paths, particularly through international work opportunities and flexible arrangements such as remote work. One interviewee remarks that *"employees have the chance to work abroad and then return with valuable international experience"* (CR7), pointing to the industry's active support for cross-border professional development. These global mobility pathways not only enhance employee expertise but also contribute to innovation diffusion across company branches and national borders. The industry's push toward open and collaborative innovation increasingly relies on culturally adaptable professionals capable of working across international networks, which in turn helps pharmaceutical firms build more resilient and interconnected R&D ecosystems (Schuhmacher et al., 2016).

Research-based pharmaceutical industry representatives believe that continuous learning is integral to employee retention and satisfaction. They note that companies increasingly invest in virtual and digital learning formats to promote both personal and professional development. One interviewee remarks, *"We believe that if you train people well, they will stay"* (CR1-1), underscoring the perceived link between training and loyalty. This view reflects broader industry trends where digital tools are being adopted to deliver scalable, flexible, and cost-effective workforce development strategies. For example, companies are using e-learning platforms, AI-driven training modules and global virtual seminars to build capabilities across diverse teams. These approaches help reduce turnover and support knowledge transfer in innovation-focused environments. Research also shows that pharmaceutical firms implementing structured development programs experience higher staff engagement and greater adaptability in fast-evolving R&D settings (Schuhmacher et al., 2016). This approach doesn't only apply for research-based pharmaceutical companies. AMPMD has also identified human resource management as a key strategic goal, emphasising the creation of a supportive working environment, clear rules, career development opportunities, and high-quality leadership to enhance employee satisfaction and retention. Their strategy includes initiatives such as health promotion, teambuilding, and training programs aimed at increasing the agency's visibility as an attractive employer (AMPMD, 2023). Moreover, addressing workforce challenges is a national priority. Events like "Tea with Reason: Solving Slovenia's Workforce Puzzle" have highlighted the need for innovative solutions in talent acquisition and retention across various sectors, including biotechnology and pharmaceuticals (British-Slovenian Chamber of Commerce, 2025).

In addition to career and personal development opportunities, most company representatives also highlight the financial benefits of working in research-based pharmaceutical companies. They note that employee compensation is strong and contributes meaningfully to the broader economy, with one interviewee stating that *"salaries are high, income taxes are high, we employ a large number of people and use local services that contribute to the country's budget"* (CR3). This perspective is supported by recent data showing that average gross

monthly salaries in Slovenia's research-based pharmaceutical sector significantly exceed the national average and the average of the generic pharmaceutical sector in Slovenia. While the national gross average salary is approximately 2,221 euros per month and the domestic gross average salary of the generic pharmaceutical sector is under 4,000 euros, the research-based pharmaceutical industry reports a gross monthly average of around 7,500 euros (The Slovenia Times, 2024). It's important to note that this calculation was based on the Slovenia Times report and that Novartis was excluded as they have both research and production facilities in Slovenia.

Beyond directly improving the financial well-being of their employees, one interviewee reveals a broader economic impact of the sector, explaining that each position at a research-based pharmaceutical company contributes to wider job creation across related industries and services: *"We provide jobs for drivers, cleaners, office building lenders, etc. Based on our estimates, each position in our company leads to the creation of five additional jobs in Slovenia"* (CR1-2). This observation aligns with a technical report from PwC, showing that the pharmaceutical sector has one of the highest employment multiplier effects among high-tech industries, owing to its interconnectedness with supply chains, contract research organisations, logistics, and healthcare services (PwC, 2019). In addition to the job multiplication, the presence of multinational firms is also seen as an opportunity for growth in local research networks. As one interviewee put it, *"The presence of multinationals brings the promise of new collaborations with domestic institutions"* (SH2).

Additionally, according to several interviewees these foreign research-based pharmaceutical companies significantly contribute to Slovenia through various forms of investment and donations. One interviewee notes, *"We invest a lot in the overall healthcare system, donate to hospitals, financially support medical education and often contribute through other forms of donations in times of need. If a pharmaceutical company has a local subsidiary here, there's much more motivation for investments and donations to the community"* (CR3). While these claims reflect stakeholder perceptions, they are supported by broader trends observed during the Coronavirus Disease (COVID-19) pandemic, when members of the Forum of International Research and Development Pharmaceutical Companies donated over €1 million in medical equipment, medicines, protective gear, and financial aid to Slovenian healthcare institutions (FarmaForum, 2021). A report by the EU executive body has also found that the presence of research-based pharmaceutical companies tends to stimulate indirect employment in sectors such as academia, information technology (IT), and regulatory consulting, further reinforcing their role as key drivers of economic growth in innovation-oriented economies (European Commission, 2022).

Another, more subtle, way research-based pharmaceutical companies are perceived to contribute to Slovenia's economy is through their impact on public health and workforce productivity. By introducing innovative therapies and promoting early diagnosis, these companies help patients recover more quickly and remain active members of the workforce for longer. As one company representative explains, *"If a patient is diagnosed earlier, they*

remain an active member of society for a longer, in this way we help shorten sick leave durations" (CR3). Beyond individual outcomes, this also addresses broader societal challenges such as population ageing, the need for preventive care, and the rising burden of chronic diseases. As another respondent puts it, *"We help address current societal challenges like an ageing population, better health, and prevention, this is how we impact Slovenia's Gross Domestic Product (GDP)"* (CR8). These perspectives suggest that improving health is not only a matter of patient well-being but also a driver of economic resilience and long-term sustainability. This link between public health and economic productivity is supported by research from Poland, which found that sickness-related absenteeism led to an estimated productivity loss of 4.33 per cent of the country's GDP in 2013, amounting to 17.09 billion euros (Genowska et al., 2017). Similarly, at the EU level, the OECD has highlighted how health system disruptions, such as delayed screenings and care, have measurable economic consequences, including reduced treatment efficiency, increased healthcare expenditure, and workforce shortages, all of which strain long-term economic stability (OECD & European Union, 2022).

Respondents from research-based pharmaceutical companies in Slovenia emphasised that their collaboration with academic institutions and involvement in education of healthcare professionals enhance the national knowledge development and healthcare practices. One interviewee described their engagement with universities in detail: *"We collaborate with universities in various ways, with professors through career centres and with students through student associations, through knowledge transfer offices, summer internships, and master's and doctoral theses"* (CR5-1), another agrees, stating, *"We regularly cooperate with universities"* (CR2). The statements are supported by a recently signed cooperation agreement between University of Ljubljana and Novartis. This strategic partnership is set to enhance cooperation with academia and contribute to the joint development of knowledge and innovation (University of Ljubljana, 2024).

In addition to their cooperation with universities, respondents from pharma companies also highlight their role in financing the continuous education of healthcare professionals in Slovenia. One interviewee notes that *"roughly two-thirds of the funding for ongoing education of doctors and healthcare staff comes from pharmaceutical companies, while the remaining third is provided by the state"* (CR2). This claim is reinforced by a report from a reputable Slovenian business news outlet, which indicated that in 2023, pharmaceutical companies in Slovenia allocated approximately 15 million euros to organisations and healthcare professionals for education, professional events, consultations and drug testing (Rednak, 2024). Company representatives describe these investments as part of a broader commitment to supporting the healthcare ecosystem, with one stating, *"a large share of our resources is dedicated to training healthcare personnel, including doctors and nurses"* (CR6) and another adding, *"we reinvest the profits we generate back into research and education of everyone involved in the healthcare ecosystem"* (CR7). Many interviewees from the companies emphasise that they not only fund the education of healthcare professionals

but also actively serve as providers of high-quality information. As one respondent explains, *"We organize local events or presentations for doctors based on global studies as part of medical education, making sure they have access to the best information and therapies. If companies leave Slovenia, it would be a major setback for the country"* (CR7), referring to the research-based pharmaceutical companies. These statements reflect a strategic effort by research-based pharmaceutical companies to foster professional development, ensure up-to-date clinical knowledge, and contribute to improved healthcare outcomes across the country. As noted in national development strategies, continuous education of healthcare professionals is a crucial pillar in building a resilient and responsive health system (AMPMD, 2023).

The topic of education for healthcare professionals is perceived very differently by various stakeholders. While company representatives primarily frame it as a contribution to professional development of doctors, non-industry stakeholders raise concerns about its potential use as a marketing tool. Some interviewees express strong criticism, suggesting that such initiatives may blur the line between education and promotion. One non-industry stakeholder cautions, "*I think their marketing is very negative, visiting doctors and so on. The education of doctors is excessive, how much education is reasonable and how much is too much? There are personal interests involved and concerns about corruption"* (SH4). In contrast, others view the situation more favourably, assuring that current safeguards are sufficient to prevent undue influence, such as corruption or inappropriate lobbying. As a non-industry stakeholder explains, *"When it comes to educating doctors, it's a bit of both, education and marketing. We are glad that the industry invests in medical education. Ultimately, it is the hospital that decides which doctor will attend the training. This is not about corruption; it's a positive approach. What's essential is the integrity of doctors and healthcare institutions"* (SH3). The same interviewee also points to a structural challenge limiting public-sector involvement in professional development of healthcare professionals, stating, *"In Slovenia, scholarships are taxed as income, which makes it difficult for hospitals to finance doctors' education"* (SH3), emphasising the continued need for industry support in this area.

Interviewees from pharmaceutical companies also believe that the industry plays a pivotal role in enhancing patient awareness in Slovenia through the sponsorship of health campaigns. As one interviewee notes, *"Most awareness campaigns are sponsored by pharmaceutical companies"* (CR3). This claim aligns with broader international trends where pharmaceutical firms fund and organize numerous health awareness initiatives. A systematic review found that between 20 and 83 per cent of patient organisations receive funding from the pharmaceutical industry, highlighting widespread commercial involvement in awareness activities (Fabbri et al., 2020). A relevant example that garnered public attention in Slovenia involves Team Novo Nordisk, a global professional cycling team comprised entirely of athletes with type 1 diabetes, established in partnership with the Danish pharmaceutical company Novo Nordisk. The team not only competes internationally but also

promotes diabetes awareness, aiming to inspire and educate the public about living actively with diabetes (Team Novo Nordisk, n.d.). Although the team is global, Slovenian media outlets have reported on its mission and local relevance, particularly when the team participated in regional competitions or campaigns (Slovenska tiskovna agencija, 2019). These examples illustrate the significant contributions that research-based pharmaceutical companies make to patient awareness efforts. At the same time, they underscore the importance of transparency to ensure that public health messaging remains unbiased and rooted in patient interests.

The presence of foreign research-based pharmaceutical companies in Slovenia contributes significantly to the country's competitiveness by introducing innovative practices, advanced technologies, and specialized expertise. As one interviewee states, *"Because we are a foreign company, we bring in foreign, new ideas for improvement"* (CR8). These companies frequently act as conduits for the transfer of international best practices, particularly in digitalization and AI, areas where local capacity remains in development. As another representative explains, *"We bring new talent from other countries to help fill the Slovenian gap, for example in the AI department"* and *"Rather than building physical infrastructure, we focus on building digital infrastructure to support the future digitalization"* (CR1-1). Slovenia's ambition to strengthen its digital capabilities is evident in its Strategy for the Digital Transformation of the Economy, which outlines the goal of becoming one of Europe's top three countries in the use of advanced digital technologies by 2030, including in AI and data analytics (Ministry of Economy, Tourism and Sport, 2022). In healthcare specifically, the Slovenia: Health System Summary 2024 stresses the need for accelerated digitalisation to improve care coordination, reduce waiting times, and enhance patient-centred services (Polin et al., 2024). However, challenges persist: insufficient integration of hospital information systems, lack of a national framework for certifying eHealth applications, and limited public Application Programming Interfaces impede full digital transformation (Bajrić, 2023). This underscores the potential of research-based pharmaceutical companies to serve as catalysts for digital advancement in the healthcare system, not only by investing in technology, but also by introducing global digital solutions and capability-building strategies aligned with Slovenia's strategic objectives.

When non-industry stakeholders are asked about what they believe would happen if research-based pharmaceutical companies were to leave Slovenia, several key concerns emerge. One of the most frequently mentioned consequences is the potential impact on access to innovative medicines. As one interviewee points out, *"If research-based companies were to leave, we would likely lose access to certain innovative medicines. There are already difficulties in obtaining some specific drugs that have no representation in Slovenia"* (SH3). Others focus more on the human capital implications, expressing concern that their divestment would worsen the already significant brain drain. One stresses, *"It would be a great minus if they left due to the loss of highly educated professionals, it would only worsen the existing brain drain. These companies are relatively competitive in terms of*

salaries, and without them, even more talent would leave Slovenia" (SH5). This same interviewee also highlights the broader, less tangible contributions of these companies to the national innovation ecosystem, stating that *"These conglomerates also bring a different way of thinking into our system, so their contribution is not just in innovative approaches and top-level science, but also in developing new perspectives. Their presence makes Slovenia more competitive"* (SH5). However, not all non-industry stakeholders view local physical presence as essential. Some emphasise that what matters most is the quality of communication and responsiveness. One interviewee explains, *"For us, it doesn't matter whether they are based here or, for example, in Zagreb, what matters most is that they can communicate with us in Slovene (especially when it comes to legislation) and that they are accessible and responsive when needed"* (SH4).

Table 2: Summary of key findings on the value-added of the presence of research-based pharmaceutical companies in Slovenia, organised by themes

Themes	**Key findings**
Access & Availability of medicines	• Improved availability of medicines • Earlier market entry of medicines • Earlier access to innovative treatments for unmet medical needs • Access to specialised expertise and advanced therapies
Innovation & Competitiveness	• Advanced medical progress through innovation and academic collaboration • Enhanced national competitiveness through innovation, digitalisation and international expertise • Stronger international reputation and relevance in global pharma industry
Human capital	• Career development through structured training, personal growth planning, and international opportunities • Stronger national human capital through knowledge transfer to academia and public institutions • Attractive employment that helps retain highly educated professionals and mitigate brain drain
Healthcare	• Improved quality of patient care and continuity of care across the full treatment path • Improved public health and workforce productivity through early diagnosis and reduced productivity losses
Economic impact	• High salaries and economic contribution through taxes and local spending • Jobs and value-added multiplication effect across related industries • Investments and donations to the local community
Education	• Support (funding and information) for healthcare professional education, with mixed views on intent and continued reliance due to limited public funding • Raised patient awareness through health campaigns, concerns about transparency

Source: Own work.

4.2.2 The current business environment and operations of research-based pharmaceutical companies in Slovenia

The decision for research-based pharmaceutical companies to establish subsidiaries in Slovenia is influenced by several factors, including the country's reputation, skilled workforce and strategic positioning. One interviewee highlighted that Slovenians' reputation for competence and follow-through plays a key role in attracting foreign investment:

"Because we Slovenians have a reputation for following through on what we set out to do, we are seen as competent. They recognised a great deal of knowledge and talent here" (CR5-1). The availability of highly skilled professionals, particularly in healthcare, further supports the country's appeal. Slovenia is seen as having a talented and highly skilled workforce with an emphasis on healthcare, which is further strengthened by Slovenia's strong GDP per capita and its advantageous geographical location (CR1-1). Additionally, as one interviewee notes, *"Slovenia loves innovation and your doctors want to be ahead of the curve. Furthermore, the life sciences sector in Slovenia is significantly larger than healthcare, which is another reason we are interested in being present here"* (CR9), which makes it an attractive destination for pharmaceutical companies. Also, Slovenia's location in Europe offers a strategic advantage, particularly given its proximity to major pharmaceutical markets, with one respondent stating, *"Slovenia offers a glimpse into the future"* (CR9), indicating that the country is perceived as a mirror of future trends. Finally, while Slovenia offers these advantages, pharmaceutical companies also consider other factors when making decisions about investments, with one interviewee explaining, *"We always consider the cost-effectiveness of each location for any new investment"* (CR5-1). Overall, the combination of a skilled workforce, innovative environment and strategic location make Slovenia an attractive base for research-based pharmaceutical companies in the eyes of company representatives. The interviewees from non-industry stakeholder organisations highlighted several additional advantages of Slovenia, noting the high value and credibility of Slovenian certifications, the excellence of public research institutes, the strong manufacturing and innovation within the pharmaceutical industry, and the possibility of Slovenia being a "test" country for these large multinationals. As one explained, *"Certification in Slovenia is trustworthy, for example, AMPMD's certificate of quality of medicinal products"* (SH2). They also emphasised, *"We have two extremely important public research institutes, a chemistry institute and a pharmaceutical institute"* (SH2). According to this stakeholder, another reason for Slovenia's attractiveness is *"due to the tradition of strong manufacturing and innovation in the pharmaceutical industry. There is a good input of resources"* (SH2). Interestingly, the country's small size was also seen as an advantage, with the interviewee noting, *"We're small enough to serve as an experiment, as an excellent test subject"* (SH2).

The extent of business functions performed within Slovenia varies greatly from company to company, though there is a clear trend towards outsourcing at least some operations. While a few companies maintain all operations within Slovenia, most agree that outsourcing is more cost-effective. One interviewee stated, *"We outsource whatever we can"* (CR6), emphasising the practical benefits of such an approach. This view aligns with a broader industry trend where outsourcing of functions such as legal, finance, and human resources has become commonplace to reduce operational costs (PwC, 2019). As one interviewee explained, *"We are outsourcing more and more functions such as legal, finance, accounting, and human resources, many of which are now managed at the regional level"* (CR3). Furthermore, outsourcing destinations such as Croatia are often chosen due to cost savings

(CR9). This approach reflects the growing recognition within the pharmaceutical sector that outsourcing can help streamline operations, enhance efficiency and lower costs, especially as companies focus on their core competencies (Moon et al., 2022).

When asked directly about the possibility of leaving Slovenia and the factors contributing to that decision, most interviewees reassured that they have no immediate plans to leave, though they acknowledged that the business environment is far from ideal. As one respondent explained, *"We have been present here for several years and intend to stay, but we do not find the business environment particularly encouraging. There is potential for improvement"* (CR1-2). Another interviewee noted that *"Access is decent but not actively encouraged. There are bureaucratic obstacles, pricing and classification regulations are limiting, there is a shortage of medicines and labour costs are extremely high"* (CR6). These challenges highlight the regulatory and economic barriers that hinder the attractiveness of Slovenia as a base for pharmaceutical companies. On the other hand, a few interviewees admitted that they are seriously considering leaving due to Slovenia's declining profitability. As one stated, *"We are thinking about it, yes, but it's not yet a reality, at least not in the next three years. We don't foresee profitable growth by 2026 and the question is how long will the company hold an unprofitable position in Slovenia before pulling the plug. Once they [the company] leave, they don't come back"* (CR9). This concern is evident in the company's gradual downsizing in Slovenia, where it has reduced its workforce by more than half over the past decade. The same interviewee further explained that countries are informally categorised into tiers based on their access to medicine within the company. *"Tier One countries receive medicines whenever they request them, Tier Two countries generally receive what they have planned for well in advance, often up to 24 months, and Tier Three countries are left with what remains"*. According to the interviewee, Slovenia mostly falls into Tier Two but is also considered Tier Three in some aspects, primarily due to pricing, as it is among the countries where medicines are the cheapest (CR9). If others share this view and Slovenia shifts entirely into Tier Three, it could have negative consequences for patient access to innovative medicines, as companies may deprioritise the country in favour of higher-tier markets. This aligns with findings that countries with lower prices or smaller market volumes often experience delayed medicine launches and reduced access to new treatments (Vogler et al., 2017). Non-industry stakeholders expressed varying views on the possibility of these multinationals leaving the country. Some believed that *"If they were to leave, it would be a significant loss, as it would result in the loss of highly skilled professionals, further worsening the brain drain. Their presence not only contributes to scientific progress but also brings fresh perspectives to the Slovenian system"* (SH5). However, others took a more pragmatic approach, suggesting that, "*No loss is pleasant but it would be a mistake to rely solely on corporate research-based pharmaceutical companies"* (SH2).

A subtle trend emerged when interviewees were asked about challenges in hiring skilled talent. While some initially reported no significant issues, stating *"We haven't had any*

issues. The people who work with us are highly sought-after professionals" (CR4), it became clear that the volume of hiring played a key role in these perceptions. Those who claimed not to face hiring difficulties also revealed that they rarely recruit, often hiring only one or two individuals at a time. As one interviewee noted, *"We have so few job listings that we don't experience problems"* (CR8). However, it was also evident that the limited pool of qualified candidates in Slovenia is a major obstacle. One interviewee remarked, *"The faculties produce good talent, just not enough of it"* (CR6). Other significant challenges mentioned included high labour costs due to taxes, which were frequently emphasised by interviewees, as well as the lengthy recruitment processes. One respondent explained, *"We have difficulties with recruitment, including in other countries, but it's particularly hard in Slovenia. Recruitment processes take the longest here compared to our other branches, especially when it comes to professionals in pharmacy"* (CR6). The lack of specialised talent, particularly in fields like pharmacoeconomics, was also a concern. As one interviewee explained, *"There is a need for specialised talent with specific knowledge but Slovenian universities do not produce enough graduates in these areas, and professionals from abroad simply don't want to come"* (CR5-2). Another added, *"It depends on the position. There is a lack of expertise in pharmacoeconomics, and these professionals need to be attracted from other companies, as this knowledge is not readily available on the market"* (CR3). The future appears promising, as new research highlights that digital recruitment tools and AI are increasingly playing a critical role in enhancing the identification of specialized skills within the pharmaceutical sector (Pires, 2025). Interviewees from non-industry stakeholder organisations largely agree that there is a shortage of skilled professionals in Slovenia, highlighting that companies across various sectors are competing for talent (SH2). They emphasise that this competition is driven by the high demand for the specialised knowledge and qualifications held by highly educated individuals in Slovenia. As one interviewee noted, *"The complexity of our expertise is our advantage"* (SH2).

When discussing current business operations, interviewees noted the ongoing challenges related to public perception of pharmaceutical companies in Slovenia. One interviewee admits, *"We are not the most popular companies in Slovenia, they still see us as "big bad pharma"* (CR3). Another expressed frustration with the negative portrayal in the media: *"The public does not recognise the good work that pharmaceutical companies do. Research-based pharma is under pressure from various stakeholders, and the media and general public are part of the problem. They do not give us the chance to present the positive side of pharmaceutical companies, the contributions and the good work we do. Instead, we are portrayed solely as profit-driven organisations"* (CR8). An interviewee from a non-industry stakeholder organisation provides a broader cultural explanation for the poor public perception, suggesting that *"As a nation, we are small, complicated and difficult"* (SH2). These views highlight a significant challenge in operating in Slovenia. Despite the professional recognition of their contributions, companies face public reluctance to engage, as noted by one interviewee, *"We are accepted by the professional community (doctors) but not by the general public"* (CR8). Moreover, public-private partnerships face additional

hurdles due to public fears, with one interviewee stating, *"We could do much more for the healthcare system, but unfortunately, we are not allowed to be involved because they are afraid of the publicity around our participation"* (CR5-2). Some interviewees from non-industry stakeholder organisations confirmed the pharmaceutical industry's concerns, noting that public agencies often keep their distance out of sensitivity to how such partnerships might be perceived by the public. As one interviewee explains, *"These days, lobbying is no longer possible the way it used to be. A lot has changed in this context over the past ten years across Europe, and Slovenia has adopted these good practices. However, the Ministry of Health still keeps its distance from companies because of lobbying concerns"* (SH5). Supporting these observations, the pharmaceutical industry's public image is often met with distrust and high scrutiny. The industry's marketing, especially with non-prescription medicines, faces challenges in building trust with consumers. In Slovenia, medicine advertising is regulated, with only non-prescription drugs allowed to be advertised to the public. Despite this regulation, pharmaceutical companies continue to face negative public perceptions driven by media portrayals, as outlined in the literature on consumer responses to pharmaceutical marketing, pharmaceutical companies have been allocating increasing resources and funding toward medicine advertising each year. Slovenia follows this trend, and although advertising is strictly regulated, it remains an important tool used by companies to influence public perception (Grivec, 2015).

When discussing financial incentives for research-based pharmaceutical companies in Slovenia, company representatives unanimously acknowledge their existence, but also point out that these incentives are so poorly suited to their needs that they are essentially ineffective. As one interviewee explains, *"There are government subsidies intended to encourage investment in less desirable parts of Slovenia, but in reality, they are so inapplicable that they may as well not exist"* (CR5-1). Another notes, *"The country does offer a lot of public tenders, but they don't communicate with the industry"* (CR1-2). This comment highlights a recurring issue: while such initiatives are intended to offer support, they often fail to meet the practical requirements of their intended beneficiaries, either due to poor alignment with industry needs or a lack of effective communication. A different perspective is offered by a representative from a non-industry stakeholder organisation, who suggests that the system is designed to provide flexibility: *"Calls for proposals exist, but they're general so that companies can design projects according to their own preferences, provided they fall within the scope, of course"* (SH2). These contrasting views reflect a misalignment between policy design and industry expectations. Supporting these perceptions, a study found that Slovenia's funding mechanisms for biotech and pharmaceutical firms are poorly aligned with industry needs. Despite their availability, such incentives are often ineffective in practice due to weak institutional coordination and limited responsiveness to private sector priorities (Vida, 2016).

In addition to direct government subsidies, there are other financial incentives, such as patent protection, which play a critical role in encouraging innovation. As one interviewee explains,

"If you want innovation, you have to give patent protection and the same goes for every industry" (CR9). Another respondent elaborates on the effective duration of patent protection in Slovenia, stating, *"A patented medicine is protected for twenty years. Twelve years are spent on research, leaving only eight years on the market. First, it must be approved by the EMA and only then do price negotiations in Slovenia begin. By the time the medicine becomes accessible to patients, only six to seven years of patent protection remain"* (CR4). Regarding the hypothetical reduction of patent protection time, all company representatives strongly disagree with the proposal, questioning whether such a decision would be well-informed. These views align with the broader academic consensus on the importance of patent protection in fostering pharmaceutical innovation. A Slovenian study explains that while the formal 20-year patent term exists, the effective market exclusivity period is often substantially shortened due to the lengthy regulatory and reimbursement procedures, especially visible in smaller EU countries like Slovenia. They caution that any policy undermining patent duration risks disincentivising R&D investment and delaying access to novel therapies (Kovac & Rakovec, 2022). While most stakeholders agree that patent protection is necessary, some point to its negative implications for the healthcare system. As one non-industry stakeholder remarks, *"Patent legislation from a healthcare perspective is very harmful"* (SH4). Although the systematic review by Tenni et al. (2022) does not directly support this claim, it does find that excessive IP protections, such as Agreement on Trade-Related Aspects of Intellectual Property Right-plus provisions, are often associated with higher medicine prices, delayed access and increased costs for both governments and patients.

Most company representatives agree that the regulatory environment within the pharmaceutical industry in Slovenia has significantly worsened over the past 15 years (CR7), becoming increasingly strict, slow, and complicated. Interviewees note that while the regulatory system is solid in certain areas, it is often too rigid and lowers efficiency. As one respondent points out, *"The system is quite good, but relatively slow with many regulatory hurdles. The small population also means the same amount of work is required for fewer patients"* (CR9). Another adds, *"It's not negative, but it is too strict. Slovenian legislation is very rigid and there is no need for it to be stricter than the rest of Europe"* (CR4). Stakeholders from non-industry organisations agree with company representatives on the topic, with one noting that *"Regulation within the pharmaceutical sector is very strong"* (SH5). Another highlights the first necessary step towards improvement, stating that *"Public administration is the first step that needs to be changed or improved"* (SH2). While there are no major issues with IP regulation or the pricing and marketing authorisation process, reimbursement remains a major bottleneck. As one representative explains, *"Regarding legislation, IP is well regulated and there are no issues with the pricing and marketing authorisation process. However, reimbursement takes far too long"* (CR4). This lengthy reimbursement process, coupled with strict regulations, creates operational challenges for pharmaceutical companies, raising questions about its broader impact on patient access to medicine and health outcomes (CR7). These concerns reflect broader systemic issues in

Slovenia's regulatory environment for pharmaceuticals. According to a report, Slovenia faces lengthy timelines in pricing and reimbursement decisions, which exceed the EU average and pose significant barriers to timely market access (OECD & European Observatory of Health Systems and Policies, 2021). Furthermore, in another report the OECD noted that although Slovenia's regulatory system is well-developed, it remains overly centralised and rigid, especially in reimbursement evaluation and HTAs, contributing to long decision-making cycles that undermine efficiency and investor confidence (OECD, 2018). As one interviewee expresses, *"There is no drive from stakeholders to change the legislation"* (CR6), emphasising the lack of urgency in addressing these issues.

Access to medicine in Slovenia is generally considered good, with the W.A.I.T. index placing the country in the better half for pharmaceutical market access. As one interviewee states, *"Access to medicines is good, typically between 9 and 12 months after EMA approval, compared to medical devices, where the system functions very poorly"* (CR2). This positive perception is shared by representatives from non-industry stakeholder organisations. One interviewee remarks, *"It seems to me that we have good access to medicines in Slovenia, regardless of how the approval processes for medicines work"* (SH5), while another adds, *"Access to medicine is the same as in the wealthiest countries in Europe, even though we don't belong among them"* (SH4). However, despite relatively good access, there are still notably lengthy drug approval processes. One respondent mentions, *"The drug approval processes are longer than we would like it"* (CR1-1), reflecting frustration with the slow pace. Furthermore, early access to medicines is constrained by rigorous procedures. As explained by another interviewee, *"When it comes to early access, in Slovenia, there are very defined procedures before a medicine reaches the market, it takes two years on average. This means we are two years behind other European countries. We lack a mechanism to move things forward quickly"* (CR6). These lengthy timelines highlight the need for a more efficient system to improve timely access to medicines and enhance Slovenia's competitiveness with other European markets. These insights are reflected in recent analyses of Slovenia's pharmaceutical access performance. A study by Janžič (2023) confirms that while access is relatively good compared to other CEE countries, patients still wait an average of 422 to 500 days from EMA approval to national reimbursement decisions. This places Slovenia in the middle tier of the W.A.I.T. index across Europe. Namely, the study also notes that rigid national procedures and multiple assessment layers, including HIIS negotiations, contribute to these lengthy timelines, particularly limiting early access initiatives. In addition, interviewees from non-industry stakeholder organisations raise an issue that company representatives do not mention. Slovenia often struggles with access to medicines for rare diseases due to its small size and population. As one interviewee explains, *"Many times, for rare disease medicines, we get access late because we are small"* (SH4). Another provides a concrete example, stating "*there has been no medication for Parkinson's in Slovenia for a long time because companies do not prioritise Slovenia"* (SH5).

According to the interviewees from research-based pharmaceutical companies, Slovenia faces significant challenges in conducting clinical trials, contributing to the low volume of trials in the country. One interviewee points out, *"Slovenia performs very poorly compared to the rest of Europe, both in the number of clinical trials and in patient participation"* (CR2). This view is shared not only by company representatives but also by interviewees from non-industry stakeholder organisations. As one notes, *"I get the impression there are some, but there should be many more. Healthcare has an opportunity to earn additional income here"* (SH4). The country's size and complex regulatory environment are often cited as key barriers to attracting and conducting clinical trials. As one respondent explains, *"Clinical trials are not attractive here because the environment is too small, which is why we don't have a dedicated department for it in Slovenia. If the structure were reorganised, it might become more appealing"* (CR8). However, not all stakeholders view Slovenia's small environment as a barrier. One interviewee explains, *"Even though we are a small environment, we still have large institutions. Our healthcare system is quite centralised, so the University Medical Centre Ljubljana (UMC) has a sufficient number of patients in many areas, such as oncology, for a particular study to be successfully conducted, but the regulation is extremely complex"* (SH3). Additionally, internal bureaucracy and administrative hurdles are seen as major deterrents for research. As another interviewee notes, *"Slovenia is unattractive due to its size and overly complicated internal procedures. The number of patients is significantly lower than in other European countries, and processes and workforce costs are extremely high for researchers"* (CR6). Non-industry stakeholder representatives also point to poor public perception as an additional reason for Slovenia's limited attractiveness for clinical trials. As one explains, *"Unfortunately, Slovenia is not attractive for clinical trials due to strict regulations and also poor public perception of it"* (SH3). These statements from company representatives echo broader academic concerns. Studies have shown that Slovenia's clinical trial landscape is hindered by rigid procedures and limited patient access, both of which discourage international sponsors. For example, a study identified regulatory barriers and administrative burdens as key factors limiting Slovenia's competitiveness in this area (Lalova et al., 2020). While another article argues that the high cost and procedural complexity outweigh the benefits for sponsors seeking trial sites in the region (Mugoša & Glušica, 2022).

Despite these barriers, the interviewees explain that there are some workarounds in place, however, these programs are not without their challenges. As two interviewees remark, *"There are some workarounds to the rigid legislation, such as patient support programmes, which can be registered with AMPMD to allow a limited number of patients to access a medicine that has not yet been approved. However, the number of eligible patients is small and the administrative burden is too high"* (CR4) and *"As for patient support programmes, the state completely blocks them"* (CR3). These seemingly conflicting views highlight the ambiguity surrounding such programmes. While legal frameworks like Compassionate Use Programmes do exist in Slovenia and are regulated by AMPMD, they remain highly restricted and administratively demanding. As Balasubramanian et al., (2016) note, Slovenia

is one of the EU member states with an established legal basis for early access schemes, yet their practical implementation is often limited in scope and perceived by industry as insufficiently accessible.

Both company and non-industry stakeholder representatives identify the lack of sufficient incentives for researchers as one of the main reasons for the limited number of clinical trials in Slovenia. One interviewee states, *"There is no incentive for doctors. They are not rewarded based on their work or treatment outcomes, and this doesn't only apply to clinical trials"* (CR2). Hospital management also contributes to the difficulties, with many healthcare institutions lacking the initiative to support clinical trials. As one respondent observes, *"The country is too rigid, and hospitals have no initiative to support clinical trials. Many directors of healthcare institutions are afraid of clinical trials because of issues related to compensation and contract agreements"* (CR2). Furthermore, specialised researchers are in short supply and often overburdened without additional compensation. As one respondent puts it, *"We lack oncology researchers, and if a scientist is involved in a trial, it's only additional work for them, they are not fairly compensated"* (CR4). The poor compensation and high administrative burden have led to a lack of participation from both doctors and patients. One interviewee describes the situation as *"very, very poor. The administrative process is complicated, it's difficult to recruit patients in Slovenia and doctors are unwilling to take part because it involves a huge amount of work for very little money, mainly due to administrative decisions at the national level"* (CR5-1). A professional in the field expresses a personal view on the topic, emphasising that the compensation is not the primary issue; *"There is actually a huge amount of work, but what bothers me the most is the lack of organisation. This is where doctors lose the most time and energy, and no one pays for this additional work. The balance between compensation and work invested, often unnecessary work, is unfair for this reason"* (SH3). These challenges are supported by academic research examining the clinical and institutional landscape in Slovenia. One study found that administrative duties account for approximately 25 per cent of family physicians' workload, with a substantial portion considered unnecessary, thereby limiting the time available for research participation (Bartolac & Vajd, 2021). Another article highlights that Slovenian regulations allow financial compensation for clinical trials only in the form of reimbursement for direct costs, effectively removing any additional incentives for physician involvement (Černelč et al., 2024). A comparative analysis of hospital systems across CEE further points to fragmented governance and outdated organisational models as key barriers to institutional engagement in externally sponsored research (Dubas-Jakóbczyk et al., 2020).

Ultimately, these challenges have contributed to a decline in clinical trials conducted in Slovenia. As one interviewee explains, *"We've lost clinical trials in Slovenia due to administrative burden"* (CR1-1). Another highlights the gravity of the situation, stating, *"Clinical trials will or rather already have, moved out of Slovenia"* (CR7). This reported decline in clinical trials in Slovenia is consistent with findings from regional studies. One article highlights that Slovenia faces reduced participation in the clinical trial market due to

lengthy regulatory procedures and insufficient research capacity. These systemic limitations raise concerns about the country's ability to retain and attract trial activity, particularly in increasingly competitive international environments (Mugoša & Glušica, 2022).

The company representatives' views on the current state of the Slovenian healthcare system are generally positive, though they acknowledge some challenges. They point out that Slovenia has the basic ingredients of a relatively healthy healthcare system (CR1-1) and that it places *"somewhere in the golden middle, but we should not be satisfied with it, we need to aspire to a Scandinavian position"* (CR8). The interviewees from non-industry stakeholder organisations also recognise the generally positive state of the Slovenian healthcare system but highlight areas for improvement. One interviewee notes, *"The healthcare system still functions quite well, especially in acute situations, but we do have a problem with prevention. A great deal needs to be done in the area of prevention"* (SH3). Another points out that, *"Slovenia lacks clear visions"* (SH4), indicating a need for more strategic direction. Additional problems lie in the system's prioritisation and balance. As one interviewee explains, *"On one hand, elective procedures are being carried out, while on the other, there are long waiting times, an increasing number of people with illnesses and the healthcare system's inability to cure them"* (SH3). Another non-industry stakeholder representative suggests that one contributing factor to the rise in health problems is the modern, fast-paced lifestyle: *"The problem is connected to people feeling burned out. Life used to be slower, the jobs were good, working hours were shorter, there was less stress compared to today's fast pace of life. In my opinion, we need to focus on the soft factors in the workplace itself, such as good managers, good pay, good conditions and a friendly environment"* (SH2). However, concerns about the future persist, with some fearing the direction healthcare might take. As one interviewee expresses, *"The forecast for healthcare in Slovenia is not good. There is fear that we are heading toward the balkanisation of healthcare, where the privatisation of healthcare has become widespread"* (SH3).

One interviewee expresses their beliefs that one of the major advantages of the Slovenian healthcare system is the organisation into primary, secondary and tertiary care, especially in terms of accessibility of doctors (CR7). This structured approach helps ensure a smooth and efficient flow of care, enabling patients to access the right level of care at each stage of their treatment journey. Despite these advantages, according to the interviewees from research-based companies, gaining access to the Slovenian healthcare system remains a significant challenge. As one interviewee notes, *"The Slovenian healthcare system has a great deal of expertise and provides good care once you're in it. The problem is getting in. Those who can afford initial consultations are at an advantage"* (CR1-2). Another respondent contributes to the topic emphasising the drastic difference between being in and out of the system, stating, *"Our healthcare system is very, very good, but it has certain specificities and shortcomings that require fine-tuning, mainly of a political nature. Once you're inside the system, it works great, but from the outside, it's extremely poor, incomparably so"* (CR5-1). Other non-industry stakeholder representatives largely agree with the views expressed by

company interviewees. As one explains, *"Once a patient enters the system, they are well treated, but up to that point, it's a problem"* (SH3). Another provides a more nuanced perspective, stating, *"It really depends; if it's serious, you will receive excellent care, but for a smaller issue, not so much"* (SH4). In discussing the reasons behind these challenges, the same non-industry stakeholder suggests that *"There is a shortage of general practitioners and as a nation, we complain too much"* (SH4). Studies examining the Slovenian healthcare system highlight a strong structural foundation, particularly through its organisation into primary, secondary, and tertiary levels of care. This tiered model acts as an effective gatekeeping mechanism, facilitating integrated care pathways and helping ensure accessible treatment once patients are within the system (Prevolnik Rupel & Marušič, 2021). However, despite the systemic strengths, research also identifies ongoing challenges in organisational access. According to patient data, while financial and cultural access to primary care is broadly positive, organisational barriers, such as long waiting times, complicated appointment processes and inadequate out-of-hours access remain a significant issue (Kert et al., 2015). These findings align with interviewee perceptions that Slovenia's healthcare performs well for those "inside" the system, but presents significant hurdles for initial access.

In addition to access issues, another serious challenge in Slovenia's healthcare system is the shortage of skilled human capital. This issue spans from the insufficient number of staff to Slovenia's inability to retain talent and a lack of skilled personnel capable of driving the digitalisation of healthcare. As one interviewee states, *"Our healthcare system is really good. The problem lies in the shortage of staff, which is only going to grow. We are not retaining talent; we are not doing enough about it. Germany, for example, is funding German language learning at the Faculty of Medicine in Portugal as part of its brain gain strategy. However, there are opportunities to optimise the current system at the human level, such as through better staff distribution across hospitals"* (CR3). This reflects the ongoing challenge of retaining trained professionals, especially in a competitive European market where other countries have more to offer. As another interviewee remarks, *"Many of our doctors cross the border to Austria due to better working conditions, better equipment, clearer paths for career advancement and higher salaries. That being said, no country is perfect"* (CR3). The concerns raised by company representatives are also reflected in national research. A study found that Slovenia's healthcare system is facing a growing shortage of staff, especially younger professionals. Many are discouraged by difficult working conditions, low compensation and limited chances for career development, which makes it harder to attract and keep new workforce. Although the government has introduced some policies to improve the situation, these changes are slow and haven't had a big impact so far. As a result, the health system is under pressure and people may wait longer or receive lower quality care because there aren't enough staff to meet the demand (Stanimirović & Pribaković Brinovec, 2023). These workforce-related challenges underline the need for strategic investments in human capital development to ensure Slovenia can meet the growing demand for healthcare services and keep pace with technological advancements in the sector.

Moreover, this shortage of staff is also hindering the digital transformation of Slovenia's healthcare system. The country lacks the personnel necessary to implement essential digital health initiatives. As one interviewee expresses, *"The digitalisation of the healthcare system is poor, it is lacking skilled personnel capable of implementing health digitalisation"* (CR8). Another respondent emphasises that the responsibility lies with management to lead this transformation, stating, *"In order for Slovenia to have a data driven healthcare system, we need capabilities in management, we need someone who will lead the digital transformation"* (CR1-1). Additionally, the incompatibility of IT systems between Slovenian hospitals is a significant barrier. As an interviewee explains, *"Each hospital has its own IT system, which makes integration impossible"* (CR3). Another non-industry stakeholder confirms, *"Digitalisation is certainly necessary because we are a modern society, but we are not poorly digitised; rather, we have poor systems, for example, the UMC has three IT systems that are not compatible with each other"* (SH4).

Slovenia's efforts to digitalise its public sector, including healthcare, are being slowed by a shortage of skilled professionals and insufficient investment in human capital. While the country performs well in certain digital infrastructure indicators, the OECD notes that Slovenia invests relatively less in developing the workforce required for digital transformation compared to neighbouring and comparable countries. This shortage of Information and Communication Technology specialists creates implementation challenges, particularly in the public sector where digital leadership and coordinated policy delivery are still evolving. The report further highlights a fragmented governance structure and insufficient institutional capacity, which make it difficult to implement a coherent national digital strategy (Russo et al., 2022).

Interviewees from non-industry stakeholder organisations emphasise that digitalisation should not be pursued blindly, rather, it must be carefully evaluated to ensure it truly benefits the people. As one stakeholder explains, *"If the information system is truly helpful, then it is necessary, but if digitalisation is only a means of itself, then it is negative"* (SH4). Another adds, *"Digital transformation must not come at the expense of people, but for the benefit of people"* (SH1), highlighting the importance of a people-centred approach to digitalisation. Some interviewees from non-industry stakeholder organisations express that while Slovenia is making progress, it still has a long way to go in terms of fully leveraging digitalisation. As one respondent mentions, *"We are quite advanced. Digitalisation makes things easier, but not as much as we expected. We have patient data, but it is not complete when it could be"* (SH3). Another interviewee notes, *"Digitalisation is a tool, a change in mindset, and Slovenia is not there yet. It's true that we have zVem, but the data is not connected"* (SH5), pointing out the current limitations in Slovenia's digital healthcare landscape. Furthermore, they warn that there needs to be a fine balance in digitalisation. As one interviewee notes, *"There is quickly too much digitalisation in healthcare"* (SH4). In addition, stakeholders underscore that digitalisation will not shorten the patient treatment process or replace healthcare staff. As one points out, *"In reality, digitisation of healthcare does not save time,*

but it improves the quality of care and health outcomes. However, it will not speed up patient treatment" (SH3). Another confirms, *"We will not replace staff with digitalisation in healthcare"* (SH4), reinforcing the idea that while digitalisation can enhance the system, it cannot replace human resources.

On a positive note, many company representatives praise Slovenia for its effective data recording, emphasising that it *"is doing quite well with entirely digitised e-prescriptions, e-referrals and a comprehensive patient summary"* (CR1-1). However, there are concerns regarding the usability of this data. As one notes, *"Slovenia has data that is properly recorded, but it is not used to drive progress in therapies and healthcare. Currently, the data is not systematically available for R&D"* (CR1-2). Non-industry stakeholder representatives share these concerns, pointing out that while Slovenia has vast amount of data, its utility remains limited. As one notes, *"There is a vast amount of data, the question is how to use it"* (SH3), while another adds, *"There is a lot of data in Slovenia, but not much information"* (SH1). Slovenia's healthcare system has made considerable progress in building a robust digital infrastructure. Nearly all prescriptions and referrals are issued electronically, around 94 per cent, and over 50 million documents are stored in the Central Registry of Patient Data, which serves as the backbone of the country's eHealth platform. Additionally, all citizens have access to their personal medical data through the zVEM portal, providing transparency and patient empowerment. However, while the volume and accessibility of recorded health data are commendable, its use for research and innovation remains limited. The existing systems are primarily designed for clinical and administrative functions, with technical and legal constraints still hindering broader applications, such as data-driven development of therapies or healthcare policy insights (Albreht et al., 2021).

Regarding data accessibility, most interviewees from research-based pharmaceutical companies agree that the data is available to them, but only what is publicly accessible. As one interviewee explains, *"We can access data for things that are publicly available, but there's no chance of getting data for anything unpublished, not even in the case of research with universities"* (CR5-1). A non-industry stakeholder adds, *"What they [companies] want from us are specific data [data that might breach patient confidentiality], which they will not get"* (SH4), highlighting the barriers to acquiring more targeted information. Other interviewees also discuss the ethical handling of medical data. One notes, *"In principle, access to data from medical reports is excellent and patient anonymity is well preserved. The only time we don't receive data is when there are too few patients and it would be possible to deduce whose data it is"* (CR2). Another non-industry stakeholder emphasises the importance of data protection, stating, *"Protecting personal data is an important aspect that we must not forget"* (SH1). While the majority's view on data accessibility is positive, some feel that data in Slovenia is not easily accessible and, in some cases, not valuable for their purposes. As one stakeholder expresses, *"The data is accessible, but not easily accessible"* (SH5). A company representative even states, *"There's not much access, that's why we don't buy [data] in Slovenia"* (CR9), highlighting drastically differing views on data

accessibility in Slovenia. The concerns align with research on data protection practices in Slovenia. According to an article, Slovenian regulations classify even pseudonymised health data as personal, making it subject to strict access limitations. As a result, data that is not fully anonymised is rarely shared, especially when sample sizes are small enough to risk re-identification (Tepej Jočić, 2021). This creates significant barriers to accessing more detailed datasets for R&D purposes, even in collaborative settings. While the country has strong mechanisms for preserving patient anonymity, these same safeguards limit the practical use of health data for innovation and industry engagement.

Furthermore, quality of data is often regarded as inadequate. Interviewees from research-based companies question its relevance, the lengthy timelines and the overall quality of reporting. As one interviewee explains, *"Some data can be obtained, but the problem is its relevance and the delays in accessing it, which creates issues for reimbursement. The biggest challenge is with data needed for clinical trials. Will we get it at all, and if so, when?"* (CR3). Another interviewee adds, *"Reporting on health outcomes is unsatisfactory"* (CR6). Interviewee challenges related to lengthy timelines and inadequate data access are supported by EU-level findings, which note that data providers often face complex and time-consuming processes when preparing data for research purposes, particularly when providing it to non-public organisations. Additionally, regarding timeliness of data, a trade-off between timeliness and accuracy is usually involved. This means that timeliness of data will play a role in its relevance (Zaletel & Kralj, 2015). Interviewees from non-industry stakeholder organisations also acknowledge a problem with the current quality of data in Slovenia. As one notes, *"Anyone can get access to data from NIPH, but many do not know how to interpret it"* (SH5). Another explains that one reason for this issue is the outdated format of the data, referring to it as *"dinosaurs"* (SH1). The importance of properly organised data is also emphasised, with several non-industry stakeholders highlighting the reasons for its disorganisation. As one states, *"When discussing any problem, anything we want to change, we should first look at the data, which is also the reason why it must be organised. Of course, one reason for the disorganisation is the increasing lack of staff"* (SH3). Another interviewee provides a data-holder's perspective, stating, *"We don't have the internal research resources, we just work hard. While we share data with universities, we ourselves lack the staff to manage it"* (SH4).

While data quality is a significant concern, the state of clinical registries in Slovenia is another area in need of improvement. As one interviewee points out, *"In the area of registries, we are far behind"* (CR2). The lack of comprehensive and well-maintained clinical registries hinders the ability to make informed decisions about which therapies and medicines are truly effective and valuable. One respondent emphasises the importance of clinical registries in improving healthcare outcomes, stating, *"Clinical registries should be established for every disease. A more thorough overview would help identify which medicines and therapies are truly important, what is worth investing in, what should be introduced to the market and what actually provides added value for patients"* (CR7).

However, some non-industry stakeholder representatives disagree, stating, *"In Slovenia, we have a bunch of registries"* (SH4). They emphasise that *"Each registry must have a purpose and a task. If activities can be carried out with the same quality without a registry, then we don't need it. Every registry means a huge amount of work for doctors"* (SH4). Slovenia's lag in developing comprehensive clinical registries has been well documented. Certain areas of the health system remain underrepresented in data collection, and the information that is available is often underutilised by decision-makers (Albreht et al., 2021). In comparison with countries that have more advanced registry infrastructures, Slovenia maintains significantly fewer disease-specific registries, limiting its ability to assess treatment effectiveness and prioritise high-value interventions (Zaletel & Kralj, 2015).

Table 3: Summary of key findings on the current business environment and operations of research-based pharmaceutical companies in Slovenia, organised by themes

Themes	**Key findings**
General	• Challenging business environment due to bureaucracy, pricing and labour costs • Frequent outsourcing of business functions due to cost-efficiency • Continued commitment to operating in Slovenia despite challenges • Concerns that profitability and regulatory barriers may threaten long-term presence
Access to medicines	• Actual access to medicines comparable to wealthier European countries • Notably lengthy timelines in drug approval processes
Human capital	• Highly skilled and competent workforce in healthcare and life sciences • High labour costs and slow recruitment seen as major obstacles • Shortage of specialised professionals, particularly in pharmacoeconomics
Public perception	• Negative public perception and media portrayal limit industry's role
Incentives	• Misaligned financial incentives with the industry limit their effectiveness • Patent protection viewed as essential for innovation and investment • Concerns that patent laws may negatively affect healthcare access and costs
Regulatory	• Regulatory inefficiencies and lengthy reimbursement procedures hinder pharmaceutical operations and market access
Clinical trials	• Activity limited by small market size, complex regulation, and high costs
Healthcare system	• Strong and well-structured healthcare system • Difficult access to healthcare despite well-functioning system once entered • Widespread shortage of skilled healthcare staff
Digitalisation & Data	• Digital transformation hindered by lack of skilled professionals and institutional capacity • Strong digital health data infrastructure with underused potential • Strict data protection rules limit use of health data for research and innovation • Health research-ready data, relevance and organisation seen as inadequate • Clinical registries seen as valuable but inconsistent in quality and purposes of their use

Source: Own work.

4.2.3 Stakeholder relationships and collaboration within Slovenia's research-based pharmaceutical ecosystem

The research-based pharmaceutical ecosystem in Slovenia relies on the interaction and collaboration of a wide range of stakeholders, including research-based pharmaceutical companies, government ministries, public regulatory agencies, healthcare professionals and patients. While patients are directly impacted by decisions in this field and their needs should be central to the system, legal and procedural constraints often prevent them from participating as active stakeholders. There is a growing emphasis on strengthening patient involvement, with ongoing efforts aimed at transforming their role from passive recipients of care to active participants in healthcare decision-making. According to most interviewees, several key institutions must work collaboratively to ensure an effective healthcare system in the field of medicines. These include the Ministry of Health, AMPMD, which is responsible for the regulation and oversight of pharmaceuticals and HIIS, which plays a crucial role in securing patient access to medicines and shaping reimbursement and pricing policies. NIPH is also highlighted for its central role in promoting and safeguarding public health. In addition, the Ministry of the Economy, Tourism and Sport is identified as an important stakeholder, particularly in promoting innovation and supporting economic development within the research-based pharmaceutical sector. The vast majority of interviewees also emphasise the importance of healthcare professionals, such as doctors, other medical staff and the healthcare institutions that employ them, as key actors in the successful implementation of new therapies and the delivery of innovative treatments to patients.

Interviewees from research-based companies express mixed views regarding the general state of collaboration within Slovenia's healthcare and research-based pharmaceutical ecosystem. While some interviewees describe their relationships with other actors as constructive, others point to persistent challenges, particularly within public institutions. One interviewee shares a positive experience, noting, *"Very good experiences with most decision-makers, we actively collaborate"* (CR5-1). Another highlights a more neutral view, stating that collaboration can work effectively when both sides act in good faith: *"As long as both sides are fair, private-public interests align"* (CR2). However, others express frustration with the pace and responsiveness of public sector partners. As one interviewee observes, *"In public administration, there is no need for fast work and adaptation; they lack a sense of urgency"* (CR4). A stakeholder from a non-industry organisation shares this concern and questions the underlying dynamics, stating, *"I wonder if it is really necessary to get employed at an institution for certain things to happen"* (SH1).

Furthermore, two barriers to an effective collaboration are often mentioned: one-sided communication and a lack of trust between the public sector and the industry. Several company representatives note that communication is often unidirectional and highly dependent on individual relationships rather than institutionalised dialogue. As one explains, *"It largely depends on individuals; it is very one-sided"* (CR3). Another interviewee from a

pharma company points to the absence of meaningful engagement mechanisms, stating, *"Not even the Pharma Forum has open communication channels; two-way communication does not exist"* (CR9). Here they are referring to the Forum of International Research & Development Pharmaceutical Companies (also known as the Pharma Forum). This perception is reinforced by concerns about avoidance, with one respondent noting that *"Public servants who should be communicating with the industry are avoiding contact"* (CR6).

Closely tied to communication issues is the deep-rooted lack of trust, which many interviewees see as a fundamental obstacle to public-private cooperation. One interviewee from a research-based company remarks, *"We are not partners to them; they see us as profit seekers"* (CR9), while another states, *"It is difficult to establish trust between the industry and public authorities. The lack of trust is immense"* (CR1-2). Although some improvement is noted in recent discourse around public-private partnerships, the prevailing sentiment remains cautious. As one respondent explains, *"In the last two years, there has been more talk about public-private partnerships, but there is a lot of mistrust regarding private companies having dealings with the government"* (CR1-1). This mistrust was especially evident during the COVID-19 pandemic. Despite international examples of successful joint leadership, one interviewee highlights that, *"What we see in certain countries is that it is quite normal for the pharmaceutical industry and public decision-makers to jointly lead certain projects. Here, however, there was no opportunity for the industry as a whole to collaborate with them through the Pharma Forum on COVID-19 vaccination coverage"* (CR2). In this context, "public decision-makers" refers to the Ministry of Health and NIPH, both of which played central roles in managing the national response.

The lack of trust is not limited to public institutions; it is also present among the general public. Public opinion plays an important role in influencing how public and private sectors work together. Several research-based pharmaceutical interviewees observe that the public often holds negative and oversimplified views of the pharmaceutical industry, particularly of foreign companies. One respondent describes public opinion as, *"Domestic pharma is super great, foreign pharma is super bad"* (CR6). This negative perception can affect how collaboration is viewed more broadly. One interviewee comments, *"The perception of public-private collaboration is very poor. The people see it as corruption"* (CR1-2). In some cases, this public view even affects decision-making. As one respondent explains, *"We are not involved in decision-making with the Minister of Health due to public perception of corruption"* (CR5-2). A stakeholder from a non-industry organisation shares the same view, stating, *"The Ministry of Health maintains a distance from companies due to lobbying concerns"* (SH5). These reflections suggest that public mistrust can act as a barrier to cooperation, limiting the role of the research-based pharmaceutical industry in contributing to policy discussions and joint initiatives.

When discussing collaboration with specific organisations, most interviewees highly praise the workings of the Pharma Forum. Respondents agree that it functions effectively and

maintains strong relationships with both the industry and public institutions. As one interviewee states, *"Pharma Forum has healthy relationships with the industry and public institutions, but public trust is not 100 per cent there. Slovenia should trust it more"* (CR1-1). Similarly, the relationship between the research-based pharmaceutical industry and academic institutions is generally described as constructive. While not all companies engage in collaboration with universities, those that do report positive experiences. As one company representative notes, *"We collaborate very well with academic institutions, but the barriers come from the government"* (CR6).

Interviewees from research-based companies and non-industry stakeholder organisations generally view AMPMD positively, particularly in terms of accessibility and professional conduct. One respondent remarks, *"Access to AMPMD and HIIS is very good, it's easy to get meetings, but if the meeting request is not of a technical nature, they don't get one, which is also not common practice in other countries"* (CR6). Others highlight AMPMD's effectiveness when working through formal platforms, such as Pharma Forum. As one interviewee puts it, *"AMPMD operates in a very correct, clear and professional manner through Pharma Forum. I can only say good things about them"* (CR7). A non-industry stakeholder shares a similar view, stating, *"AMPMD performs its duties; there are no particular issues and the collaboration is very good"* (SH3). There is also recognition of AMPMD's role in shaping the national medicines list, with one respondent stating, *"Our [Slovenia's] basket of medicines is very wisely chosen"* (CR6).

However, several challenges are noted, particularly in relation to slow pricing and drug approval processes. One interviewee describes how a lengthy timeline in obtaining approval for the maximum allowed price of a medicine can impact the company's ability to bring products to the market: *"It often happens that AMPMD rejects our proposed maximum allowed price for a certain medicine, but then a year later contacts us to ask if we are still interested, only by then we can no longer afford it"* (CR3). Others echo similar concerns about the pace of regulatory procedures, with one noting, *"The drug approval processes are longer than we would like them to be"* (CR1-1), and another adding, *"There is room for improvement, the procedures could move faster. AMPMD is rigid"* (CR8). This perception of rigidity is a recurring theme. As one respondent explains, *"AMPMD has established procedures, but they are difficult and lengthy"* (CR6). Another elaborates, *"It's difficult to build a relationship with AMPMD. They are very strict and tend to follow protocol without addressing the whole picture—they are just checking boxes. Unfortunately, the protocol itself is outdated, written 15 to 20 years ago"* (CR9). Despite these criticisms, AMPMD is recognised for its responsiveness in urgent situations. As one interviewee points out, *"They cooperate very well during exceptional events, such as out-of-stock situations or medicine shortages"* (CR2).

Stakeholders from research-based companies express varied perspectives on the role and performance of HIIS, with most acknowledging both its importance and its challenges. In terms of general collaboration of HIIS, one interviewee notes, *"They play the role they are*

supposed to, but sometimes they cross into unprofessional territory, for example, inappropriate communication. In the end, we manage to find common ground despite tough negotiations" (CR7). Another stakeholder from a pharma company points to a disconnect between Pharma Forum-level and company-level interactions, stating, *"At HIIS, we reach a meeting at the Pharma Forum level, but the issue arises at the company level when negotiating prices. HIIS is really getting worse now"* (CR3).

Efficiency is also raised as a concern, with one respondent observing, *"Due to the efficiency of operations, they tend to lean towards a very simplistic approach"* (CR6). One reason for this simplified approach may be HIIS's limited internal capacity. Several interviewees report that the institute struggles with staff shortages, which in turn contributes to lengthy timelines and bottlenecks. *"The team at HIIS is too small, that's why everything gets delayed"* (CR4), one company representative notes. Another adds, *"There are too few staff at the HIIS to handle the data"* (CR3). These limitations have a direct impact on the availability and timeliness of information, with one company representative commenting, *"Regarding HIIS, we would like more up-to-date data on drug consumption, but the current system takes two years to produce a report"* (CR6).

However, a representative from a non-industry stakeholder organisation offers a different view, stating, *"HIIS regularly releases its report on drug expenditure and consumption by April and its business operations report by June for the previous year"* (SH4). The same stakeholder also suggests that public institutions may be more agile in some respects, remarking, *"HIIS is much more flexible than they [the companies] are"* (SH4). Another non-industry stakeholder highlights a more fundamental issue, pointing to the unclear institutional positioning of HIIS: *"The role of HIIS in Slovenia is poorly defined. On one hand, it is an insurance company and on the other, it acts as a monopolistic budget holder. We are somewhere in between, and this position is poorly defined"* (SH3). This ambiguity between functioning as a public health insurer and as the country's dominant national payer creates confusion about its mandate and contributes to inconsistent expectations among stakeholders.

The pricing systems at HIIS are also the subject of considerable debate among interviewees, with both critical and supportive views expressed. Some company representatives criticise the institute's narrow focus on direct costs, arguing that broader health system impacts and clinical value are not sufficiently considered. One interviewee remarks, *"They only look at the cost of the medicine and not at the indirect costs, such as the clinical value of the medicine"* (CR4). Another elaborates, *"The overall impact of the medicine on the healthcare system is not sufficiently considered; the perspective is too narrow. Both the clinical and economic aspects of the medicine are evaluated at the HIIS level, but the problem is they only consider the financial side"* (CR3).

However, others provide a more positive assessment. One respondent from a research-based company explains, *"HIIS correctly assesses and classifies medicines and is very good at*

evaluating their clinical value, but I must admit, they are tough negotiators" (CR6). Another offers a broadly supportive view of the pricing system, stating, *"The HIIS is quite correct regarding pricing. The current leader is honest, incorruptible and wants the best for Slovenian patients, while also managing the budget well"* (CR2). Nonetheless, the same interviewee acknowledges a structural weakness in the system, noting that *"The system is okay, but it largely depends on the head of the department. It is very reliant on the individual in charge"* (CR2), suggesting that consistency and institutional resilience may be undermined by over-reliance on individual leadership.

Additionally, one company representative points to a specific flaw in how HIIS handles the pricing relationship between originator medicines and generics. While acknowledging that the overall system maintains good pricing standards, they state that *"the way prices of generics versus originators are calculated is flawed"* (CR3). This suggests that current pricing formulas may not adequately reflect key differences in clinical value, availability or therapeutic characteristics, potentially resulting in occasional pricing anomalies.

Company representatives express consistent concerns regarding the limited collaboration between NIPH and research-based pharmaceutical companies. Several describe NIPH as largely unwilling to engage with the industry. One respondent remarks, *"NIPH doesn't want anything to do with the pharmaceutical industry, but they can't do without us either. Without collaboration, it's hard to accomplish anything"* (CR4). Another shares a similar perspective, stating, *"They are not open to active collaboration with companies on projects"* (CR2), while a third adds, *"NIPH does not want to have meetings; they are inaccessible"* (CR7). In contrast, most interviewees from non-industry stakeholder organisations described their cooperation with NIPH positively. As one stakeholder explains, *"With NIPH, everything can be agreed upon and they respect all agreements"* (SH3). These differing views suggest that NIPH's approach to collaboration may vary depending on the type of stakeholder involved.

Despite these issues, interviewees from research-based companies generally view NIPH's data access policies more favourably, though some point to areas for improvement. One interviewee explains, *"If we request the data, we receive it, for a fee of course, but there is no automatic process. For studies, access to data is quicker. It would be great if this improved"* (CR4). Others praise the quality and availability of the data, with one noting, *"In principle, access to data from medical reports is excellent and patient anonymity is well preserved. The only time we don't receive data is when there are too few patients and it would be possible to deduce whose data it is"* (CR2). The same respondent adds, *"NIPH has an excellent database. We pay a reasonable, even low, fee for the data"* (CR2). However, concerns are raised regarding the time it takes to obtain this data, which some attribute to staffing shortages. As one stakeholder observes, *"NIPH is facing a shortage of staff, which further delays the process of obtaining data"* (CR6).

Interviewees from research-based pharmaceutical companies express a general sense of distance and inconsistency in their interactions with both the Ministry of Health and the Ministry of the Economy, Tourism and Sport. While both ministries are seen as important institutional actors within the healthcare and pharmaceutical landscape, companies often experience limited direct engagement. As one stakeholder explains, *"We don't work directly with the ministry much, only through the Pharma Forum"* (CR2). Another adds, *"We have no direct contact with the ministries, only through the Pharma Forum, and we don't feel that their doors are open"* (CR8), suggesting that communication typically occurs via intermediaries rather than through regular dialogue. In addition to these structural barriers, frequent personnel changes are highlighted as a challenge to long-term planning and policy consistency. *"Stability would help, with the same person in place for a longer period. Each person has a different strategy, so there is no long-term plan"* (CR9).

Despite these challenges, the Ministry of the Economy, Tourism and Sport is generally seen as more open to collaboration, with one company representative stating, *"The Ministry of Economy, Tourism and Sport has no reservations about collaboration"* (CR5-1). However, another respondent points to a broader issue that affects not only this ministry but the wider government approach: *"The Slovenian economy faces a significant barrier due to the lack of systemic collaboration between state institutions, industry and other stakeholders. Although the government [Ministry of Economy, Tourism and Sport] actively promotes economic development through calls for proposals, it is evident that the process of preparing and implementing these calls is overly focused on state institutions and too little on communication and collaboration with other stakeholders, even before the calls are announced"* (CR1-2). This highlights the need for stronger cross-sector engagement and improved coordination between government and industry, especially in the design of economic development initiatives.

On the other hand, company representatives consistently identify the Ministry of Health as the most difficult institution to engage with. Several describe the Ministry of Health as largely closed to dialogue, even unwilling to meet or acknowledge proposals from the industry. One respondent explains their collaboration, *"None at all, they are too closed off for collaboration, not even willing to have a conversation, let alone listen"* (CR7), while another remarks, *"The Ministry of Health is problematic, we haven't even had an official meeting at the Pharma Forum level. We send letters, but they rarely respond and often disregard feedback… They reject all meetings and there is no transparency whatsoever"* (CR3).

According to interviewees, these challenges are largely rooted in the political sensitivity surrounding the pharmaceutical sector and the negative public perception of foreign pharmaceutical companies. As one stakeholder notes, *"We are not involved in decision-making with the Minister of Health due to public perception of corruption"* (CR5-2), and another adds, *"For the Ministry of Health, meeting with the 'big bad pharma' is political suicide"* (CR3). However, a few company representatives offer a more measured view.

One interviewee suggests that some of the industry's frustration may stem from unrealistic expectations, commenting, *"I believe some companies have a wrong perception of the ministry due to their limited beliefs"* (CR1-1). Another observes that while the Ministry may be perceived as distant, its core functions are often delegated to other bodies such as HIIS, AMPMD, and NIPH, which limits the need for direct engagement: *"There is no direct connection between the companies and the ministry, as all functions are carried out by other bodies"* (CR2). Still, the overall perception of interviewees from research-based pharmaceutical companies remains that the Ministry of Health is not sufficiently engaged in active collaboration with the industry and that greater transparency, consistency, and political openness would be needed to strengthen this relationship.

Interviewees from non-industry stakeholder organisations generally acknowledge the Ministry of Health's limited accessibility, though their interpretations varied. One stakeholder expresses concern about the absence of regular communication with the companies, stating, *"It's not right, it doesn't make sense! Communication is necessary and must exist because we all work in the same field, but they must be careful to maintain integrity"* (SH3). Others view the Ministry's cautious approach more positively. As one respondent notes, *"I am glad that they do not have access to the Ministry of Health at the company level"* (SH4), while another observes that *"The communication between the Ministry of Health and the industry is very formal; they meet at meetings with Pharma Forum, where companies are not involved"* (SH5).

When it comes to decision-making, stakeholders report that the Ministry of Health follows formal consultation procedures. One interviewee explains, *"If the Ministry of Health is changing any laws, all stakeholders are part of the public discussion"* (SH5). The same respondent elaborates that *"In public discussions, anyone can submit comments, and they are considered through the Pharma Forum if deemed relevant. Therefore, they are considered open to all stakeholders"* (SH5). However, several interviewees still see room for improvement in how collaboration is structured. One notes, *"The Ministry of Health will not have joint projects with the industry just like that. However, a common dialogue is important for the strategy of Slovenian healthcare"* (SH5), while another emphasises the need for more structured engagement, stating, *"If there were collaboration between the Ministry of Health and the industry, it should be a strict and structured partnership"* (SH1).

Beyond collaboration, institutional challenges are also highlighted. One stakeholder points to deeper structural issues within the Ministry of Health, identifying *"three problems. First, the political approach to professional issues, which changes with daily politics, leading to instability. Second, a staff shortage, which results in poor coverage or an inability to cover certain areas. Third, there is not enough listening to expertise or science, partly due to the lack of staff"* (SH3).

Lastly, stakeholders from non-industry organisations express a mix of appreciation and criticism regarding the role of research-based pharmaceutical companies in Slovenia. Many

acknowledge the industry's value in developing new therapies and improving public health, but are also critical of its commercial motives. As one non-industry stakeholder explains, *"The pharmaceutical industry has two interests. On one hand, to innovate and produce medicines for those who need them, which is a noble act, and on the other hand, to make as much profit as possible, which taints their solidarity. We are on different sides, societal wellbeing and profit. But we must find ways to collaborate"* (SH5). Another interviewee adds, *"The industry is here to serve as part of society. In this case, it should not make a profit at society's expense. If society fails to realise this and seeks to reduce social wellbeing for the sake of capitalism, we are not on the right path"* (SH4). Some non-industry stakeholders also question how the industry positions itself in public debates, with one noting, *"They are not as deprived as they make it seem. When the wealthiest member of society complains, it is truly inappropriate"* (SH4).

Others voice concerns about the way companies attempt to influence public decision-making. One interviewee remarks, *"The companies influence decision-makers, often providing information that is not always publicly available, but sometimes it goes too far and becomes marketing"* (SH3). Beyond these ethical and reputational concerns, non-industry stakeholders point to structural limitations in how companies engage with the broader healthcare ecosystem. *"There is a lack of an ecosystemic approach from them"* (SH2), one notes, suggesting that collaboration is too often fragmented or reactive. Another non-industry stakeholder highlights that internal structures within companies themselves may be a barrier to more agile collaboration: *"There are no serious issues, the main problem is that companies are hierarchically structured. Many companies make decisions very high up in the hierarchy chain, even though we are talking about a small country like Slovenia"* (SH4).

Communication practices are also seen as increasingly limited and slow. As one interviewee explains, *"With them, response times can sometimes take weeks. We have fewer and fewer meetings; now we mostly communicate in writing. Meetings only occur for more serious issues"* (SH4). Another adds that communication often happens on the companies' terms: *"We had one-on-one communications when companies felt the need for it"* (SH2). Transparency is also cited as a crucial issue. Due to concerns about lobbying and undue influence, all meetings between public officials and the industry must be reported. As one non-industry stakeholder explains, *"Due to lobbying concerns, every meeting with the industry must be reported using a form for potential lobbying activities. We must be very transparent about collaboration and communication with the industry, and this is how it should be"* (SH5). These procedures are required under Integrity and Prevention of Corruption Act, which aims to safeguard transparency and prevent undue influence in public decision-making (Commission for the Prevention of Corruption, n.d.).

Table 4: Summary of key findings on stakeholder relationships and collaboration within Slovenia's research-based pharmaceutical ecosystem, organised by themes

Themes	**Key findings**
General	• Mixed experiences with collaboration in the pharmaceutical ecosystem • Public sector seen as slow and disengaged from industry
Communication	• Communication with public institutions one-sided and lacks open channels
Trust & Public perception	• Lack of trust between public authorities and industry limits collaboration • Negative public opinion of foreign pharmaceutical companies • Public–private collaboration widely seen as corrupt by the public • Public mistrust reduces industry influence in policy decisions • Ministry of Health keeps distance from industry due to lobbying concerns
Pharma Forum collaboration	• Pharma Forum effective platform with strong institutional ties • Limited public trust in Pharma Forum
Academic collaboration	• Generally positive collaboration with academic institutions
AMPMD - collaboration	• AMPMD as professional, accessible, and collaborative, especially via Pharma Forum • AMPMD as responsive and cooperative in urgent situations
AMPMD - regulatory performance	• AMPMD's procedures rigid, outdated, and slow • AMPMD's pricing and lengthy approval processes limit timely market access
HIIS - collaboration & performance	• Collaboration with HIIS good via Pharma Forum but poor at company-level price negotiations • Limited HIIS staffing causes lengthy timelines • HIIS provides drug data, but access is slow and insufficient • Mixed views on HIIS timeliness and flexibility • Mixed views on HIIS accuracy and fairness in medicine pricing and value assessment
NIPH - collaboration & performance	• Industry sees NIPH as uncooperative, non-industry reports good collaboration • NIPH data access generally positive but slowed by staff shortages • NIPH ensures strong data protection and affordable access to anonymised data
Engagement with ministries	• Industry has limited direct engagement with ministries, relying on Pharma Forum
Ministry of Economy, Tourism and Sport - collaboration & incentives	• Ministry of Economy, Tourism and Sport more open to collaboration than Ministry of Health • Government economic initiatives lack early, structured collaboration with industry
Ministry of Health - collaboration & accessibility	• Ministry of Health viewed by industry as most closed and unresponsive • Mixed views on whether Ministry of Health's limited accessibility is appropriate • Political sensitivity and public perception limit collaboration with Ministry of Health • Limited engagement with Ministry of Health linked to its indirect role in operations
Research-based pharmaceutical companies - collaboration & motives	• Industry valued for public health contributions, but profit motives strain trust • Industry seen as profit-driven rather than a partner • Hierarchical industry structures slow collaboration and decision-making • Industry lacks ecosystem-wide collaborative approach

Source: Own work.

4.2.4 Slovenia's path to a regional research-based pharmaceutical hub

Slovenia has the potential to strengthen its position in the life sciences sector and evolve into a regional hub for research-based pharmaceutical activity. However, interviewees highlight that realising this vision will require targeted improvements across several interconnected areas. From systemic reforms and regulatory adaptation to stronger collaboration and investment in innovation, stakeholders outline both the obstacles currently limiting Slovenia's attractiveness and the changes needed to unlock its long-term potential.

One of the first limitations highlighted by several interviewees is Slovenia's small size, which many view as a key barrier to becoming a regional pharmaceutical hub. As one respondent puts it, *"Slovenia is far too small to be able to cover the entire region"* (CR4), while another simply notes that *"size is important"* (CR9). However, not all stakeholders see size solely as a disadvantage. One company representative suggests that Slovenia's scale could in fact offer benefits, stating, *"We are not moving in that direction because of our small size, even though that could be an advantage"* (CR8). Another adds, *"We are a small market, which makes us great for testing and rolling out new ideas, but the conditions for a hub just aren't there yet"* (CR6). This idea of positioning Slovenia as a testing ground is acknowledged also by a non-industry stakeholder, who explains, *"Companies are welcome to come to us with an idea, particularly if it affects the entire ecosystem. If there's a need to test something, we can temporarily set a rule aside to make it possible"* (SH2). The same stakeholder advocates for a cultural shift, stating, *"There should be a culture of a testing environment, a sandbox approach, both for technological and regulatory matters"* (SH2).

In addition, poor transport connectivity is cited as another major obstacle. *"Our biggest challenges are connectivity and taxation. We have especially poor air connections…"* one interviewee notes (CR3). Another adds, *"Ljubljana as a regional centre faces poor transport connections, hardly anyone flies out of Slovenia anymore. A stable economic environment would be essential, and there is currently not enough construction. In the future, we would like to see more foreign investment in the country"* (CR2). The idea that stability is essential is also mentioned by others, with one company representative emphasising the importance of predictability: *"A more transparent and predictable environment would be welcome"* (CR3). Another underlines the need for stronger regulatory support, stating, *"Innovation should be recognised and supported across all areas. A suitable regulatory environment needs to be created to enable it"* (CR5-1). A stakeholder from a non-industry organisation points to the systemic inertia in healthcare, remarking, *"Companies are agile and things move quickly, while changing healthcare practice takes much longer. We need to build a bridge to help turn this large ship more easily. An innovative medicine alone is not enough, the entire approach to patient care needs to change"* (SH5).

One of the most frequently raised topics in the interviews is taxation, particularly the burden of wage taxes. Most interviewees agree that this is one of the primary, if not the central, reasons Slovenia struggles to position itself as a regional pharmaceutical hub. As one

representative from a research-based pharmaceutical company explains, *"We would need lower taxes on wages. This is the main reason why companies relocate their centres elsewhere"* (CR7). Another adds, *"Our workforce is not competitive enough for us to become a hub; it is both limited in size and too costly"* (CR5-2). Several company representatives compare Slovenia unfavourably to regional competitors. One states, *"Slovenia has no chance of becoming a regional hub. Countries like Ireland and the Netherlands are much stronger, even Croatia is ahead of us because of its favourable tax policy and lower labour costs"* (CR4). Another points to Serbia's proactive approach: *"The Serbian government is proactively encouraging pharmaceutical companies to set up centres of excellence in Belgrade, offering various incentives. Even though Slovenia is nearby, it is not even being considered as an option due to its considerably higher operational costs"* (CR9). Despite these challenges, some respondents from pharma companies offer suggestions for improvement. One notes, *"The conditions for a hub just aren't there yet. Lower taxes and making it easier to hire people from abroad would be a big step in the right direction"* (CR6). Another emphasises the importance of attracting international talent, stating, *"Let's shape the legislative environment in a way that makes Slovenia attractive to top talent in the region"* (CR1-2).

Interviewees also emphasise the need for greater procedural flexibility, faster institutional responses and a stronger emphasis on collaboration and public-private partnerships. The call for more effective cooperation between the private and public sectors is consistently shared across all stakeholder groups within the research-based pharmaceutical ecosystem. As one company representative puts it, *"We want more communication with everyone who has an impact on our operations"* (CR5-2). A non-industry stakeholder shares this sentiment, stating, *"We would like even more collaboration and communication"* (SH2). Several interviewees go further, stressing that what is lacking is not isolated cooperation, but systemic and structured collaboration across the ecosystem. As one company representative explains, *"What is missing in Slovenia is implementation that involves and connects all stakeholders. There is a lack of systematic collaboration with stakeholders in co-creating and carrying out initiatives"* (CR1-2). A non-industry stakeholder agrees, highlighting that *"We want better stakeholder engagement and collaboration between different actors. Having a good dialogue is essential"* (SH5).

Interviewees highlight that stronger public-private partnerships could not only improve collaboration but also help address the problem of poor public perception in Slovenia. As one representative from a research-based pharmaceutical company notes, *"We want to encourage collaboration through easily accessible public-private partnerships. More successful examples are needed for this approach to become standard practice"* (CR1-1). Another urges the need for a more structured approach: *"We need a formal way of collaborating on projects. Let's be open to proposals and joint initiatives. Let's make it clear to society that healthcare is a priority. The government should invite the industry to take part in projects, so that knowledge and funding can be invested jointly"* (CR1-2). They offer

a specific example: *"Money could be invested in clinical trials, partly by companies and partly by the government, which would send a clear message that such cooperation is acceptable and would help trigger changes in the system"* (CR1-2). Another company representative highlights the opportunity for collaboration at the international level, stating that Slovenia should pursue *"projects involving multiple European countries where the industry would be included. Initiatives like these could significantly improve the situation"* (CR6). A stakeholder from a non-industry organisation confirms that such mechanisms are already in place, explaining that *"At the moment, there is the Innovative Health Initiative, which includes all EFPIA partners and functions as a public-private partnership, where projects are developed together. Slovenia already participates, so this kind of collaboration already exists. Companies could be more involved in European mechanisms and partnerships, which could then be applied in Slovenia as well"* (SH5, Innovative Health Initiative, n.d.).

Another issue that particularly frustrates most company representatives is their limited involvement in decision-making processes in Slovenia and the perception that they are not treated as equal partners. As one interviewee explains, *"We would like to sit at the same table in certain panels or working groups so that we can have a voice in how to resolve certain issues. At the same time, we believe that this collaboration should be clearly defined"* (CR5-2). Another supports the call for inclusion, stating, *"We genuinely want to be included as stakeholders in discussions and decision-making. Listen to us, and then you can assess whether it makes sense"* (CR3). A third respondent points to the media's role in shaping negative perceptions that influence their exclusion: *"We wish to become a more relevant partner in decision-making and that the perception of pharmaceutical companies improves. I am referring here to the media, which portray us as profit-driven monsters. There is a need to raise awareness among journalists"* (CR8). This view is shared by a non-industry stakeholder, who stresses the importance of inclusive dialogue: *"A whole range of national problems could be solved much more easily if different stakeholders knew how to come together and think in terms of the common good"* (SH4). One company representative builds on this point, identifying a broader cultural and institutional challenge: *"There needs to be more consensus, greater trust, and more open collaboration when discussing legislative changes. To begin with, we need to start talking and listening to one another"* (CR2). They also criticise the government's frequent use of emergency procedures: *"The current government holds the record for the number of emergency laws. This is problematic because changes are adopted through fast-track procedures without any real consensus. It is important to gather opinions and coordinate with as many different stakeholders as possible before drafting legislation. In our case, doing this through the Pharma Forum would be sufficient. I would like to see that when legislation is being passed, it is better aligned with stakeholders before being made public"* (CR2).

The development of the healthcare system is seen as essential for progress, particularly in areas that have long stagnated, such as clinical trials and health registries, as well as in

establishing a more comprehensive understanding of the broader societal value that medicines bring. Several interviewees stress the need for greater awareness and more open discussion about the contribution of medicines to society as a whole (CR3).

One non-industry stakeholder explains in detail why Slovenia should improve its clinical research landscape, noting that while the presence of clinical trials may not directly influence the development of new medicines, it would have a significant impact on the healthcare system itself. *"These studies are very labour-intensive and require adherence to good clinical practice, meaning well-organised documentation, clear patient data and fully informed patients. In short, everything that defines good medicine. Conducting clinical trials contributes to better organisation in the departments where they are carried out. At the same time, it increases awareness and knowledge in the field of drug development. In essence, it brings expertise through conducting research"* (SH3). They also point to the main barrier, stating, *"Clinical trials could also generate income for hospitals, but the biggest problem is the lack of organisation"* (SH3). In essence, better medical expertise within the country leads to greater potential for Slovenia to position itself as a regional hub.

According to interviewees, digitalisation is another area where Slovenia must improve if it is to position itself as a centre of operations for the pharmaceutical sector. As one company representative explains, *"Although everything is digitalised, it is not organised in a usable way. We need a high-quality, standardised data structure that allows for meaningful analysis and informed decision-making"* (CR1-1). A stakeholder from a non-industry organisation shares this view, stating, *"Digital transformation is still halfway there. We are collecting data, but the systems don't really work together. If this information flowed more efficiently, we could support the healthcare system much better with it"* (SH1). Interviewees from research-based pharmaceutical companies also highlight a specific gap within the broader digital landscape: the lack of well-developed digital clinical registries. One respondent stresses the need for progress in this area, noting that *"Companies want the digitalisation of registries and the establishment of clinical registries for every disease"* (CR8). Another explains why registries are critical for evidence-based care and value assessment: *"A better overview would show which medicines and therapies are truly important ... what brings added value to the patient"* (CR7).

Following the previous point, company representatives emphasise the need to measure the true value of a medicine in order to price it appropriately. As one explains, *"What is missing on the government's side is active measurement of the added value of medicines in Slovenia. The benefits of treatment are clear, but there is a lack of insight into how much money and time is being saved for hospitals by keeping people out of them"* (CR6). Another adds, *"Clinical value should be assessed independently from economic value. The broader impact of a medicine on the healthcare system is often overlooked, as the evaluation is too narrowly focused"* (CR3). While some company representatives express concern that the evaluation of medicines in Slovenia is too narrowly focused and lacks a comprehensive measurement of added value, recent developments at the EU level offer a structural counterpoint. The

HTA Regulation, which came into effect in January 2025, introduces mandatory JCAs for new oncology medicines and ATMPs, with the scope expanding to all centrally authorised medicines by 2030. These assessments are coordinated at the EU level and aim to provide a transparent, scientifically grounded evaluation of a medicine's clinical value. Other non-clinical dimensions such as economic, organisational, legal and ethical considerations remain the responsibility of individual countries (European Commission, 2023a).

Many interviewees highlight the absence of a coherent, long-term strategy as a key barrier to Slovenia's development as a regional pharmaceutical hub. One company representative stresses the need for consistency and forward planning, stating, *"It is necessary to define the country's long-term strategic objectives, identify its main pillars and key stakeholders to involve, and ensure continuity regardless of who is leading the government"* (CR8). Another adds that the government's priorities must shift, emphasising that *"the government should focus on growing the economy, not saving on healthcare"* (CR9). A non-industry stakeholder supports this sentiment, warning that Slovenia has previously missed opportunities due to political inaction: *"We used to be a regional centre in several industries, but lost many of them due to limited political action. Public administration is the first thing that needs to change or improve"* (SH2). At the same time, some see Slovenia's small size as an opportunity, suggesting it could serve as a model for experimentation. *"We could be a lab for trying out new things. We're small enough to serve as an excellent guinea pig, but we need to, as a nation, adopt a mindset that sees such experiments in a positive light"* (SH2). Others call for more mission-driven policymaking, noting that *"the country plays a key role in driving innovation in new technologies. It is important that it sets clear goals through mission-driven strategies"* (SH2). Practical suggestions for strengthening the system are also raised. One non-industry stakeholder underlines the need to *"strengthen the Slovenian healthcare system by improving working conditions for doctors"* (SH3), and points to the value of sustainable institutional support: *"Technical, organisational and administrative support that would be permanently available in major institutions, like hospitals, would help a lot"* (SH3).

Ultimately, several interviewees stress that Slovenia's success as a regional hub will depend not only on individual policy reforms but on a coordinated national effort. As one respondent puts it, *"We want to become a centre, through cooperation, partnership, and a clear long-term vision. This means cutting through bureaucracy, supporting clinical research, publicly endorsing public-private partnerships and launching a long-term awareness programme to emphasise that we all share responsibility for Slovenia's progress. Without long-term investment in healthcare, quality of life will decline"* (CR1-2). Others point to the importance of creating the right business conditions to support this ambition. As one interviewee explains, *"Supportive business legislation, as seen in countries like Switzerland and Singapore, fair taxation and effective policies for talent exchange and attraction are key to becoming a centre of operations"* (CR1-1).

Table 5: Summary of key findings on Slovenia's path to a regional research-based pharmaceutical hub, organised by themes

Themes	Key findings
Country characteristics	• Slovenia's small size is seen by most as an obstacle, though some view it as an advantage for piloting new solutions
Infrastructure	• Improvement of transport connectivity and infrastructure
Business environment	• Creation of a stable, transparent and predictable business environment to attract investment
Innovation support	• Development of a testing-oriented culture, including regulatory sandboxes, to support innovation • Strengthening of regulatory support for innovation
Taxation & Costs	• Reduction of wage taxation to boost competitiveness • Reduction of labour costs to improve regional competitiveness
Investment attraction	• Introduction of more attractive incentives for pharmaceutical investment
Foreign talent & Human capital	• Simplification of procedures and legislative changes to attract and retain international talent
Public-private partnerships	• Development of accessible and standardised public–private partnership models • Pursuit of cross-border public–private initiatives • Leverage of EU-level partnerships to support local collaboration
Stakeholder engagement & collaboration	• Inclusion of companies in panels and working groups to strengthen their role in decision-making • Recognition of the pharmaceutical industry as a relevant stakeholder in national decision-making • Strengthening of structured, inclusive stakeholder collaboration across policymaking, implementation, and national problem-solving
Trust & Perception	• Improvement of public trust and perception of foreign pharmaceutical companies
Digitalisation	• Improvement in data structure and interoperability to enable effective digitalisation
Medicine evaluation & tracking	• Improvement in the evaluation of medicines to reflect their broader value • Development of digital clinical registries for every disease to support evidence-based care and assessment of treatment value
Clinical trials	• Expansion of clinical trials as a national priority, supported by improved organisational capacity, joint public–private investment, and recognition of their contribution to hospital quality and medical expertise

Source: Own work.

4.3 Set of targeted recommendations for specific stakeholders

Table 6 presents targeted recommendations addressing the needs and responsibilities of key stakeholders in the research-based pharmaceutical ecosystem. Based on empirical findings and the literature review in earlier chapters, these recommendations are tailored to each group's roles, responsibilities and capacities, offering context-specific, evidence-based guidance to support a thriving business environment for research-based pharmaceutical companies in Slovenia.

Table 6: Set of targeted recommendations for specific stakeholders

Stakeholder	Set of recommendations
Universities	• Make academic services more time-efficient by offering flexible, timely solutions that match the pace of industry needs, prioritising practical progress over perfection
AMPMD	• Clarify advertising guidelines for medicinal products, including clearer definitions • Improve data access procedures and contract clarity, ensuring greater predictability and transparency • Accelerate regulatory procedures to improve efficiency and reduce lengthy administrative processes
HIIS	• Address the measurement of broader value added of a medicine through a clearer distinction between clinical value and economic value in the evaluation process • Increase the frequency and timeliness of reporting to ensure up-to-date and relevant data • Introduce greater flexibility in pricing and reimbursement models, including the use of innovative approaches such as outcome-based agreements or performance-linked payments • Address staff shortages
NIPH	• Improve openness to collaboration and communication with the research-based pharmaceutical industry • Develop a comprehensive digital registry of medicines to support monitoring and evidence-based decision-making • Strengthen engagement in public health communication, including greater efforts to raise awareness about vaccination and promote responsible medicine use • Address staff shortages
Ministry of Health	• Enhance accessibility and engagement of the Ministry of Health with the research-based pharmaceutical industry through regular communication, consultation mechanisms, and inclusion in relevant policy discussions • Include research-based pharmaceutical industry in relevant national and EU-level working groups, such as those related to the JCA and broader health policy development
Ministry of Economy, Tourism and Sport	• Align financial incentives and public calls for proposals with the needs of the research-based pharmaceutical industry, through stakeholder involvement in the design of incentives
Industry	• Increase involvement in European-level public–private partnerships, such as the Innovative Health Initiative
Ministry of Health & Industry & NIPH	• Increase public–private collaboration on raising awareness about appropriate medicine use and patient adherence
Ministry of Health & NIPH	• Create joint public–private initiatives for national public health priorities, enabling structured collaboration with the industry through platforms such as Pharma Forum
Both ministries	• Increase public–private partnerships in the research-based pharmaceutical sector, following examples such as Biotech Hills in the generic industry
Multi-stakeholder	• Make collaborative efforts by public health institutions, the Ministry of Health, patient associations, Pharma Forum, academic institutions and the media to improve public perception of foreign research-based pharma companies • Improve data structure and interoperability by the NIPH, HIIS and the Ministry of Health to support effective digitalisation and enable integrated, data-driven health system planning • Expand clinical trials as a national priority led by the Ministry of Health, supported by improved organisational capacity within public hospitals, joint investment from the industry and enabling support from the Ministry of the Economy, with regulatory oversight provided by AMPMD

Source: Own work.

4.4 Limitations of the thesis and future research directions

This thesis offers valuable insights from the literature and perceptions of selected key stakeholders regarding the business environment for research-based pharmaceutical companies in Slovenia. However, several limitations should be acknowledged, and addressing them may help guide future research in this field.

One limitation of the thesis is its narrowed stakeholder scope. By focusing only on those directly involved in regulatory and policy matters, it does not include perspectives from hospitals, healthcare providers or patients. This means the broader dynamics of the pharmaceutical ecosystem are not fully captured. Future research could expand the stakeholder base to include these groups and explore how their experiences intersect with regulatory and industry dynamics.

Another potential limitation is the subjective nature of the interview data. As with any qualitative research, there is a possibility that some participants shaped their responses to reflect their organisation in a more favourable light or avoided expressing critical views. While efforts were made to create a confidential and open interview setting, the findings may still reflect elements of self-presentation or strategic framing.

Participation in the research was voluntary, and not all invited stakeholders agreed to take part. This may have influenced the range of perspectives captured, particularly if those who declined hold significantly different views.

Due to the scope and accessibility of participants, the sample did not include representatives from every research-based pharmaceutical company or policy-relevant stakeholder institution. While efforts were made to capture a diverse range of perspectives, the findings may not fully reflect the views of all relevant actors.

Another limitation is that the research mostly includes only one representative per stakeholder organisation. This means the findings reflect individual viewpoints, which may not fully capture the range of perspectives that could exist within each organisation.

A potential limitation lies in the data analysis process, which was conducted solely by the author. While the analysis was carried out systematically and with multiple rounds of review, the absence of additional researchers means that the interpretation of themes and patterns reflects a single analytical perspective. This limits the opportunity to discuss the findings with other researchers.

Due to the bilingual nature of the interviews, some interviews are translated into English. While care was taken to preserve meaning and clarity, there remains a small risk of nuance being lost in translation.

The findings are shaped by the regulatory and institutional environment in Slovenia. While they provide relevant insights for the local context, they may not be directly transferable to countries with different healthcare systems or policy frameworks. Future research could explore similar questions in other national settings to enable cross-country comparisons and identify context-specific or transferable practices.

Given the evolving nature of the research-based pharmaceutical policy landscape, some insights presented in this thesis may change over time. This is particularly relevant for recommendations, which are based on the context and stakeholder positions at the time of data collection.

Lastly, another limitation is the limited depth of the recommendations presented. While a set of targeted proposals is included for specific stakeholders, this part of the thesis is relatively brief and does not offer a fully developed analysis. Given the complexity of the issues involved, a more detailed exploration of stakeholder-specific strategies is beyond the scope of this thesis and would be better suited to dedicated future research.

5 CONCLUSION

This thesis explores how Slovenia can foster a more supportive business environment for research-based pharmaceutical companies, with the broader aim of improving patient care. By examining the value these companies bring, the conditions shaping their operations and the dynamics between key stakeholders, the thesis provides an in-depth look at the opportunities and obstacles within Slovenia's research-based pharmaceutical ecosystem. Through qualitative analysis of selected stakeholders' perspectives and review of relevant literature, the thesis identifies areas of alignment and divergence not only between public and private sector actors but also within each group, and highlights the changes needed to enhance the sector's long-term potential.

The findings confirm that the presence of foreign research-based pharmaceutical companies in Slovenia is widely recognised as beneficial. These companies contribute to public health by introducing innovative therapies, supporting early diagnosis, and improving treatment outcomes. Their investments in workforce development, education, and medical infrastructure enhance the country's healthcare capabilities. Moreover, their presence supports economic growth through high-value employment, local service engagement, and indirect job creation. Companies are also active in promoting patient awareness and public health campaigns, while their digital solutions and global networks accelerate knowledge transfer and innovation diffusion. Nevertheless, some non-industry stakeholders remain critical of certain commercial practices, such as the blending of educational and promotional efforts, which they believe may undermine transparency. Despite these concerns, the overall perception remains that the contribution of these companies extends well beyond medicine provision and includes broader support for the national healthcare and knowledge systems.

The thesis also explores the complexity of the current business environment in Slovenia. While the country benefits from a highly educated workforce, the limited supply of specialised talent in areas such as pharmacoeconomics, regulatory science, and digital health is a recurring challenge. High labour costs, slow recruitment processes, and complex bureaucratic procedures further hinder the ease of doing business. Companies often resort to outsourcing business functions abroad, which limits domestic economic spillovers. Although Slovenia offers relatively good access to medicines compared to other CEE countries, access timelines remain inconsistent, especially for innovative therapies. Regulatory inefficiencies, particularly lengthy pricing and reimbursement approvals, further complicate the market entry of new medicines. Moreover, limited capacity for clinical trials and the absence of robust disease-specific registries reduce the attractiveness of Slovenia as a research destination.

Another key insight from the thesis concerns the state of stakeholder relationships within Slovenia's pharmaceutical ecosystem. Both company representatives and non-industry stakeholders agree that collaboration between sectors is underdeveloped. Public sector institutions are often perceived as slow, reactive and lacking structured communication channels. Trust remains limited, with some stakeholders questioning the integrity of industry-sponsored activities, while others highlight the rigidity of public institutions as a barrier to cooperation. Despite this, there is mutual recognition that more inclusive, long-term collaboration could yield significant benefits. Suggestions include creating multi-stakeholder platforms, increasing the involvement of industry experts in policy planning, and building public–private partnerships in areas such as digitalisation, data use, and clinical research. Companies express willingness to engage, but call for clearer rules, transparency and acknowledgment of their role as relevant stakeholders.

Finally, the thesis examines the potential for Slovenia to strengthen its position as a regional hub for pharmaceutical research and innovation. Many stakeholders agree that the country has a strong foundation, including its location, talent base and healthcare system, but that current structural limitations prevent it from fully realising this ambition. Key areas for improvement include enhancing digital infrastructure, investing in transport connectivity, simplifying hiring procedures and promoting Slovenia's capabilities internationally. Expanding clinical research, improving interoperability of health data and supporting the development of registries are also viewed as critical. Slovenia's small size is seen by some as a constraint, but others argue it could be an advantage in piloting innovative models of care, regulatory testing and partnership-driven solutions. Targeted reforms and strategic positioning at the EU level could allow Slovenia to evolve into a more attractive and strategic centre within the regional research-based pharmaceutical ecosystem.

Taken together, these insights highlight the need for targeted reforms that address workforce capacity, streamline regulation, promote clinical research and create formal mechanisms for inclusive stakeholder dialogue. By acting on these areas, Slovenia can strengthen its strategic

position and become a more attractive hub for pharmaceutical innovation, to the benefit of patients, professionals and the wider healthcare system.

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APPENDICES

Appendix 1: Interview questions for company representatives

Main question 1:

What is the value-added of having research-based pharmaceutical companies present in Slovenia?

Potential sub-questions:

Who are the most important stakeholders for your company?

In what way are you satisfying their needs and wants?

How has your company affected the labour market in Slovenia? (number of jobs, quality, skills, and training programs)

Have you in any way contributed to the growth of healthcare in Slovenia? (early access to innovative medications, offering employment and training opportunities for highly skilled, developing intellectual property that can be globally licensed)

What innovative practices or technologies has your company introduced to Slovenia?

How have you contributed to the overall knowledge ecosystem in Slovenia? (collaborations with universities, introducing good business practices from abroad, corporate social responsibility)

Do you have any measures taken inside your company regarding diversity and inclusion?

What does the employee demographic look like in your Slovenian branch?

How do you think the presence of foreign employees contributes to the internationalization of Slovenian society?

Main question 2:

Why did you decide to establish your innovation branches in Slovenia and what is the current business environment like?

Potential sub-questions:

What were the primary factors that attracted your company to establish operations in Slovenia?

What were the biggest challenges in setting up your pharmaceutical operations in Slovenia?

Do you perform all functions within Slovenia? Why yes or why not?

Are you thinking of backing out of Slovenia? Name two biggest reasons/obstacles

Do you have any hiring problems in Slovenia? (knowledge or skills gap)

How do you perceive the regulatory environment in Slovenia for innovative pharmaceutical companies, particularly in terms of drug approval processes, clinical trials and intellectual property protection?

What is your relationship with public institutions? (Government, AMDMP, NIPH, HIIS, universities/institutions)

In what ways do you collaborate with others to achieve your aim?

How do you perceive the collaboration, do you feel like there is a distance/gap between you and them?

How much access to data, health records and large datasets do you have in Slovenia for your company's research and development activities?

How is the overall healthcare infrastructure in Slovenia in terms of supporting the development of new innovative pharmaceutical products?

Main question 3:

How could Slovenia further stimulate and enable you to develop within the region?

Potential sub-questions:

How can government, academia, and the industry work together more effectively to drive innovation?

Are there any financial incentives or support programs that would encourage your expansion of operations within Slovenia?

In your opinion, what would it take for Slovenia to become the centre of operations for innovative pharmaceutical companies in the region?

Could you share with us what are in your opinion five most important things a country can provide for an innovative pharmaceutical company? How would you rank them?

Do you have any concluding thoughts, remarks, or suggestions relevant to our research you'd like to share with us?

Appendix 2: Interview questions for non-industry stakeholders

What is your opinion on the research-based pharmaceutical industry?

What is your view on the contribution of the presence of research-based pharmaceutical companies in Slovenia? Positive or negative?

How could research-based pharmaceutical companies better meet the needs of their stakeholders?

Are there any of your expectations that the industry does not fulfil or address?

Do you think your interests align with those of the industry? Why or why not? If not, how does this affect the overall well-being of the public?

What does the collaboration between you and the industry look like? Is there a communication barrier or distance present?

As a country, do we want research-based pharmaceutical companies to remain in Slovenia, even those that will not build production facilities here? Why do we want them here?

In your opinion, what consequences would there be if research-based pharmaceutical companies closed their branches and left Slovenia?

What is your view on the current situation of clinical trials? How could they be made easier to implement?

How can Slovenia address the challenges associated with rising healthcare costs and ensure access to treatment for its population? Can research-based pharmaceutical companies contribute in any way?

What challenges and opportunities do you see for digital health in the Slovenian healthcare system?

What kind of support or investment is needed to accelerate the adoption of innovation and improve access?

What is your opinion on the accessibility and usability of data for healthcare purposes?

How many of your suggestions/opinions are considered by the industry in practice? Could more be taken into account, or is there some sort of barrier on their side? Where do you think the hesitations lie? And vice versa?

Do you have any final thoughts or comments relevant to our research that you would like to share with us?