MASTERARBEIT | MASTER'S THESIS

Titel | Title

The impact of EU regulations on the R&D department of international European pharmaceutical companies

verfasst von | submitted by

Veronika Wolfsgruber

angestrebter akademischer Grad | in partial fulfilment of the requirements for the degree of

Master of Science (MSc)

Wien | Vienna, 2025

Studienkennzahl lt. Studienblatt	Degree programme code as it appears on the student record sheet:	UA 066 914
Studienrichtung lt. Studienblatt	Degree programme as it appears on the student record sheet:	Masterstudium Internationale Betriebswirtschaft
Betreut von	Supervisor:	Mag. Dr. Lola Raich M.A.

Acknowledgements

First and foremost, I would like to thank my supervisor, Dr. Lola Raich, for the opportunity to write my master's thesis with her, but also for her unwavering support and guidance throughout the whole research process. The valuable knowledge I have gained from your mentorship will aid me in my future both professionally as well as personally.

I would also like to extend my gratitude to my family, who have supported me through my academic, professional and personal development. I would not be where I am today without your constant love and encouragement.

Furthermore, I would like to thank my fellow students Viktoria and Melissa for their valuable insights and support during my entire master's studies, but also during the writing process of my master’s thesis. This has not only helped me find my footing academically but equipped me with friends for life. Finally, I am also especially grateful to my best friend Maryam, who was also writing her master’s thesis at the same time and thus shared this experience with me. Her support and encouragement helped me a lot and made what was often a difficult time much easier.

List of Abbreviations

CTR	Clinical Trial Regulation
DACH- region	Germany, Austria and Switzerland
EC	European Commission
EFPIA	European Federation of Pharmaceutical Industries and Associations
EMA	European Medicines Agency
F&E	Forschung und Entwicklung
IP	Intellectual Property
R&D	Research and Development
VFA	Verband der Forschenden Arzneimittelhersteller

List of Figures

List of Tables

Table of Content

Abstract

This master's thesis examines the impact of European Union pharmaceutical regulations on research and development and thus innovation activities by pharmaceutical companies in the European Union. Through an extensive literature review and by conducting expert interviews with key stakeholders from different pharmaceutical companies, it examines how regulatory frameworks influence R&D investments and innovation initiatives.

The results illustrate the ambivalent nature of the EU regulatory framework in the field of human pharmaceuticals: While harmonization and standardization have fostered growth and predictability in the industry, the rigidity of the regulatory framework poses a major challenge to innovation. This leads many companies to conduct their R&D activities in more flexible environments such as the United States and Switzerland. The study examines the exact current framework conditions of the pharmaceutical industry, as well as the newly proposed pharmaceutical strategy for Europe and describes the experiences, but also the expectations of the industry regarding the current, but also future regulatory framework.

The study confirms that the complexity of the regulations and the administrative burden have a negative impact on time-to-market and innovation potential. On the other hand, European harmonization is seen as a key advantage that enables operational efficiency across Europe. Ultimately, this master's thesis highlights the need for a tailored balance between regulatory compliance and the need for flexibility to support innovation and competitiveness in the global pharmaceutical landscape.

Keywords: EU Pharmaceutical Industry, Innovation/ R&D, Pharmaceutical Strategy for Europe, Impact of regulations, Qualitative Research Methodology, promoting innovation in the European Union

Vorwort

Diese Masterarbeit untersucht die Auswirkungen der pharmazeutischen Vorschriften der Europäischen Union auf Forschung und Entwicklung und somit die Innovationskraft von pharmazeutischen Firmen in der Europäischen Union. Durch eine weitreichende Literaturanalyse und die Durchführung von ExpertInneninterviews mit wichtigen AkteurInnen aus verschiedenen Pharmaunternehmen wird untersucht, wie regulatorische Rahmenbedingungen F&E-Investitionen und Innovationsinitiativen beeinflussen.

Die Ergebnisse verdeutlichen den ambivalenten Charakter des regulatorischen Rahmens der EU im Bereich der Humanpharmazeutika: Während Harmonisierung und Standardisierung das Wachstum und die Vorhersehbarkeit in der Branche gefördert haben, stellt die Starrheit des Rechtsrahmens eine große Herausforderung für die Innovation dar. Dies veranlasst viele Unternehmen ihre F&E-Aktivitäten in flexibleren Umgebungen wie den Vereinigten Staaten und der Schweiz durchzuführen. Die Studie untersucht die genauen aktuellen Rahmenbedingungen des Pharmaindustrie, sowie die neu vorgeschlagene Pharmastrategie für Europa und beschreibt die Erfahrungen, aber auch die Erwartungen der Industrie an den gegenwärtigen, aber auch zukünftigen Rechtsrahmen.

Die Studie bestätigt, dass sich die Komplexität der Vorschriften und der Verwaltungsaufwand negativ auf die Markteinführungszeit und das Innovationspotenzial auswirken. Auf der anderen Seite wirkt die europäische Harmonisierung als einen entscheidenden Vorteil, der operative Effizienz in ganz Europa ermöglicht. Letztendlich unterstreicht diese Masterarbeit die Notwendigkeit eines maßgeschneiderten Gleichgewichts zwischen der Einhaltung von Vorschriften und der Notwendigkeit zur Flexibilität, um Innovation und die Wettbewerbsfähigkeit in der globalen pharmazeutischen Landschaft zu unterstützen.

Stichwörter: Pharmazeutische Industrie der EU, Innovation/ F&E, neue Pharmastrategie für Europa, Auswirkungen von Vorschriften, Qualitative Forschungsmethodik, Innovationsförderung in der Europäischen Union

1. Introduction

1.1. Background information and relevance to the topic

The European pharmaceutical industry is an essential key asset of European Union's economy (Efpia, 2022, p. 3). Therefore, the EU is continuously developing the regulations and strategy laid out for the pharmaceutical industry in Europe. On November 25th, 2020, the Union adopted the "Pharmaceutical Strategy for Europe" with the aim to support the industry and built a framework that is steadier and more resistant against unforeseen circumstances. One of the four pillars that the focus is laid on is the increase of innovation and competitiveness of the industry (European Commission, 2023a).

In the last 50 years the EU has set a series of legislations for the pharmaceutical field in order to not only regulate the quality and safety of the medication produced (European Commission, 2017b, p. 1f), but also to ensure the competitiveness of the companies working on these products in comparison to other players in the industry like the United States of America or China (Efpia, 2023b). In order to achieve both of these goals the EU has revised the pharmaceutical legislation constantly, with the latest revision in 2023. This new directive and regulation are now to revise and replace the existing general pharmaceutical legislation. Therefore the European Commission has drafted a proposal for the Pharmaceutical Directive, as well as one for the Pharmaceutical Regulation (European Commission, 2023i). While the commission states in these proposals that the general objectives are to "guarantee a high level of public health by ensuring the quality, safety and efficacy of medicinal products for EU patients" and to "harmonize the internal market for the supervision and control of medicinal products and the rights and duties incumbent upon the competent authorities of the Member States.", one of the four specific objectives of this revision is to "offer an attractive innovation-and competitiveness friendly environment for research, development, and production of medicines in Europe". (European Commission, 2023g & European Commission, 2023h, pages 3). This increase in R&D should be achieved by consistent and stable rules, a faster authorization as well as less administration for innovative medicine and general incentives for R&D by rewards through an incentives system (European Commission, 2023e).

The research and development done within the industry not only increases the health of the European and worldwide population, but also ensures the competitiveness and progression of the individual companies. In 2021 the research-based pharmaceutical industry employed

roughly 840.000 people and invested around 41.500 million euros in R&D activities. This number has risen steadily over the past years (Efpia, 2022, p. 4). This demonstrates how important the sector is for the economic goals of the European Union and explains why the EU is constantly working on new regulations and strategies to strengthen the companies and keep them competitive.

The literature suggests different reasons for the increase in R&D and innovation activities in pharmaceutical companies. A huge impact on innovation have regulations and incentives given by the government or the EU (e.g. Bénard et al, 2018 & Nayroles et al, 2017). Bénard et al state in their published work in 2018 that the incentives given to pharmaceutical companies ensure investments in time and cost intensive investments and therefore have proven themselves effectively increasing innovation (p. 84). On the other hand, Nayroles et al stated that a highly regulated industry leads to lower prices for consumers, but also to reduced R&D expenses invested by the companies (2017, p. 1). In order to recognize the exact influence of the regulations in the European Union on pharmaceutical companies, this master's thesis is dedicated to this topic and examines it from different perspectives. It builds on the existing literature, but also conducts empirical research to further close the research gap.

1.2. Aim of the study

This master thesis aims to investigate the impact that new regulations within the European pharmaceutical industry have on the companies acting in this sector, specifically examining the influence on the companies' innovation process and R&D. By exploring this transdisciplinary research area, which integrates aspects of International Business, Innovation Management, and European Studies, this study intends to illustrate the complex relationship between regulations and innovation in R&D within the pharmaceutical sector. In order to comprehensively explore and analyze the effects of European Union regulations on innovation and R&D activities, the research will pursue several key objectives:

Firstly, it seeks to provide a deeper understanding of how EU pharmaceutical regulations shape R&D activities and impact the level of innovation within the sector. This involves examining how regulatory frameworks influence the decision-making processes and investment strategies of pharmaceutical firms.

Secondly, the thesis aims to assess the current regulatory landscape governing the pharmaceutical industry in the EU. By critically evaluating existing regulations and their

implementation, the study seeks to identify strengths, weaknesses, and potential areas for improvement within the regulatory framework.

Thirdly, the research endeavors to identify the challenges and opportunities presented by EU pharmaceutical regulations for European companies. By uncovering barriers to innovation and R&D, as well as potential avenues for growth and development, the study aims to contribute to the formulation of strategies that enhance the competitiveness of European pharmaceutical firms in the global market.

Lastly, the thesis aims to integrate insights from European Studies and international strategic management to draw meaningful conclusions from this interdisciplinary investigation. By synthesizing knowledge from diverse fields, the study seeks to offer valuable insights that can influence policymaking, corporate strategies, and academic research within the pharmaceutical industry.

Overall, through a comprehensive analysis of the complex interplay between regulation, R&D, and innovation, this master thesis endeavors to shed light on key dynamics shaping the European pharmaceutical industry and contribute to the advancement of knowledge in this fundamental field.

1.3. Research Questions and Hypothesis

Based on existing literature regarding the topic and the opportunities to explore current research gaps, this master thesis will be mainly based on two Research Questions, RQ1 and RQ2, as well as correlating hypotheses, H1 and H2.

The Research Questions are stated as followed:

- *RQ1: How does the regulatory framework for the pharmaceutical industry in the EU impact the research and development investments of European companies operating within the sector?*

RQ1 was selected to investigate the direct impact that the EU pharmaceutical regulations have on the R&D investments of European pharmaceutical companies. Understanding how these regulatory frameworks influence the companies' decisions regarding R&D expenditure is crucial for comprehending the broader dynamics of innovation within the pharmaceutical sector. By addressing this question, the aim is to explore the mechanisms through which regulations shape R&D strategies and investments, thereby providing insights into the effectiveness and efficiency of these regulatory frameworks.

- *RQ2: What are the main challenges and opportunities that European companies encounter due to pharmaceutical regulations in the EU, and how do these affect their R&D and innovation initiatives?*

RQ2 was chosen to explore the broader implications of pharmaceutical regulations on European companies, beyond their direct impact on R&D investments. This question seeks to identify the challenges and opportunities that companies encounter because of those regulatory requirements imposed by the EU. By examining how these regulations affect various aspects of companies' operations, including R&D and innovation initiatives, the aim is to gain a comprehensive understanding of the multifaceted impact of regulatory frameworks on the European pharmaceutical industry. Addressing this question will enable us to identify potential barriers to innovation and growth, as well as opportunities for companies to thrive within the regulatory environment.

In order to answer RQ1 and RQ2 the following two hypotheses are proposed:

- *H1: European pharmaceutical companies that strategically align their R&D efforts with EU regulatory requirements see higher and more efficient investments in research and development.*
- *H2: Increased regulatory complexity and administrative burden can negatively impact the time-to-market for new pharmaceutical innovations in the EU and therefore have a hemming impact on innovation and R&D.*

These questions were set with the aim of reducing the research gap. As will be shown in the following literature review, there is already quite some literature and research conducted on the topics of pharmaceutical R&D, as well as what impact regulations can have on companies and how these are influenced by rules set by the government. The research gap was identified as follows: The exact relationships between the impact of regulations on the very specific industry of pharmaceuticals largely concern the influence of price regulation for example. The focus on R&D is less researched here, and this happens more in studies that concern the American market. Thus, the aim of this work is to explore precisely this gap, namely the research in development of pharmaceutical companies in the EU and their actions under EU regulation.

2. Literature Review

2.1. European Pharmaceutical Industry

2.1.1. Recent historic developments of the European pharmaceutical industry

The pharmaceutical legislation in the European Union dates back almost 60 years. In the year 1965 a set of rules were established by the Council Directive regarding the authorization of medical products, as well as their distribution (European Commission, 2015). One of the reasons for this rethink was a previous incident involving the drug thalidomide, which caused limb deformities in newborns, which ultimately led to a focus on measures for greater drug safety (European Commission, 2017a). Even though the legislation and regulations have evolved over the last decades, some of the principles founded in 1965 are still valid up until today. One of them being that medical products must be authorized, before they are to be released into the market (European Commission, 2017a, p. 1).

Since then, the legislation has changed significantly over the years, i.e. with another big milestone reached in the year 1972, when the joint position of the EU on market authorizations was introduced, including a multistep procedure as well as a common committee. Over the years new rules and regulations were established, the process of developing and releasing new medicine on the market became more and more centralized, new cooperation between nations grew and organizations like the European Medicines Agency (EMA), were founded (European Commission, 2017b, p. 1f).

As a result of all these changes, Europe has become a key player in the field of pharmaceutical products. Since the year 2000, production figures have risen from 127.5 million euros to around 300 million euros. Switzerland leads the way with the highest production volume of over 53 million euros, followed by Italy and Germany. Overall, Europe is, after the US, the second largest pharmaceutical market, accounting for 23.4 percent of global sales (Efpia, 2022, p. 3ff). Considering research and development within the EU, especially the northern European countries are leaders regarding their innovation performance. The report of the European scoreboard 2023 shows that Austria and Germany are considered strong innovators as well, presenting an innovation performance higher than the average EU rate. The most innovative European country though is Switzerland (European Commission, 2023d, p. 2ff).

2.1.2. Status quo of the DACH region

Taking a closer look at the DACH region, starting with Germany, it shows that the country has an outstanding pharmaceutical sector, employing more than 132.000 people (Pharma Deutschland, 2023, p. 7). In 2021, the industry generated sales of around 55 billion euros, the majority of which was generated abroad. With an average of almost eleven percent of their turnover spent on internal R&D, the pharmaceutical field is the industry conducting the most research and development, which pays off in terms of numbers, with a total of 46 new drugs with new active ingredients launched on the German market in 2021 (Kirchoff, 2022, p. 4ff). In general, Germany is an important and notable location for conducting research and development in the pharmaceutical sector. Almost 40 percent of the 42 companies being a member of German Association of Research-Based Pharmaceutical Companies (VFA) operate laboratories in Germany, including companies whose headquarters are in other parts of the world. In terms of clinical trials sponsored by the industry, Germany is especially significant for its extensive involvement in global clinical trials, ranking second worldwide after the USA (VFA, 2019). Although Austria is much smaller in comparison to Germany, the country is still a strong key player in the field of pharmaceutical industry. In Austria the industry provides jobs for around 18.000 people in around 150 pharmaceutical companies and had a production volume of around 1.45 billion euros in 2022, having a positive trade balance (Pharmig, 2023).With a total investment of around 311 million euros (year 2017) in R&D alone, which corresponds to a share of expenditure of 3.1 percent (year 2019), the country is the eighth most innovative country in the EU. These figures have risen slowly but steadily in recent years (Pharmig, 2021, p. 32). Finally, the last country belonging to the DACH region is Switzerland. The Swiss' pharma industry is outstandingly productive, compared to the national average the pharmaceutical sector is more precisely 5 times as productive. With 47.000 employees and a value added of 37 billion CHF (~39,4 billion euros) the industry contributes significantly to the national economy. Through investments of seven billion CHF, the pharmaceutical industry is the industry with the highest and most extensive research and development program in the country (BAK Economics AG, 2021, p. 6). Switzerland holds the largest global export surplus in pharmaceutical products. Beyond being a key production hub, it is also a significant center for research (Switzerland Global Enterprise, 2020, p. 1f).

There are multiple factors affecting the success of this European region in the field of pharmaceuticals. A common advantage of the DACH region is the close network of universities, research facilities and other companies like start-ups (VFA, 2019). Another factor that has a positive impact on productivity is the presence of highly skilled and qualified

workers and scientists (Switzerland Global Enterprise, 2020, p. 2), but good infrastructure, successful collaborations and political support also play a role (VFA, 2019).

While Germany and Austria are member states of the European Union, Switzerland is not part of the EU. Even though Switzerland is not an EU member state, it still maintains strong relations with the European Union. Apart from being an important trading partner, there are also certain agreements between the two partners that support their respective pharmaceutical industries. Through these agreements, such as mutual recognition of conformity agreements or the joint research agreement, collaboration is simplified, sales get promoted, and it ensures that the value chain activities across the border work efficiently. Also, Switzerland is able to achieve access to various EU fundings. Without these framework agreements, both parties would experience adverse consequences (BAK Economics AG, 2021, p. 10ff). Three agreements are particularly important: the Agreement on the Free Movement of Persons (AFMP), the Mutual Recognition Agreement (MRA) on conformity assessment and finally the Research Cooperation or framework programs for research and innovation (Interpharma, n.a.).

2.1.3. Innovation and R&D in the pharmaceutical industry

In order to research the impact that the EU has on pharmaceutical innovation and R&D, it is important to define those measures as a first step. One way to define innovation is for example “the creation of new resources which contributes to progress” (Pelkmans & Renda, 2014, p. 2). The European Union defines innovation as “the use of new ideas, products or methods where they have not been used before” and “a new or significantly improved product (good or service) introduced to the market, or the introduction within an enterprise of a new or significantly improved process.” (Eurostat, n.a.). This new innovation then has to be implemented, for example during market authorization or within the company as a new innovative process (Gault, 2018, p. 618). In general, there are four kinds of innovations: process innovation, product innovation, organizational innovation and finally marketing innovation. This typology was set by the OECD in 2005. Furthermore, there is a distinction between disruptive or radical innovation and incremental or follow on innovation, which is a sequence of many small improvements (Pelkmans & Renda, 2014, p. 2). It is important to define innovation in a general but also more narrow sense, because it allows the policy makers, who have an interest in increasing innovation in the industry, to have a more detailed discussion on what is needed to achieve that goal. It also then provides a way to compare the innovation outcomes achieved within the industry and therefore measure innovation, the type

of innovation and the connections in between player of the industry and outside of the industry boarders. Through the possibility to measure innovation in a more detailed and standardized way it is then possible to see outcomes that are short term, but also long-term impacts of innovation on the economy (Gault, 2018, p. 618). Maria Mazzucato on the other hand also emphasizes in her report that, despite standardization, there is no “one size fits all” strategy or mission in the area of innovation. The EU should therefore make its missions and goals in the area of innovation management flexible in order to really create an impact in the industry (2018, p. 9f).

In regards to the pharmaceutical innovation, the pharmaceutical research and development process follows a structured and systematic approach to ensure the safety and efficacy of new medication. The R&D process begins by identifying the need for new medication, typically based on gaps in current treatments and the targeting of specific diseases. Researchers then identify a crucial target molecule and discover, refine, and optimize potential compounds for safety and efficacy in order to then proceed to preclinical testing. Clinical trials are conducted in three phases. In Phase I, the drug is tested on healthy volunteers to assess its safety and pharmacokinetics. Phase II involves initial efficacy studies with a small group of patients, focusing on determining the appropriate dosage and identifying potential side effects. Phase III expands the scope to a larger patient population to further confirm efficacy and monitor for any adverse reactions (VFA, 2023). These steps are all taken before launching the products onto the market and are the main focus of innovation in the pharmaceutical industry, since in these stages of the product life cycle the medicines are developed (Vogler et al, 2018, p. 2). After the clinical trials, data is then submitted to regulatory authorities like the EMA for approval, followed by Phase IV post-market surveillance to monitor and analyze the long-term effects and efficacy of the developed products, in order to ensure that only safe and effective medication reaches the market (VFA, 2023). These steps after the market authorization are important as well for innovation management, since the EU still has to monitor and evaluate the products post launch (Vogler et al, 2018, p. 2). For the European Union it’s therefore important to understand the processes within the pharmaceutical industry and how innovation is made in order to adapt their regulatory framework. Policy learning and the adaptation to the reality in the industry depends on multiple factors, but also on an extensive system of evaluation and efficient monitoring (see more in chapter 2.2.2.) (Gault, 2018, p. 621). Since innovation in one sector is not separated from the rest of the economy, it is important to have a strategy that involves different sectors and disciplinaries, enabling companies to invest in research and development (Mazzucato, 2018, p. 15).

2.2. Pharmaceutical Legislation of the EU

2.2.1. Key regulatory Bodies

One of the most important regulatory bodies in the EU's Pharmaceutical Industry is the European Medicines Agency (EMA). Its mission is "to foster scientific excellence in the evaluation and supervision of medicines, for the benefit of public and animal health in the European Union" (European Medicines Agency, 2024a). Therefore, the EMA plays a crucial role in supporting the development of new medicines and increasing the accessibility of the products across Europe. It is responsible for the thorough assessment of marketing authorization applications in order to ensure that only safe and effective medicines reach the market, while continuous monitoring and surveillance of existing medicines to ensure the safety and efficacy throughout their entire lifecycle, from market entry to post-market use. The EMA is also tasked with provision of accurate and up-to-date information to patients and healthcare professionals, fostering informed decision-making and proper medication use (European Commission, 2023a). Thus, the EMA accompanies and supervises the entire process from scientific advice for pharmaceutical companies, through research and development, evaluation, authorization, to continuous safety monitoring (European Medicines Agency, 2024a) Within the agency, there are various committees for different fields of work, such as the CHMP, an impartial and qualified committee representing amongst others all EU member states. The committee for Medicinal Products for Human Use forms the basis for the EMA's opinion and decisions regarding all medicines for human use. These opinions are always in line with the EC's regulations (Pignatti et al, 2011, p. 5221).

Regarding policy making, the EC, European Commission is the core executive body within the EU. By combining intergovernmentalistic as well as supranationalistic elements it has a broad variety of functions, including the initiation, development and monitoring of the implementation of policies. Apart from that the Commission plays an important role in external relations and acts as a mediator between the EU member states, amongst others. Inside the EC there is a college of 27 Commissioners, who are nominated by one member state each. Each commissioner then has their own cabinet of six to seven advisors (Egeberg, 2022, p. 145ff) who's focus increasingly on the vertical relationships in the Commissions structure, or in other words between the different commissioners and cabinets. By doing so, feedback and objections of different commission departments can be included at an early stage (Egeberg, 2014, p. 243). The Commission Departments, also called Directorates-General (DG) all serve different purposes and areas of expertise, the one most relevant for this

Master thesis is the DG for Health and Food Safety (SANTE). This DG is also responsible for the pharmaceutical policies, including the Pharmaceutical Strategy for Europe (European Commission, 2023a). In summary, the EC is not only involved in the drafting of the legislation but ultimately, after the legislation has been approved by the European Council and the European Parliament, also for the implementation and monitoring at national level. Before implementation, not only the Commission, i.e. the heads of state of the EU member states, and the European Parliament have a say, but also national governments and other stakeholders can make proposals and extensions. However, the final decision lies with the EC (Egeberg, 2022, p. 143). Therefore, the EC works together closely with the national authorities of the member states, especially in the process of monitoring the implementation of the legislation (Egeberg, 2022, p. 152).

In conclusion the EU's pharmaceutical regulatory network is a highly coordinated and close regulatory network, consisting of the EC, the EMA and the national competent authorities (NCAs) of the member states within the European Economic Area (European Medicines Agency, 2024b). While the EC is responsible for the drafting, implementation and monitoring of the legislation, the EMA and the NCAs, with the Heads of Medicines Agencies as their network of Heads of Medicine Agencies (HMA), indeed providing feedback and advice, their main responsibility however lays in regulating the medicines in the EU (European Medicines Agency, 2024c, p.4).

2.2.2. Legislative Instruments and Regulatory Procedures

According to Article 288 of the Official Journal of the European Union there are different forms of legislative instruments and acts that institutions of the EU can make use of. Apart from regulations and directives, there are also decisions, recommendations and opinions. All of them have different areas of application and bindingness. While opinions and recommendations are not legally binding to the member states, decisions are indeed completely binding, though only to whomever they are specified to (European Union b, European Union, 2012, p. 125f). A regulation on the other hand is a legal act that is entirely binding in all member states of the EU, and is directly, uniformly and immediately (within 20 days after publication) applicable. Therefore, it doesn't need to be additionally incorporated in the national law (Publications Office of the European Union, 2022a). In comparison, while directives are also binding, they are not directly applicable. The released directives have to be transposed into the national law of the EU member states to which it is addressed, whether that be all, several, or just one member state. A directive is binding regarding the outcomes it

aims to achieve. However, it grants national authorities the discretion to determine the form or methods utilized to achieve these outcomes. Depending on the directive, the EU set different requirements for the transposition (Publications Office of the European Union, 2022b). These different forms of legislative instruments are used and combined in the different legislations and policies of the EU.

In order to explain the process of policy making, a framework called policy cycle can be used to explain the different stages that law-making in the European Union entails. As can be seen in figure 1, the policy cycle contains five steps, that are continuously repeated (Best, 2022, p. 238).

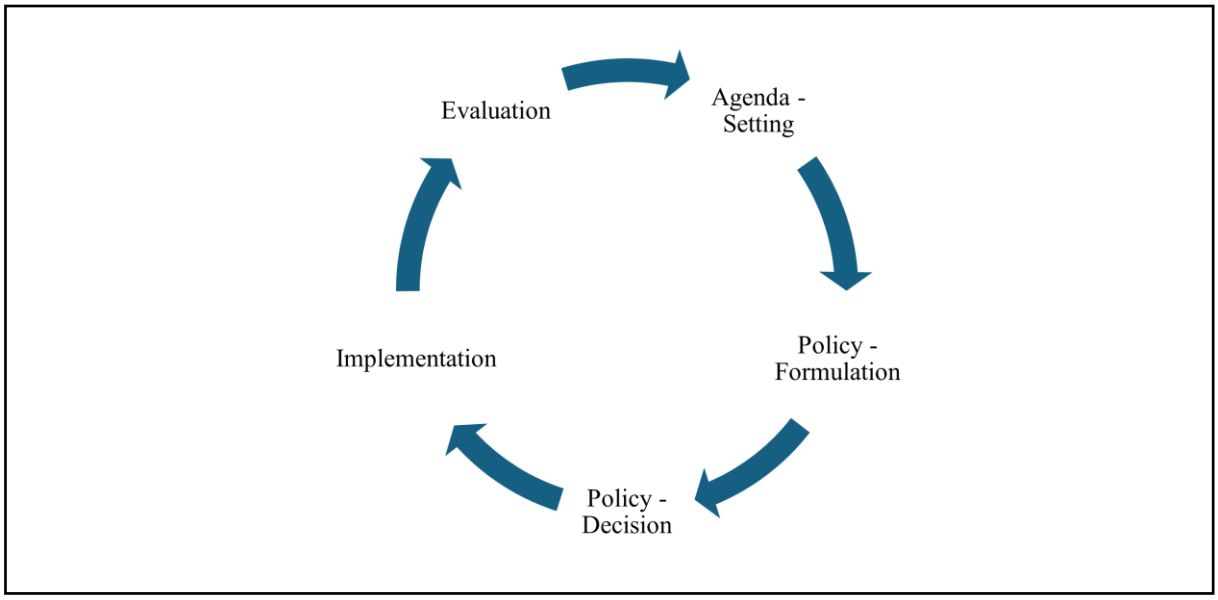

Figure 1: Policy Cycle (Best, 2022, p. 238ff)

It should be noted that the real process of policy development does not always follow these different stages in complete detail and some stages may overlap or change (Young & Roederer-Rynning, 2020, p. 45). Nevertheless, this framework offers the possibility of visualizing a possible process. The beginning of the policy cycle is the setting of the agenda. While the process includes extensive communication between different institutions, the European Commission can make the final decision on which proposal is going to be presented. This is due to the fact that because of the Interinstitutional Agreement on Better Law- Making (IIABL), the Commission, the Council and the Parliament together select the priorities, that are pursued in the upcoming year. A proposal is then drawn up as part of the policy formulation process, usually also by the Commission (Best, 2022, p. 238ff). Before making final decisions on policies, the EU uses a tool called Regulatory Impact Assessment, RIA, to evaluate the impact and efficiency of the regulations ex ante the implementation. In

this process the member states are closely connected with evaluations and feedback (OECD, 2022, p. 70). These impact assessments are deeply rooted within the EU, through initiatives like the Better Regulation initiative they have become an essential part of the European Policy Cycle (Sattelli, 2023, p. 100). After the second step the following stage, decision making, refers to the establishment of fundamental rules that impact a specific policy area. These are considered “legislative acts” and are typically adopted by the Council and the European Parliament through the “ordinary legislative procedure”. These legislative acts can then be regulations, directives or decisions. The following stage would then be the implementation phase. EU policy implementation operates at multiple levels, with national authorities responsible for applying and enforcing laws, including transposing EU directives into national legislation. The European Commission assists member states and may initiate infringement proceedings if obligations are not met. In cases requiring uniform application across the EU, the Commission adopts binding decisions, called "implementing acts", in consultation with member states through comitology committees. These acts apply the basic rules set out in legislative acts but do not modify them, unlike delegated acts (Best, 2022, p. 238ff). In the pharmaceutical industry, the EMA also plays an important role in the area of implementation, but also in the subsequent evaluation, monitoring the application of regulations and guidelines across the EU. This includes assessing the effectiveness, efficiency, and impact of the regulatory framework (European Medicines Agency, 2024b). Finally, the evaluation of takes place, which purpose is to assess if the implemented legislative acts have the wanted outcome and purpose. This stage is particularly important, to ensure the effectiveness of the legislation. Included in the process is a thorough stakeholder consultation. As shown in figure 1, the process of the policy cycle continuously repeats itself over time (Best, 2022, p. 238ff).

Luchetta describes the EU policy cycle very similarly but places more emphasis on impact assessments and evaluation. According to him, the process starts with evaluating the previous legislative framework, he calls it stock-taking exercise, which is followed by the consultation of the public. Before the draft or proposal is drawn up, the first impact assessment is carried out ex ante. This is followed by the legislative procedure, as well as the transposition of the legislation and implementation in the member states. Finally, the policy cycle ends with the enforcement of the measures taken (2013, p. 8f). Also Brooks emphasizes that the maybe traditional view on policies, a linear system, is rather outdated and is replaced by a constant stream of evidence and input by different stakeholders, all coordinated by the authorities, who finally make the decisions (2018, p. 12). While RIAs and the involvement of various stakeholders is already an established procedure of the European Commission and is already

being strongly implemented, studies such as those by Saltelli et al. indicate that there is still potential for further development for the EU. In addition to political, sociological and scientific input, the inclusion of other humanitarian science perspectives reduces the possibility of neglecting certain marginal interests. The Horizon Europe program, for example, which has been running since 2021, attempts to address these deficits (Saltelli et at, 2023, p. 100).

At the level of the EU the process of formulating and implementing policies poses a special challenge, since the structure and multiple actors of the Union have to be considered. Therefore, it is important to be in communication with different interest groups and coordinate the various actors (Young & Roederer-Rynning, 2020, p. 46). In order to do so, these policy assessments, both before, ex-ante, or after, ex post, of the implementation are an important requirement to take the balance between benefits and costs into consideration, as well as to measure if the intended objectives were delivered to and in the member states. An OECD report though shows, that whereas the majority of European Member States participate in assessment ex ante of the implementation, only around half of the states provide an evaluation ex post, even though there are indicators that the later form could be more effective in comparison to given feedback before policy implementation (OECD, 2022, p. 98f). Luchetta also describes the impact assessments as the most important tool of the European Commission during the policy cycle, as it promotes and enables other important instruments such as public consultation or simplification programs. The assessments cover three areas of impact that the change in legislation could have: economic impacts, social impacts and environmental impacts. Even though these three areas are part of the IA, the focus is on the impacts that affect the economy (2013, p. 9f). Continuous learning from past policy processes, so-called policy learning, is also particularly important. By monitoring current policies, assessing the status quo and incorporating impact assessments, conclusions and comparisons can be drawn (Gault, 2018, p. 621). In order to optimally implement this regulatory framework, Luchetta names four important aspects: (1) interaction with stakeholders, on a national and regional level, (2) working with set goals and milestones when measuring the impact of policies, (3) setting up instruments to encourage bottom up solutions, like incentives for states or companies to engage and comply and finally (4) enable flexibility and proactivity (2013, p. 16ff). In the case of the pharmaceutical legislation the interaction communication with stakeholders would include the EMA, national authorities and also pharmaceutical companies (see more in chapter 2.2.1.) But also other input streams, like journalists or a civil society group can be part of the process (Brooks, 2018, p. 12). With regard to point 2, the

responsible department of the EC, the DG for Health and Food Safety, currently under the leadership of Commissioner Stella Kyriakides, regularly draws up strategic plans, such as the current one covering the years 2020 to 2024, as well as other assessments on the state of health in the European Union (European Commission, 2024). Points 3 and 4 can then be found directly in the respective legislations and proposals, such as in this case in the current regulations in the pharmaceutical sector, or the proposal for the pharmaceutical strategy for Europe (see more in chapter 2.3.) Through the Better Regulation initiative of the Europea Union, which aim it is to improve decision- transforming policy- making to a process that is more evidence- based, transparent and inclusive of different views and stakeholder, the EU not only changed the pharmaceutical industry, but the whole legislative system of Europe (Listorti et at, 2020, p. 1559f). Brooks also emphasizes the importance of coalition between the individual players in the industry in her article on the concept of the Advocacy Coalition Framework. The interaction and inclusion of the views of individual stakeholders gained from this is particularly important for effective legislation. (Brooks, 2018, p. 12).

Since the policy cycle as a step-by-step guide often does not represent reality, there are also proposed alternatives by researchers, such as the "multiple streams framework" or the "advocacy coalition framework", which do not present the process of policy making as successive stages, but more as more or less independent streams of problems and solutions, or activities of policy formulation and how they are promoting solutions to specific definitions and problems. There are also attempts to combine the different approaches. Whatever approach is used in the end, important is to understand the needs and processes of the policy in the making in order to implement a most effective policy possible and reach the best outcome possible at the end of the process (Howlett, 2019, p. 414ff). In conclusion, while there are multiple ways to look at the process of decision making, it's essential that in order to revise and improve regulations, impact assessments and policy learning, as well as strategic planning are necessary.

2.3. Pharmaceutical Strategy for Europe

2.3.1. Strategic Objectives

The in November of 2020 launched Pharmaceutical Strategy for Europe, an initiative by the European Council in order to address the gaps and deficits of previous regulations and to prepare and strengthen the pharmaceutical industry for the future (European Commission, 2023a). In general, the focus is largely on building a robust ecosystem for companies in Europe to operate in, meeting patients' needs and increasing the accessibility of medicine that

is affordable as well as increasing the innovation in the European pharmaceutical industry, to make Europe more competitive in the global market (European Commission, 2020b, p. 2f). More precisely, the objectives are summarized into two general objectives, namely to "guarantee a high level of public health by ensuring the quality, safety and efficacy of medicinal products for EU patients" as well as to "harmonize the internal market for the supervision and control of medicinal products and the rights and duties incumbent upon the competent authorities of the Member States" (European Commission, 2023h, p. 2). These general objectives are supplemented by four further specific objectives. The first one concerns the affordability and accessibility of medical products while objective two is about ensuring the security of necessary supply for the unknown future demand. Thirdly, the goal to increase the environmental sustainability of medicine is also included. The fourth specific objective deals with innovation and R&D and is formulated as stated: to "offer an attractive, innovation-and competitiveness friendly environment for research, development, and production of medicines in Europe." (European Commission, 2023g, p.2).

Concerning the area of competitiveness of the industry and the planned increase in innovation the European Commission has established a set of incentives and changes, that are meant to ease the process of research and development for European companies. The new proposed regulation and directive are in many respects similar. Both the regulation and the directive state that based on evaluations, stakeholder consultations as well as impact assessments, there are some shortcomings in the existing legislation. The main insufficiencies are in the area of the patients' medical needs, the affordability and accessibility of medical products, lacking supply of needed medical products, negative environmental impacts insufficient orientation on innovation through the regulatory system, as well as its high administrative burden (European Commission, 2023h, p. 7f). Therefore, it is crucial to revise the previous legislation in order to strengthen the global competitiveness of the pharmaceutical sector, while increasing innovation and meeting set goals of the Pharmaceutical Strategy for Europe (European Commission, 2023g, p. 1f).

2.3.2. Content

The current legislation is mainly based on two legislative acts the Regulation (EC) 726/2004 and the Directive 2001/83/EC, stating the procedures, requirements, and rules for releasing new products into the market, as well as monitoring already released products (European Commssion b, 2023). While the regulation dictates the procedure of centralized market authorization unionwide, the supervision as well as the pharmacovigilance of the EMA, the

directive lays down the framework applied by the individual member states authorizing medicinal products (Mellein & Schwarze, 2021, p. 4). In addition, the two regulations (EC) 1901/2006 for medicines for children and (EC) 141/2000/EC for orphan medicinal products are in place (European Commission, 2023f). As part of the pharmaceutical strategy for Europe, the EC is currently investigating this legislation in order to revise and replace this existing pharmaceutical legislation (European Commission, 2023i). So far, the proposal for the new pharmaceutical strategy framework consists of a proposal for Pharmaceutical Regulation as well as a Pharmaceutical Directive, which were adopted by the EC on the 26th of April 2023 (European Commission, 2023f). Furthermore, the Regulations 1394/2007 and 536/2014 are amended by the new Regulation (European Commission, 2023h, p. 1), while the new directive also repeals the directive 2009/35 (European Commission, 2023g, p. 1), as stated in the proposals.

In general, therefore, the two main pillars of pharmaceutical legislation, the regulation as well as the directive, build the core body of the EU acquis for the use of human medicinal products. They are consequently also the focus of the revision of the legislation, the Pharmaceutical Strategy for Europe. Summarized, the proposed regulation, COM(2023) 193 final, is establishing the procedures for approving and overseeing human medicinal products within the European Union and setting regulations for the governance of the European Medicines Agency (European Commission, 2023j, p. 0). The Directive, COM(2023) 192 final, is similarly structured and is based on the same assessments and evaluations as the proposed regulation (European Commission, 2023c, p. 7f). However, not the whole legislation will be changed, but rather those parts and articles that are deemed necessary for change. This targeted approach by the EC is therefore an acknowledgment that the pharmaceutical legislation as it is in place right now is in need of some alteration, while already being a solid foundation for the pharmaceutical industry (Mellein & Schwarze, 2021, p. 10).

The goal for the combined proposals and thus the new pharmaceutical legislation is to increase innovation by improving different areas of the regulatory framework. In alignment with the Pharmaceutical Strategy for Europe, the European Parliament and the European Commission have worked out a series of rules, obligations and incentives for the companies of the pharmaceutical industry in order to equalize the shortcomings stated in chapter 2.3.1. (European Commission, 2023j, p. 2). As already communicated in 2020 by the EC in its letter COM(2020) 761 final, there are three main points for action in order to enhance innovation and R&D, staring with ensuring a fertile, flexible and stable environment for the European

pharmaceutical industry to work in, facilitate innovation, while laying a strong focus also on digital transformation and making the regulatory system more flexible and secure for the companies to navigate through. This includes streamlining the procedures, regulatory efficiency, optimizing the network structure between the EU, EMA and the national authorities, as well as the adaptation and decrease of the approval times (European Commission, 2020, p. 10ff). By only adapting affected parts deemed necessary to be changed in the existing legislation, the European Commission is able to have more control over the outcome of the changes and solve the targeted problems more specifically. However, since the new Pharmaceutical Strategy for Europe is not fully implemented yet, the exact changes are not set in stone yet (Mellein & Schwarze, 2021, p. 10). Nevertheless, there is already feedback to the publications of the EC, showing their support or disagreement with the possible changes. The following chapter will go more into dept about the perceived impact the new legislation will have on the industry.

2.3.3. Critique and feedback

There has been considerable feedback on the numerous changes proposed by the European Commission, both voices that are enthusiastic about the proposal and suggestions for changes and points of criticism. For example, the European Commission's plan to focus more on joint procurement is seen as a positive step by the World Health Organization, as the cooperation and exchange of information between countries had already worked well during the Covid-19 pandemic (Garanttini et al, 2021, p. 2). The European Federation of Pharmaceutical Industries and Associations, too, welcomes the intentions and efforts of the EC in order to improve the legislation and strengthen the EU's regulatory framework for the future, but also sees weaknesses and setbacks in the proposal (Efpia, 2023b, p. 2). As part of the evaluation of the proposal, EFPIA commissioned the Dolon Institute to produce a report to assess the impact of the potential new legislation. According to this report, innovation would be lagging behind particularly in the area of intellectual property and changes to RDP, regulatory data protection (Neez et al, 2023, p. 1). This substantial reduction of rights of companies' intellectual property, in combination with unworkable and incompatible criteria to make up for the lost protection in intellectual property would not only set back innovation but have a multitude of other negative trends like a reduced accessibility for European citizens to access innovative medicine (Efpia d, 2023, p. 25). Neez at al expect in their report that the drop in innovation, due to the new pharmaceutical legislation, would be at 22 percent over the years 2020 until 2035 with the changes in RDP named as the key factor for the decrease (2023, p. 16). For this reason, Efpia proposes to increase regulatory data protection and in return create incentives

that are predictable and meaningful to encourage R&D and innovation (Efpia, 2023b, p. 3). EUCOPE, the European Confederation of Pharmaceutical Entrepreneurs, comes to the same conclusion. Not only would the changes in the RDP lead to a reduction in incentives for R&D in Europe and thus also affect the availability of innovative medicines, but the proposed special regulations would also lead to increased regulatory and bureaucratic burdens for pharmaceutical companies. EUCOPE also emphasizes that SMEs with smaller product portfolios would be particularly affected by this change in the law. The predictability required for innovation would not be given by the new legislation (EUCOPE, p. 8f). The VFA takes a similar position and identifies the reduced RDP time as problematic in the new proposals. In addition, according to the VFA, incomplete and inadequate environmental risk assessments are used as ground for a refusal of application for authorization, as were the measures to combat medicine shortages (VFA, 2023, p. 1f). Again, EUCOPE agrees and expresses that especially for SMEs companies the changes regarding the Environmental Risk Assessment would be negative as they are an immense burden for such companies and advocates a balanced approach of the assessment, which is also more science-based and proportionate (2023, p. 11f). EFPIA agrees with all these points, the European Commission's proposal shows some gaps and setbacks for innovation in the pharmaceutical industry. In addition to the reduction of RDPs, a number of unfeasible conditions would also be necessary to access certain incentives, and EFPIA's assessment also comes to the conclusion that companies are struggling with disproportionate shortage management requirements. Overall, the novel changes would lead to high bureaucratic burdens and would guarantee uncertainty with regards to the interpretation of the law (EFPIA, 2023b, p. 2).

Despite the negative feedback, there are also several points in the new proposals that are seen as positive and commendable by pharmaceutical companies and associations, and which will certainly serve to promote research and development in the EU. EUCOPE, for example, highlights in particular the simplification of the regulatory system, as well as streamlining to reduce obstacles to innovation such as regulatory burdens. Measures such as increased digitalization are also praised. Phased reviews, i.e., more dynamic approaches to the authorization of medicines, a possibility for accelerated trials called PRIME are also seen as positive developments, as well as the shortening of regulatory decision making from 210 days to only 180 (EUCOPE, 2023, p. 13f). The industry also appreciates the focus on market gaps in the areas of rare diseases, pediatric medicine and individualized medicine. However, it is emphasized that the measures have to be even more focused, targeted and ambitious (VFA, 2023, p. 1). Furthermore, EFPIA welcomes the change in pharmaceutical legislation, and sees

areas such as streamlining, accelerated regulatory pathways, or also the aforementioned phased reviews, PRIME or changes in the CTR with opportunities for simplified and parallel set-up of data throughout the process (EFPIA, 2023b, 10ff). Garanttini et al. summarize that the EC's proposals may bring about an important change in the pharmaceutical industry, but that it is important for the European Union to intensively address the needs and wishes of the industry in order to make the final legislative changes as effective and productive as possible for innovative research and development (2021, p. 4). Also the feedback from academia regarding the roadmap presented by the EC was positive, but it was also stressed that in order to increase research, cooperation within the industry has to be enhanced and promoted. This aligns also with a consultation held by the EU to receive feedback on their plans. In their online public consultation fostering cooperation between research entities like universities, pharmaceutical companies and research centers was deemed the most effective way to provide an innovative landscape. Also, the adaptation of the current framework to the so fast changing technologies and new advances made is science is essential. These two actions were named even before public funding programs when it comes to the effectiveness of support by the EU for innovation in the pharma industry (European Commission, 2020a, p. 3ff).

2.4. Impact of regulatory frameworks in R&D

2.4.1. General impact of regulatory frameworks on R&D

The exact mechanism of how regulation affects R&D is a complex issue. Nevertheless, regulations are an important factor affecting the innovation generated within companies. In order to explain this complex relationship between the impact of regulations and the level of innovation different models or frameworks can be used to foresee the changes that the regulations have in practice. One possible method is the so-called endogenous growth approach (Blind, 2016, p. 1). This approach by Carlin and Soskice allows for a determination of a rate of equilibrium of technological progress endogenously, and therefore also of innovation. This equilibrium is found through the Solow growth model, or also called Solow relation, and the Schumpeter relation (Blind, 2012, p. 392). The Solow relation establishes a negative relationship amongst the rate of labor productivity (level of capital per efficiency unit of labor) and innovation (rate of technical progress). Conversely, the Schumpeter relation presumes that as capital intensity increases, the availability of resources for R&D investments does so too, leading to a rise in the rate of technological progress and innovation (Carlin & Soskice, 2006, p. 542f). With the introduction of regulations into the model, two effects then have to be considered. These two effects are compliance costs and incentives for higher

investments. Compliance costs lead to a reduced capital intensity and regulations on the other hand might also have an unexpected or secondary economic impact, therefore a lower level of innovation and technical progress. Which shifts the Solow Relation more to the right. Incentives like patent protections increase the investment in research and development, shifting the Schumpeter Relation to the left or vice versa with restrictions about price or other market rules, hemming the investments. The shift in the curves can be seen in Figure 2.

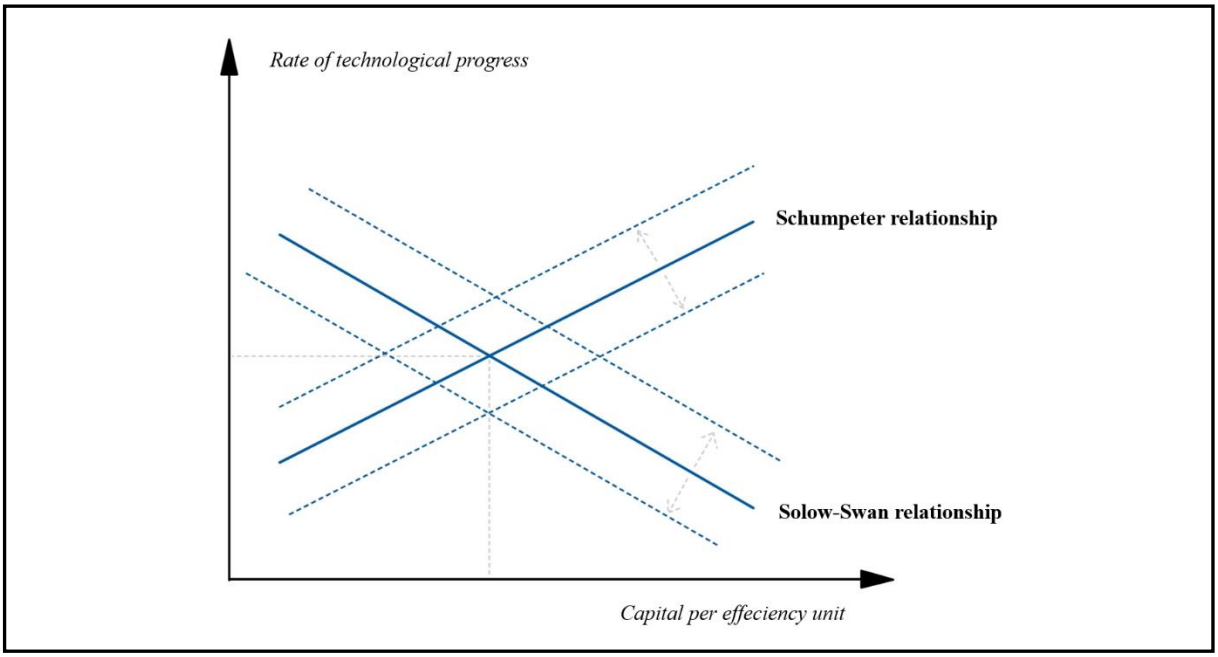

Figure 2: Schumpeter and Solow-Swan Relationship (Carlin & Soskice, 2006, p. 542ff)

Therefore, according to the endogenous growth approach, the impact of regulations seen on innovation depends on compliance costs as well as the effects of incentives given to the companies. Another factor to be considered is the type of regulation of interest, categorized in economic regulations, social regulations and institutional regulations (Blind, 2012, p. 392). These three types of regulations are set by the OECD and help to understand why it is important to reform and renew regulations. Economic regulations directly influence market decisions related to pricing, competition, as well as market entry or exit. Social but are primarily designed to safeguard public interests, including health, the environment, safety or social cohesion. Lastly, institutional or also administrative regulations, often referred to as "red tape," involve paperwork and formalities. Through this the governments gather information and influence individual economic decisions (OECD, 1997, p. 6). Apart from the area or type of regulation, the addressed time-period also influences the outcomes of the regulation changes. Depending on short-term or long-term, a regulation may have an evolving impact. Often regulations have a negative impact in the short- run, looking at the bigger picture and with more time the implications are positive in the long run (Blind, 2012, p. 395).

Certain regulatory measures and policies can have swift and substantial positive effects on innovation processes, though they are rare, and their importance is often overlooked (Chataway et al, 2006, p. 183). In general, though, empirical studies exploring the impact of regulations on innovation are painting a fairly heterogenous picture. Even when in theory the impact may be predicted a certain way, in practice other results are seen (Blind, 2012, p. 395). Another possibility to consider is expressed by Chataway et al, stating that policies and regulations for one specific area may have negative effects that were not expected for another area. That's why it is imperative to create an environment with regulations that are enabling desired directions and open possibilities for companies to be innovative, instead of being restrictive or constraining (2006, p. 183).

2.4.2. Impact of EU regulatory frameworks on R&D

Whether the European Union has a good environment for companies to conduct R&D and be innovative is however a question to which opinions may vary. While the former Commissioner for Research, Innovation and Science spoke of an "innovation emergency" in the EU (Geoghegan- Quinn, 2012), the new European Innovative Scoreboard report from 2023 states that there is an upturn in innovativeness in the EU. Since 2016, European innovation performance has increased by around 8.5 percent (European Commission, 2023d, p. 2). While the studies researching the exact interaction and connection between regulations in the EU and the produced innovation are still quite scarce, the general acknowledgement that those two topics are intertwined is increasing (Pelkmans & Renda, 2014, p. 2).

It is important to mention that a policy implemented by the European Union can have varying effects and impacts on different European member states. There are multiple studies on what influences the impact of regulatory changes on a national level. Therefore, it could vary across countries and policy sectors in a rather unsystematically way, or depend on a mixture of institutional compatibility between the EU and member states with the national opportunity structures (Knill & Lehmkuhl, 2002, p. 255f). While the EU is built on a single and internal market with numerous policies shared by all member states, not all of these are horizontally applied to every country but rather by sector for the different industries (Pelkmans & Renda, 2014, p. 14). Because various mechanisms and policies of Europeanization are interdependent, pinpointing specific actions or their outcomes can be challenging. This difficulty is compounded in real-world scenarios beyond controlled studies, because multiple factors interact in complex, hybrid constellations. Some effects are either weakening or reinforcing each other, which makes it even more important to understand the mechanisms of

Europeanization and how to implement policies in order to achieve to the best outcome (Knill & Lehmkuhl, 2002, p. 276). With the steadily increasing Europeanization, it is consequently important to research the impact that European policies have on the national level of each member state. The European Union deepening the Single Market, improving and implementing regulations, as well as the deployment of new EU agencies, is working to bring the Union closer together and streamline the processes (Pelkmans & Renda, 2014, p. 16). Other so-called key framework conditions of the EU in order to regulate the market and support the industries are financial support, such as the program Horizon 2020 or various funds, as well as the protection of intellectual property, partnerships and collaborative initiatives and the promotion of an overall culture of innovation (Reillon, 2016, p. 12ff).

According to Pelkmans & Renda, will and possibility to be innovative depends amongst other things on four different factors: (1) The availability of and access to funding in order to transition an innovative concept from inception to commercialization, (2) the ease of securing intellectual property, defined by how readily an innovation can be appropriated by competitors and how costly it is to protect innovation, (3) the market size of the existing and potential markets and lastly (4) the risk, that companies have to carry in case innovation or product is not successful and considered a failure. Therefore, the regulations that influence these factors will also have an impact on innovation. Generally speaking, regulations that increase the availability for loans and credits also increase innovation, the same applies to regulations that allow companies to have a higher legal certainty regarding their investment prospects, as well as rules that facilitate technology transfer, for example with universities. As mentioned before, there is not always one clear outcome for the impact of regulations though, for example regarding rules of Intellectual Property Protection. Higher and longer protection can on the one hand be a reward for companies to be innovative, on the other hand limiting the protection can be an opportunity for more competition and other companies, so called follow-up inventors, to increase their R&D in this field (2014, p. 9). These same insights are also stated in the Economics Paper of BERR, the British department for Business, Enterprise and Regulatory Reform. They describe the relationship of regulations and innovation as complex and multi- dimensional, dynamic and ambiguous. Regulations are able to have direct or indirect positive and negative impacts on R&D, naming for example also the IPRs as a showcase for how the development of innovation can swing either way, depending on the unique situation of the case. It highlights the fact that because of innovation the situation and market always change, new ones emerge, and old ones fail, thus leading to a change in the regulatory framework again. This dynamic enables regulations to improve and increases the

chance that companies receive a higher benefit from these regulations than they have costs (BERR, 2008, p. 17ff). In order to achieve the best regulatory framework possible, the EU uses RIA, regulatory Impact assessment. Already before the implementation of regulations this tool enables the government to tailor the measures to the needs of those affected in order to make the legislation as effective as possible. Therefore, the costs, benefits and risks associated with planned regulation get analyzed ex-ante. The member states base their RIA to the EU on the impacts on government, business, environment and competition and most of the European member states make use of this option and poses an effective option to control and influence the European decision-making process (OECD, 2022, p. 69ff).

In general, it can be said that that the EU affects the whole innovation process, beginning with research and development until the commercialization of the finished product. These regulatory approaches can affect innovation differently though, with rigid, prescriptive regulations often discouraging R&D, limiting commercialization options, and locking economies into less optimal standards. In contrast, flexible frameworks like co-regulation or performance-based standards, along with low compliance costs and reduced administrative burdens, tend to foster greater innovation (Pelkmans & Renda, 2014, p. 26).

2.4.3. Impact of regulatory frameworks on pharmaceutical R&D

"While the pharmaceutical industry may fulfil other important socio-economic objectives, such as employment and commercial profitability, these are not fundamental to its *raison d'etre* [reason for existence] because other industries also possess such objectives. If the provision of employment and commercial viability were the only purposes of the pharmaceuticals industry, then, in theory, it could be replaced by the expansion of other industries, which could absorb an additional workforce and steer a profitable course. However, what makes the pharmaceutical industry special is that its products are supposed to contribute to medicine and therapy for patients." (Abraham & Davis, 2007, p. 387f).

This statement by Abrahams and Davis highlights that the pharmaceutical industry is unique because its primary goal is to develop medicines that directly impact public health, unlike other industries focused solely on factors like profitability and employment. Consequently, a strong sociological component plays into the design and impact of regulations in this industry (Abraham & Davis, 2007, p. 388). In his article with John Reed, published five years earlier, Abraham emphasizes the importance of differentiating between technological innovation and social progress, highlighting legislation as an important regulator in finding a balance (2002, p. 338).

As can also be seen in the article by Knut Blind, a pharmaceutical company and in general the whole industry is very strongly regulated. Beginning with the innovative process of developing a new product until the market authorization and marketization of the finished product. While the exact impact of regulations on the industry is always hard to predict, as mentioned in previous chapters, it can be seen that streamlining the process has a positive influence on the innovation outcome (Blind, 2016, p. 13). Higher inconsistencies in national regulations lead to wasteful and unnecessary duplications and workload, driving up costs and inhibiting R&D (Abraham and Reed, 2002, p. 341). Therefore, even when stringent regulatory framework may seem to have a decreasing effect, with clarifications and streamlining it can turn out to be an advantage in the end for the industry. On the other hand, studies have shown that the higher the price regulations of pharmaceutical products are, the more research and development of these products will reduce (Blind, 2013, p. 13). To the same conclusion derives the research of Eger and Mahlich, that high regulations regarding the final drug prices lead to less investment in R&D and therefore less new drug discoveries (2014, p. 3).

2.5. Impact of the EU regulatory framework in R&D in the Pharmaceutical Industry

Combining the aspects of the previous chapters it can be said that the impact that the European Unions' regulatory framework has on the innovation of pharmaceutical companies, is quite versatile. While there are multiple factors that promote research and development, there are also a number of measures and regulations that hinder the progression of innovation within the pharmaceutical industry and make it less attractive for companies to conduct their R&D in the EU. According to a study by Pelkmans and Renda there are five mayor aspects of regulations influencing the outcome of innovation: The extent of the administrative burden, as well as the stringency and therefore the degree of compliance, the timing, as well as flexibility and finally uncertainty. Depending on the formulation of the regulatory framework and the dimension of the policies weighing on these five factors, innovation will either be enabled or constrained (2014, p. 10). Starting with the burden of administrative work, it can be said that the EU, as the large association of states that it is, has a large bureaucratic apparat. Nevertheless, the European Union is continuously working on reducing this amount of bureaucracy, for example as part of the "Better Regulation Guidelines", adopted in November 2021. The EU wants to reduce this burden through an increased feedback culture and regular evaluation, for example through programs such as REFIT, the regulatory fitness and performance program (European Commission, 2021, p. 8f). Nevertheless, pharmaceutical legislations are highly complex and with some requirements overlapping, increasing the

administrative burden on the pharmaceutical companies (Heikkinen et al, 2023, p. 2). The high level of red tape and bureaucracy hinders innovation by depriving companies of time and resources that could be spent on other activities like R&D. The same can be applied for the burden of compliance (Pelkmans & Renda, 2014, p. 11). The European Union aims to support member states regarding the implementation of regulations with guidance and information while in return collecting feedback in the form of compliance checks and reports to analyze and quantify the costs (European Commission, 2021, p. 37f). The pharmaceutical companies on the other hand report directly to the EMA regarding compliance with the regulatory framework. During the R&D process, companies are obligated to verify their compliance concerning Good Laboratory, Clinical and Manufacturing Practice (GDP, GCP, GMP) as well as sampling and testing, together with quality defects and recalls. During market authorization application of the products the compliance also includes pharmacovigilance inspections and good distribution practices (GDP). As part of this, inspections are also carried out by the national authorities for the EMA (European Medicines Agency, 2024d). While compliance may increase costs for pharmaceutical companies, the stringency of the regulatory framework can also result in an increase of innovation. Examples have shown that high stringency also forces investments leading to an increased R&D through changing their strategy and adapting their behavior (Pelkmans & Renda, 2014, p. 11). On the other side representatives of the pharmaceutical industry suggest that reducing stringency and increasing the use of soft law tools would increase flexibility and adaptability (Heikkinen et al, 2023, p. 3). This is consistent with the research of Pelkmans & Renda, which suggests that flexibility is an innovation-promoting measure. Similar to compliance stringency also the aspect of timing shows a trade-off between advantage and disadvantage for innovation. (2014, p. 12). While allowing companies to take too much time to comply with regulations, it leads to delays of the purpose and benefits intended by the EU regulations. On the other hand, if companies do not have enough time to comply, the technological, social and economic outcome may be inferior (BERR, 2008, p. 29). Finally, the aspect of uncertainty plays an important role in how regulations of the European Union impact innovation in the pharmaceutical industry. Uncertainty can both drive and inhibit innovation; while it may push firms to explore alternatives in anticipation of future regulations, excessive uncertainty or frequent regulatory changes can hinder technological development by destabilizing the investment environment (Pelkmans & Renda, 2014, p. 12).

To summarize these five aspects, the EU provides on the one hand advantages for pharmaceutical R&D, on the other hand there are still aspects of the legislation, that are not

supporting innovation. As part of the EU's new proposal for the pharmaceutical strategy for Europe, EFPIA's Innovation Board has published an article to provide feedback on the proposed legislative change. Among other things, it summarizes the current influences of the EU. The authors argue that the EU regulatory framework imposes a significant administrative burden and high compliance stringency, which can be challenging for companies. Delays in approval processes and a lack of flexibility hinder the EU's competitiveness, particularly in emerging fields, while regulatory uncertainty discourages investment in innovation. However, the system is praised for its strong commitment to safety, efficacy, and quality, ensuring high public health standards, and there are ongoing efforts to modernize and streamline the framework to better support innovation (2023, p. 2ff).

2.6. Strategic Alignment with the regulatory framework

In order to work efficient it is crucial to incorporate compliance in the core strategy of a company in order to ensure the long-term success and continuity of its business activity (Rossi, 2010, p. 816). This process should be well integrated in the business process in cooperation of multiple departments (Benedek, 2012, p. 143). There are numerous options in regard to complying with legal requirements and what strategies to use in order to best align a company to follow regulations given by the government or the EU. One of these is through a regulatory affairs department or unit. Within this unit experts focus specifically on the implementation of regulations and communication of regulatory requirements within the respective company. Furthermore, this department acts as a contact point to the different regulatory agencies. A strong connection to engaged leadership, with a focus on compliance management can help in reaching the goal and objectives. A good option is it to not completely decentralize the compliance department, but rather have a more centralized approach with a good line of communication (Jagun, 2018, p. 84ff). Rossi also emphasizes the role of compliance leadership in order to structure the rules of compliance within the company accurately, up to date and transparently. (2010, p. 817). Another strategy to comply with the given regulations would be the recruitment of qualified and skilled workers and providing various trainings as well as fostering continuous learning. Through both internal as well as external education and training it is possible to enhance the knowledge of the workforce on compliance management and therefore facilitate the process of complying with the regulatory requirements. This includes, for example, the development of SOPs or similar instructions for certain work processes (Jagun, 2018, p. 93ff). Apart from several different forms of training, periodic internal reviews are also necessary to make sure that these measures are up to standard (Benedek, 2012, p. 143). Combining regulatory requirements and

also ethical considerations, a code of conduct can be drawn up to summarize and streamline the company's way to deal with these issues (Benedek, P. (2012, p. 141). Rossi goes as far as to say that it is essential to integrate compliance into the firms' ethical culture, in order to motivate employees to follow protocol and value the guidelines as a strong strategic opportunity (2010, p. 818). A third option or strategy would be to directly navigating through and overcoming barriers of the regulatory framework in order to enhance compliance. Addressing regulatory compliance barriers requires a multi-faceted approach. Therefore, a continuous internal dialog within the company is crucial, as well as continuous interaction with regulatory bodies and collaboration with advocacy groups for collective influence. Hereby thorough preparation and planning is key to deliver a well structed feedback and review. Another important strategy is to adapt to the existing resource limitations or barriers given by finding viable alternatives (Jagun, 2018, p. 106ff). In this case it is important to weigh the rewards for companies that stem from complying with regulations against risks of not doing so and define limits suitable for the respective company (Benedek, 2012, p. 142). While compliance is often associated with cost for a business, it brings a competitive advantage and enhanced reputation over other companies not following the guidelines a strictly. (Rossi, 2010, p. 819).

3. Methodology

This master's thesis is based on two parts. First, a literature review is compiled to create a theoretical basis in order to summarize the necessary contexts and facts in a compact and precise manner. This literature review will focus on the European pharmaceutical industry, but also on EU regulations. Furthermore, it provides a theoretical impression of how regulatory frameworks and regulations affect R&D activities, how they influence them and how companies can deal with these regulations. The literature analysis will incorporate reports and official documents of the European Union and pharmaceutical companies, but also of academic literature and papers to guarantee a structured review of the already existing theories and literature. The aim of the literature analysis is to create a theoretical starting point for the subsequent interviews and to show the current state of knowledge. To ensure a comprehensive and methodical approach, a variety of reputable sources and research databases will be utilized. The University of Vienna's library will be a primary resource, offering access to a broad spectrum of academic journals, books, and databases relevant to pharmaceutical research, EU regulations, and R&D activities. This resource serves as an invaluable starting point for acquiring both historical and contemporary sources on the subject matter. In addition to the university library, several online research databases and search engines will be employed to broaden the scope of the review. Specifically, databases such as Google Scholar, ScienceDirect, JSTOR and EBSCO. These platforms are renowned for their extensive repositories of peer-reviewed articles, industry reports, policy documents, and other scholarly publications. Utilizing these databases ensures that the literature review incorporates a diverse range of perspectives and findings from leading experts and researchers in the field. The literature review will adopt a systematic and well-structured approach, adhering to scientific standards. It will start by identifying relevant keywords such as "EU pharmaceutical regulations", "innovation in pharmaceuticals" and "regulatory impact on drug development." These keywords will help locate pertinent studies and documents. An initial search will be followed by a screening process to select the most relevant articles, focusing on recent publications and their relevance to EU regulations, R&D investment, and the pharmaceutical industry. This will narrow down the literature to a manageable scope for detailed review. The selected articles will then be categorized thematically into key areas, each theme will then be thoroughly examined, and the findings are summarized and combined to provide a comprehensive understanding. This review aims to analyze existing research, identify knowledge gaps, and outline areas requiring further investigation. By categorizing and

synthesizing the literature, the review will establish a solid theoretical framework for the empirical components of the study. This comprehensive approach will lay a robust foundation for understanding the regulatory context and its implications for R&D investment and innovation in the pharmaceutical sector.

The second part of this master's thesis is a comparative case study in which pharmaceutical companies are analyzed, how they have reacted to EU regulations in the past and how these regulations are influencing the R&D activities of these companies. This empirical part is the main focus of this academic work and is based on the expert interviews. The interviews are conducted with experts in the pharmaceutical industry, in order to find out the exact connections between the EU regulations and their effects on the pharmaceutical industry. These experts are working in one of the many fields of the innovation process of different pharmaceutical companies, starting with R&D to the Regulatory Affairs Departments and Market Access Units. This multi-method approach ensures a thorough and comprehensive analysis of the impact of EU regulations on the R&D departments of international European pharmaceutical companies.

3.1. Research Approach

Based on the literature review a comparative case study analysis will be conducted to gather more information about companies working in the pharmaceutical industry. Specifically, the research design is a multiple case studies approach, where a case study in form of an interview will be conducted on multiple international pharmaceutical companies. The chosen companies will be located in the DACH area, covering Germany, Austria and Switzerland. Through the communality and the similarity between the companies it is possible to compare the findings with each other and analyze the differences (Tomaszewski et al, 2020, p. 3). These multiple case studies are picked based on their fit and their properties and are expected to show similar results, even though there is also the possibility of having different outcomes for each company (Baskarada, 2014, p. 4). After the literature review and the selection of the interview partner, the data collection for the case study will start. The data collected for these cases will be triangulate data and contain multiple types and sources of interrelated evidence (Tomaszewski, et al, 2020, p.4). Therefore, data that will be used in the research study are documents related to the R&D Department, like press releases but also annual reports of the companies and specific reports on the collaborations as well as the information gathered in the expert interviews. Another mayor source of information will be information provided by the

European Union, like their protocols, statements and regulations. As Yin states, case studies base their evidence on multiple sources and many different variables (2018, p. 15).

In conclusion, the multiple case study approach is chosen because the various sources and the diversity of triangulated data promotes a broader understanding of the research topic (Tomaszewski et al, 2020, p. 4). As written in Yin's work in 2018, multiple case studies are also considered to be more robust and compelling. On the other side multiple case studies can be objective to a high time and resource effort, finding the right data for all the different case studies (Yin, 2018, p. 90). Therefore, a potential limitation to this work could be finding adequate and similar data for all cases, which would be crucial to an accurate and comprehensive comparison.

3.2. Description of Research Method

This master thesis is mainly based on qualitative empirical social research. Sabina Misoch defines the aim of empirical social research as making statements about the nature and structure of the social reality that surrounds us. While quantitative research tries to be able to produce quantifiable and statistically evaluable statements based on empirical data that is as representative as possible, qualitative research stands out by analyzing a certain social phenomenon deep and differentiated (2019, p. 1). There are several principles that must be fulfilled in qualitative research. Mayring, for example, emphasizes five principles in particular, namely subject relatedness, the description and interpretation of the research subjects, the everyday environment in which the subjects are studied and, finally, the generalization process of the results (2002, p. 19). In principle, it is therefore particularly important for qualitative social research to understand the exact processes, motives and attitudes and to analyze them in depth. As already described by Mayring, the focus here is on the subject, who presents and reconstructs their subjective reality in the research and presents their point of view (Misoch, 2019, p. 25ff).

This subject-relatedness is used in this master's thesis in the context of semi-structured interviews to determine the exact connections between EU regulations and the R&D activities of pharmaceutical companies. More precisely, this form of interview is also called an expert interview (Misoch, 2019, p. 119), the expert in this case being the subject. It belongs, like all open and semi-structured interview forms, to the category of problem-centered interviews. This form of interview allows the interviewee to speak as freely as possible but is still centered around a specific problem (Mayring, 2002, p. 67). It also opens up the possibilities for follow up questions that arise during the interview (Denny & Weckesser, 2022, p. 1). This

allows the interviewees to present subjective perspectives, explain complex relationships and cognitive structures, but also to question questions in more detail and concretize them. It is therefore important that the exact problem is defined and analyzed beforehand. (Mayring, 2002, p. 67f). In the case of this master's thesis the literature review is building the necessary base of knowledge used for the interviews and will thus provide the necessary theoretical foundations and basic knowledge to build up the interview guidelines well to then embed the results in this theoretical framework. As part of the selection process of the participating companies and the preparation of the interview guidelines, documents and reports of the respective companies are also studied and read in order to expand the knowledge base and to gain a deeper understanding of the R&D processes of the companies in recent years. Thus, as mentioned at the beginning of this chapter, the master's thesis is largely qualitative research, but further data is used to ensure the triangulation of information and thus present as coherent and meaningful a picture of the overall situation as possible.

3.3. Research Design

The research is designed so that at the end of the work the research questions can be answered, and the hypotheses affirmed or disproved. Thus, the interviews are designed to identify the key regulatory factors influencing R&D investments in European pharmaceutical companies; to explore the challenges and opportunities these companies face due to EU pharmaceutical regulations, and finally to assess the effectiveness of strategically aligning R&D efforts with regulatory requirements to increase R&D investments. These objectives will guide the data collection and analysis processes.

When conducting qualitative research, in this case expert interviews, there are some guidelines and principles to consider. Misoch has presented a clear procedure in her work to structure the process (see Figure 3) (2019, p. 125).

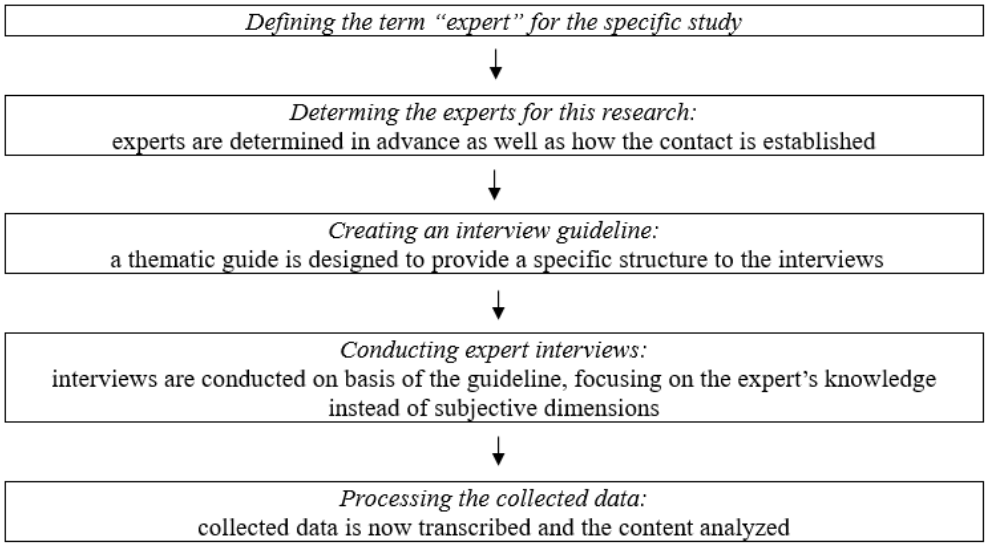

Figure 3: Process of expert interviews by Misoch (Misoch, 2019, p. 125)

Mayring has a similar approach but changes the procedure of his problem-centered interviews slightly, as can be seen in Figure 4 (2002, p. 71).

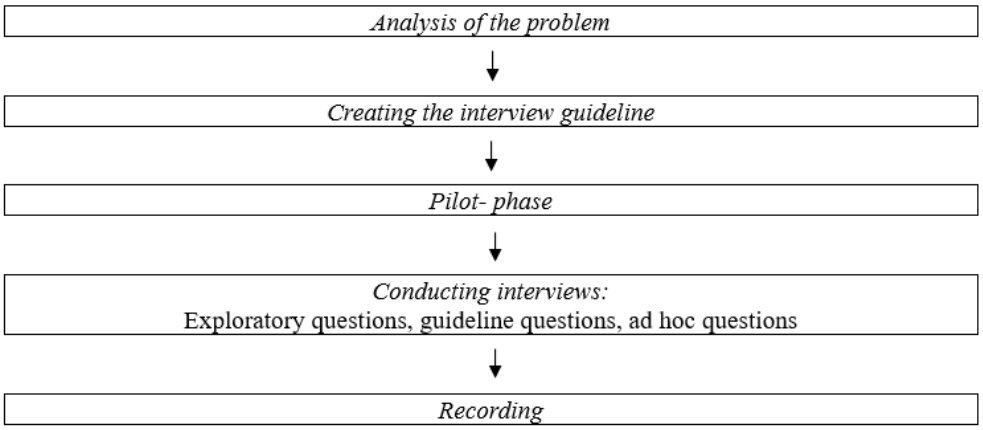

Figure 4: Process of expert interviews by Mayring (Mayring, 2002, p. 71)

In this qualitative research, the methods of Misoch and Mayring were combined to create a structured yet flexible approach to conducting expert interviews. The process began with a detailed analysis of the research problem, specifically understanding the impact of EU pharmaceutical regulations on R&D investments and the current state of knowledge in literature. The experts were then selected based on their deep knowledge of pharmaceutical regulations and R&D strategies. A structured interview guide based on the literature and the research questions was created, followed by a pilot phase with academic peers to refine the questions. During the interviews, the questions of the interview guideline were asked, but flexibility was maintained for unexpected insights through exploratory and spontaneous

questions. After the interviews were recorded and transcribed, the data was analyzed thematically to identify patterns and regulatory factors influencing R&D investments. This combined approach allowed for the collection of rich, nuanced insights, addressing the research questions concerning the challenges, opportunities, and strategic alignment of R&D with regulatory requirements in the pharmaceutical industry.

3.3.1. Sample Design and Datal Collection

According to Misoch's five step plan (figure 3) the first course of action is to define the experts (Misoch, 2019, p. 125). Therefore, the experts have to be determined as a first step. For this study, the interviewees with be part of international European pharmaceutical companies, working in the DAC region. This group of experts comprises individuals who possess extensive knowledge of both R&D processes and EU pharmaceutical regulations. The experts should have firsthand experience navigating the regulatory landscape and aligning their company's R&D strategies with these requirements. Since the interview partner are working in different areas of the companies, a broad picture can be drawn from these interviews.

The second step is to contact the interviewees. This is possible in two ways. The first is to contact the potential interviewees directly, in writing or verbally. For this purpose, experts with the appropriate qualifications were identified through research and approached. The second way is through a so-called gatekeeper, i.e. a person who is part of the field themselves due to their (professional) position and therefore has the opportunity to mediate or motivate a suitable interviewee to participate in the research. This facilitates access to the research field ((Misoch, 2019, p.201). In the case of this master's thesis, the expert selection process was rather semi-direct. The front offices of the selected companies were contacted with a request for a scientific interview and the companies then suggested a suitable person for this interview. In addition, people were also found directly based on their qualifications through either the company platforms or career portals such as LinkedIn. The organization Pharmig was also a great support, forwarding the request for interview partners to suitable companies.

For this research a total of 10 interviews were conducted. Since the area of investigation focusses on Germany, Austria and Switzerland, the experts are mainly German native speakers. Therefore, the interviews are either conducted in German and then translated or directly conducted in the English language. In order to keep the data confidential, the names will be randomly assigned a number from one to ten during the analysis of the interviews,

therefore the individual answers of interview partner will be kept anonymous. A list of the experts can be found in the following table 1.

Interviewee	Position in Company	Area of work	Country
Brigita Belin-Atarac	RCV Regulatory Affairs Head	Boehringer Ingelheim	GER
Doris Henn	Senior Director, Site Management & Monitoring Cluster	AstraZeneca	GB
Ena Atarac-Simic[1]	Associate Director GCO Austria & Switzerland	Janssen (Johnson & Johnson)	GER
Helmut Baranyovski	Head of Staff + Head of Operations	Marinomed	AUT
Jörg Mahlich	Market Access and Government Affairs Lead	Miltenyji Biomedicine (former employee of J&J: Head Health Economist and Outcomes Research)	GER
Liane Höfferer	Senior Vice President R&D Plasma	Octapharma	CHE
Max Wegner	SVP Head Regulatory Affairs	Bayer AG	GER
Pamela Pietrzak	Process Improvement Unit Lead	Boehringer Ingelheim	GER
Raimund Schütz	Dir. International Production Integration	Octapharma	CHE
Thomas Metcalfe	Head of Healthcare System Partnerships Cluster, Medical Affairs[2]	Roche	CHE

Table 1: Interviewpartner for the Expert Interviews

These companies were selected because, on the one hand, they have a large international presence in Europe, but on the other hand, they have important locations in the DACH region and therefore have insights into the scientific and economic region.

[1] Disclaimer von Janssen-Cilag Pharma GmbH: „*Das Interview mit der Vertreterin der Janssen-Cilag Pharma GmbH, a Johnson & Johnson company, unterliegt einem rein informativen Charakter. Die Antworten auf die gestellten Fragen sind ausschließlich im Rahmen und für den Zweck der Diplomarbeit der Studentin zu verwenden.“*

[2] Additionally, Thomas Metcalfe is the representative of Roche in the innovation committee oft he EFPIA

3.3.2. Interview Guidelines

Interviews will be semi-structured in order to ensure a balance between consistency of each interview and flexibility to explore questions more in depth with the opportunity to ask follow-up questions. Each interview is expected to last approximately 30 minutes to an hour and will be conducted either via video conferencing tools such as Zoom or Microsoft Teams or in person, depending on the participant's preference. With the participant consent, audio recordings will be made and subsequently transcribed for analysis.

The interview guide was designed after a detailed literature analysis and picks up on the most important topics discussed in this analysis. The following categories of questions are thus formed:

Pre-Interview: A short introduction will be provided for the interviewees with some general information on the purpose of the research and the content. Apart from the possibilities to ask clarifying questions beforehand, the interviewee will also be asked for consent to be recorded, and their answers be used in the thesis.

1. Regulatory Impact on R&D Investment: The questions within this theme are designed to uncover how specific EU regulations influence the financial and strategic decisions related to R&D investments. These inquiries focus on understanding the overall impact of regulations, identifying recent changes that have affected R&D budgets and allocations, and seeking quantitative examples that illustrate these effects. This information is vital as it directly addresses the RQ1, helping to pinpoint key regulatory factors that influence R&D investment decisions in European pharmaceutical companies. Gaining this understanding lays the groundwork for comprehending the broader effect of regulatory frameworks on innovation and competitiveness within the sector.

2. Challenges and Opportunities: In this category the questions aim to identify the major obstacles and potential benefits that EU regulations present to pharmaceutical companies. By exploring specific challenges, such as financial constraints and administrative burdens or the influence of patents, it will deliver insights into what hinders R&D efforts. On the contrary, by identifying opportunities, questions are asked to see how certain regulatory frameworks may support or incentivize innovation and compliance. This category is to receive a balanced perspective on the regulatory landscape.

3. Strategic Alignment with Regulatory: This category of questions examines how companies align their R&D efforts with EU regulatory requirements. It investigates strategies used and examples of successful alignment to understand best practices. This is essential for testing H1 that alignment leads to higher and more efficient R&D investments. By understanding these strategies, effective practices that enhance R&D outcomes while ensuring compliance can be identified.

4. Effects of Compliance on Innovation and Time-to-Market: These questions focus on how regulatory complexity affects innovation cycles and the time-to-market for new products. It examines whether stringent regulations stifle or foster innovation and the extent to which regulatory challenges cause delays, which is critical for providing evidence on the negative impact of regulatory complexity on innovation and time-to-market, informing industry practices and policy formulation.

5. Future Regulatory Changes and Preparedness: This las group of questions captures expert opinions on anticipated future regulatory changes and company preparedness. Exploring expectations and preparation strategies helps anticipate challenges and opportunities, offering insights into proactive approaches and long-term planning. This is important for maintaining the relevance of the research and identifying adaptive strategies that support sustained innovation.

Post-Interview: After the interview and the recording there will be final remarks, any clarifying questions about the use of the data will be addressed as well as the following steps regarding the research.

3.3.3. Analysis of the Data

The analysis will be carried out based on Mayring's qualitative content analysis. The recorded audio documents produced during the interviews are transcribed and evaluated using computer software, in this case MAXQDA, with the help of coding. Mayring distinguishes between deductive and inductive methods. In this work, categories were first formed deductively, based on the literature analysis. The categories were then revised inductively, which is the dominant method. An inductive category definition, on the other hand, derives the categories directly from the material in a generalization process, without referring to previously formulated theoretical concepts. By combining the two, the categories could be well conjoined and evaluated both on the basis of previous knowledge and with the new knowledge gained from the interviews (Mayring, 2010, p. 84). The categories along with their definitions are presented in the appendix. Subsequently, in the findings (Chapter 4.1.) quotes

corresponding to each category were transcribed into an evaluation table. This table organizes and visualizes the data by paraphrasing and condensing the reference examples for each category. Ultimately, this table forms the foundation for interpreting and analyzing the collected data material. In chapter 4.2. the findings will then be discussed with the already existing literature described in the previously conduced literature review. In this way, the similarities between the data collected and the existing literature are identified, but the differences are also made clear.

3.3.4. Justification and Limitations

In this master's thesis qualitative research with a comparative case study approach is chosen because of multiple reasons. Yin for example states that a case study is fitting for research that doesn't require control over the behavior that is analyzed while studying contemporary problems and events. Both of these criteria are applicable for this thesis. Furthermore, a case study is the right approach to answer the given research questions (Yin, 2018, p. 9). Further reasons for choosing qualitative research would be both the differentiated description of processes and the identification of individual attitudes or perspectives (Misoch, 2019, p.2) that are queried in the interviews. In addition, there are several sources that provide evidence, which enables a triangulation of the data and thus provides particularly deep insights into the processes (Yin, 2018, p. 15f).

Furthermore, the form of the expert interviews provides data that represents specific knowledge that can be applied precisely to this specific situation. The people in question have usually acquired this special knowledge through long periods of education and work (Misoch, 2019, p. 119). The use of semi-structured interviews also provides a higher degree of standardization, as the comparability of several interviews is increased. The data from the multiple interviews can be related to the respective guideline questions and thus be evaluated more easily. Even though the interviews are structured, they still retain the character of open, trusting conversations. (Mayring, 2002, p. 70ff).

Yin also emphasizes the factors of reliability and validity in order to provide qualitative and scientific results. A study is reliable, if a researcher is able to repeat the study with the same results. In order to achieve this, it's important to have a protocol to follow and maintain the chain of evidence during the data collecting process. Validity has multiple forms: construct-, internal- and external validity. Internal validity ensures that connections and relations between two factors are not drawn arbitrarily. To prevent this, models as well as rival explanations were used to find results. Finally, external validity, i.e. the ability to generalize, was achieved

as far as possible by conducting repeated interviews with different interviewees (Yin, 2018, p. 42f).

While the expert interview is one of the best known and most frequently used methods of qualitative social research, there are also limitations that need to be considered. For example, there is no standard definition of the term "expert". Accordingly, a broad understanding of the term can be applied, but it is not a protected title and thus allows anyone to be seen as an expert of some kind. In order to clarify a distinction, the term "expert" must be expert must be competence-related and specified (Misoch, 2019, p. 126). Another point of critique is the question of the possible generalization of qualitative methods such as case studies. It should be kept in mind here that although case studies are in fact generalizable, this applies in terms of theoretical propositions rather than to an entire population (Yin, 2018, p. 20). In addition, critics often consider qualitative social research to be generally uninformative due to its "lack of representativeness". It should therefore be noted that qualitative research in comparison to quantitative research is based on a different concept of representativeness. Rather than statistical representativeness qualitative research builds on representativeness of content, meaning that all relevant characteristics and combinations of characteristics must be sufficiently represented (Misoch, 2019, p. 202). Mayring says of qualitative research that "it is particularly important for qualitative research not to blindly apply ready-made instruments, but to develop and apply the procedures to the specific subject matter" (Mayring 2002, p. 149). The individual situation of the research must therefore always be taken into account and the research design adapted accordingly.

4. Data Analysis

4.1. Findings of the Expert Interviews

4.1.1. General Statements

The following subchapter presents the general and overall impressions of the interviewees on various topics of pharmaceutical regulation. While these findings in this chapter are kept on a more general and summarizing level, the following chapters will then go into more detail on the individual opinions of the questioned experts on the regulatory framework. The exact evaluation scheme and the coding for the following chapters can be found in chapter B. of the appendix.

1.a. General improvement since the establishment of the current regulatory framework

Generally, it can be said that the improvements brought about by the current legal framework are felt by all interviewees and all are of the opinion that the pharmaceutical industry has been promoted and supported by the EU since the early 2000s with the implementation of the Regulation and the Directive. The area of harmonized regulations within the EU states is particularly decisive for this, as it has helped create a more certain and predictable environment for pharmaceutical companies operating across different European member states. This is also consistent with literature, as it is shows clearly that the European pharmaceutical industry has grown steadily in recent years. The regulatory framework therefore provides a good basis for the continued existence of pharmaceutical companies in Europe. Nevertheless, it became clear during the interviews that due to the constant further development and implementation of additional guidelines and legal texts, the entire regulatory framework has become a very large and often rigid system, which often offers little leeway and flexibility, especially in the area of research and development. Countries such as Switzerland and the USA, which have a different regulatory framework and are therefore much more flexible, were also repeatedly mentioned. This makes Europe a very safe location for patients, as critical attention is paid to scientific standards, but this often makes innovative research more difficult for pharmaceutical companies. In general, the rigidity and inertia of European pharmaceutical legislation is one of the main reasons preventing pharmaceutical companies in the EU from effectively pursuing innovative R&D. The lack of agility for research then encourages companies to carry out their research outside the EU, for example in the USA, Switzerland or the UK. While all of the companies included in this study are international and therefore have company sites in all different countries, the majority of the

companies have their main research site outside of Europe in the US for example, since the rules and regulations are less stringent.

1.b. General awareness and planning for new Pharmaceutical Strategy for Europe

Even if the planned Pharmaceutical Strategy for Europe has not yet been adopted and implemented, the companies are for the most part following and monitoring events. While concrete strategic changes have not yet been made, it became clear during the interview that the new proposal is largely welcomed in terms of content, but it is still unclear how great the impact will really be, especially in the area of research and development. On the other hand, it remains to be seen what the exact impact will be after the final implementation. Here in particular, associations and groups are more involved than individual pharmaceutical companies and provide feedback as a unit and are more active in discussions with the authorities. As the draft law has not yet been implemented, companies and associations still see the possibility that the contents of the proposals may still change and that the implementation of the regulatory framework will look like in the end, therefore it is not possible yet to fully plan ahead for the new legislation. In general, it can also be said that the different interview partners often didn’t know exactly about the specific content of the new pharmaceutical legislation. However, it was made clear during the interviews that even if the interview partners may have had little contact with the EU's new strategy to date, communication within the individual companies is very good and the necessary information on the final legislative changes is passed on by the respective departments.

1.c. General support of more centralized/ decentralized procedures

As already mentioned in point 1.a., the interviewees were generally in favor of more harmonization and streamlining through common EU regulations and directives. Nevertheless, there are areas, such as in the field of clinical trials, in which an overarching EU umbrella of regulations has not only brought advantages. In the context of the CTR, for example, there are currently often longer waiting times and bureaucracy, as the system has not yet been optimized and does not bring the desired relief compared to the national legislation, which was already very well established and routine. Nevertheless, there is a clear sentiment in favor of European solutions. Even with current criticism of European solutions, it is mentioned that with time and more experience, harmonization will continue to progress and thus make the procedures simpler. This also applies to the Pharmaceutical Strategy for Europe. While the interviewees are still somewhat skeptical and it is not yet certain to what

extent the current system will change, steps to improve the current system are viewed favorably.

1.d. General Relationship with Authorities

One of the EU's main contact points is the EMA, the European Medicines Agency. The interviewees also consider it to be very supportive and useful. Even if not all companies are in contact with the EMA in the early phases of drug development, but rather work actively with the authority in the area of approval, the EMA is considered to be very useful in terms of providing feedback and support in the R&D process. This feedback loop is critical for companies seeking to navigate the complexities of regulatory compliance effectively. It is also possible to provide feedback on new regulations, if this is not done directly via the EMA, then via national associations or bodies such as the EFPIA. On the other hand, points of criticism include the fact that feedback is not sufficiently accepted, as well as the long waiting times and lack of capacity for optimal implementation of the guidelines. Another major point of criticism is the frequent lack of coordination with national authorities, which leads to overlaps and requires companies to undertake similar efforts multiple times, ultimately consuming valuable resources. As can also be seen from the literature, feedback and impact assessments are very important for the EU and the EMA in particular plays an important role in communicating and receiving this feedback. Even if the individual interview partners are not involved with the EMA or other authorities, feedback is collected and forwarded to the respective bodies in order to continuously improve the EU system.

1.e. General outcome of compliance on efficiency

With regard to compliance with the EU legal framework and whether the obligation to comply impairs the effectiveness of companies, the feedback is largely neutral. The majority of interviewees stated that they did not feel any significant impact on productivity, as compliance with regulations has already become the industry standard. This reflects an industry that has adapted over time to meet regulatory demands. Two out of the ten interviewees even see it as an advantage, as the legal framework thus provides a kind of template or template in which one knows how to act. The consensus is that the European regulations have been in place for a long time and that companies have now become accustomed to the working methods and processes. Compliance with the regulatory framework therefore has neither a very positive nor a very negative effect, but is neutral throughout. During the interviews, however, it was clear that compliance in the pharmaceutical industry is an extremely important issue and is now seen as necessary and

understandable by companies. So, while compliance is not a hurdle for the companies and their R&D, problems are seen more in the general strict regulations and bureaucracy for example.

1.f. General Expectations and needs for the future

The main needs of European pharmaceutical companies are faster approval times and a more flexible and agile legal system. Time is repeatedly cited as a particularly important factor in the pharmaceutical industry, and this is often not supported by the current system, with time-to-market tending to be longer. This requires more, but above all, more effective streamlining such as joint assessments and inspections, as well as increased and open exchange with the authorities as part of impact assessments. The majority of the IPs thus find the new changes proposed in the new regulatory proposals to be positive. Even if they are skeptical about the actual implementation of the changes, the areas of streamlining, flexibility, digitalization, and speed of the authorities would make the biggest difference for companies. In addition, apart from the narrower view of pharmaceutical regulations it would also be important not to look at pharmaceutical regulations with a tunnel vision, but to develop a comprehensive concept with various research institutions such as clinics or universities and thus a holistically coherent innovation system. This can also be seen with the paper by Saltelli et al, in which it is described that the EU should include further perspectives in its impact assessments. The interviews state that not only the pharmaceutical industry alone needs to be reviewed, but also the environment of the pharmaceutical industry such as research institutions or schools and universities.

4.1.2. Strategies to cope with the requirements

The following subchapter deals with the interviewees' answers to their company's strategic alignment with the regulatory framework, how compliance with the European regulations is handled and how the companies are able to ensure that their actions and activities remain coherent with EU legislation.

2.a. SOPs

One way to deal with regulatory requirements and adapt is through Standard Operating Procedures, SOPs. IP4, for example, points out the importance of SOPs in their company to simplify processes and also to gain experience to use as a learning process and also for future cases. IP8 also describes the use of SOPs, for example through templates. These templates are used again and again, such as when submitting documents to authorities, in order to achieve

the highest possible success rate and to learn and benefit from previous experiences. According to IP9, this highlights the importance of continuous learning in order to rethink and refine processes.

> “We also have these queries that have come in, and we collect them so that we can take these lessons learned with us. We look at this and see if we can do it like this again. So that we really do take lessons learned with us and learn from every submission and its queries.” (IP4, Pos. 56)

In general, documenting and learning from actions that have already been carried out is considered particularly important in order to be able to access them for future submissions or problems. This ensures that certain standards are anchored in the individual processes and contributes to greater consistency in compliance. This is also in line with what Jagun (2018) and Benedek (2012) state, namely that SOPs and continuous reviews are essential for strategic alignment.

2.b. Good General Strategy

A very important point in this context is also a good and coherent overall strategy of the company. Since regulatory requirements are constantly changing and important areas such as research and development are not neglected during compliance, it is essential to design the company strategy in line with the regulatory framework and to be future-oriented.

> “But in 20 or 30 or 50 years I would no longer bet that there won't be something for [a specific therapy] that doesn't require [specific product]. And if that's the case, then of course as a pharmaceutical company or biotech company you have to be prepared or set up to use other platforms.” (IP2, Pos. 30)

The interviews revealed that a clearly defined and well-integrated strategy is crucial for alignment with regulatory frameworks. The papers by Rossi (2010) and Benedek (2012) cited in the literature review, both speak about the importance of well-integrated strategies in the business process and the transfer of these strategies to the individual departments. It is also evident in the individual interviews that a clear and well-developed company-wide strategy is very important for alignment with regulatory frameworks, but is also extremely valuable for innovation and R&D.

2.c. Training

Training is also an important part of compliance management. Both internal and external training is used to develop the knowledge of employees and to ensure that legal requirements are adhered to in individual work steps and processes. IP4, for example, describes that documents provided by the EU or the EMA, as well as the national authorities, are used for further training, but also that in-house training documents are created in order to achieve the best possible output.

> "There was a lot of training, […] so both internal and external training courses were used. I have to say that the resources on the internet are also very good, as far as the EMA is concerned, as far as our ethics committee is concerned, there is also a new website for the ethics committee called Austrian Ethics. It is really well set up and we rely heavily on it, and in this respect, we work very closely with checklists and try to include them in our SOPs. It is simply really anchored." (IP4, Pos. 18)

This emphasis on training showcases a commitment to continuous improvement and adaptation to regulatory changes. This not only confirms Jaguns (2018) statement about the importance of training, but also shows that the individual strategies such as training, SOPs and effective communication are strongly interconnected.

2.d. Communication

Apart from a uniform strategy, the importance of good communication within the company is mentioned most frequently in order to be compliant with the given regulations. Since processes in international companies constantly run across departments, internal communication and coordination are particularly important to all different workers and departments to always stay up to date. However, cooperation is not only essential within the company, but also to a certain extent with the authorities, as it can also simplify processes.

2.e. Regulatory Affairs Unit

In addition to submitting applications, Regulatory Affairs units and departments also monitor changes in legislation and have many other responsibilities. Within a company, they also prepare information for colleagues and serve as a point of contact with authorities. This applies at national and local levels, as well as central and higher levels. IP8 describes how the increased number of EU directives has also made regulatory affairs more important for local processes at a central level. This importance arises from the need for harmonization and

standardization in the European Union, making European rules crucial at the national level. Regulatory affairs units are therefore not only essential internally within the company, as they are familiar with the regulatory framework and know how to apply it, but also for external communication with authorities or the EU in order to always stay up to date, maintain relationships and pass on feedback to the relevant departments.

2.f. Teams

In addition to regulatory affairs units, team building to deal with certain problems, processes or guidelines is also an important part of compliance management. While IP7 speaks of policy groups that specifically monitor developments at the EU level, IP8 reports on specialized teams that act as coordinators for the various research phases and are centrally superordinate. This not only increases efficiency, but also reduces the likelihood of errors. These coordinators are often also responsible for the training mentioned above. IP4 also describes the introduction of a subject matter group within the department in order to work out the small details as optimally as possible.

> "That we built a team, several teams, which of course dealt with the regulation. Very early on, I think it was shortly after it came into force, before CTIS existed, we already had a team at a global level that was strategically supporting the whole process. So, from all the different functions, we always looked at: what does this mean for us, where do we need to work towards, what could a model look like for the future, how do we adapt? What we have done is, as I said, this regulatory group, for Part 1 there is now a separate group that takes care of it. Of course, there is further communication with us and for Part 2 we now have several colleagues at the European level, we also call them Part 2 coordinators, who are really there to help." (IP8, Pos. 16)

These collaborative efforts not only facilitate compliance but also enhance innovative capacity by allowing teams to leverage a wider range of expertise. In addition to qualified and skilled workers, it is therefore also important to have specialists in the individual processes or departments who deal with the individual requirements of the regulatory framework and are particularly familiar with it in order to then make this knowledge available to other people.

2.g. Alternative ways

Alternative ways mean that if certain R&D cannot be carried out due to regulations, then companies try to work with the authorities to find solutions so that certain projects and studies can still take place. IP6, for example, reports that new ways must be found through innovation

in order to continue to be innovative. A solution must then be discussed with the authorities in order to possibly make the project possible. In this context, IP2 also says that there is generally the possibility of taking legal action if the authorities treat the company unfairly. IP2 thus makes it clear that there are often ways to defend yourself against certain breaches of competitiveness. It is precisely for this reason that companies and associations in the European Union are giving feedback that the regulatory framework should be made more flexible. Due to the rapid transformation of technology and science, it is particularly important that the legal regulations are constantly adapted to the scientific conditions in order to create a fast and effective innovation process.

2.h. Strict compliance

In conclusion, one form of compliance management is strict adherence to the guidelines imposed by the EU and the authorities. The majority of interviewees are aware that this legal framework simply has to be complied with and that there is no way around it.

> "It's a very difficult trade- off for organizations like [the company's name] to make that deal, you have to be compliant. I mean, you obviously need to understand exactly where the limits are, but you can't afford, you know, in a particularly a large organization like ourselves, you can't afford to be non-compliant. So, compliance is a must. There is no way around it." (IP7, Pos. 20)

As already described under point 1.e., according to the IPs, the companies have already become accustomed to the European regulations through long-term activity. For this reason, most companies are very experienced and well-rehearsed when it comes to compliance. As long as the product does not require any special regulations, the companies must adhere to the regulatory procedure.

4.1.3. Negative Impact of regulatory framework on companies (Challenges)

The next subchapter deals with the negative impacts that the EU regulatory framework has on pharmaceutical companies.

3.a. External factors

External factors are not directly part of the EU legal framework for the pharmaceutical industry, but rather tend to be what is missing from this legal framework, which creates a challenge and a negative impact for pharmaceutical companies in R&D. IP5, for example, points out that Europe should generally regulate more for innovation instead of just

concentrating on the pharmaceutical industry. This includes incentives for start-ups, universities, but also more extensive risk management. IP7 says that the USA, as the largest pharmaceutical market, has a completely different structure and way of thinking that is more liberal and risk-friendly, and thus offers a strong advantage for innovative R&D. The combination of these factors and the fact that there is no direct solution to this problem in the area of the pharmaceutical legal framework makes it more difficult for companies to actively conduct R&D in the EU.

This was also taken up by Mazzucato (2018) and highlights how important an overall strategy for Europe is in relation to innovation. The connection between academia, start-ups and large pharmaceutical companies is cited as a key point in order to effectively expand Europe's innovation system. But a generally increased cooperation, the willingness to take more risks in general and a more flexible system within pharmaceutical legislation are also cited as important aspects in order to increase and promote innovation within the European Union. It is therefore particularly important for the EU in the coming years not only to revise the individual industries' regulatory frameworks, but also to design overarching programs such as the Industry Strategy, the Green Deal or Horizon Europe in such a way that the individual industries can absorb them well and incorporate them into their strategies. As already mentioned by Saltelli et al in their paper, it is therefore extremely important to include a broad range of inputs and opinions in decisions in order to create a coherent strategy for the whole European Union, rather than many small individual strategies that may not be mutually beneficial.

3.b. Too rigid and unflexible framework

The most frequently cited answer to the question of what the biggest challenges are for research-based pharmaceutical companies in the EU is the very rigid and strict regulatory framework. On the one hand, this makes it difficult to navigate within this framework and to carry out new projects such as studies or the like, but it is also difficult to change existing circumstances.

> “And what we are now realizing is that it is very complex. The testing approval procedures in Europe for clinical studies, the CTIS database and the corresponding clinical trial regulations are very complex, and very time-consuming. So other regions are overtaking Europe, that must be said quite clearly.” (IP6, Pos. 7)

> "We do not have a within Europe a very agile and flexible approach to the enactment of hard legislation, and I think one of the views of the industry would be that if Europe is to remain competitive in broadly in fields which are extremely innovative and/or complex and as I say innovative, then it needs to find a way to be to some extent more agile and flexible in the overall process of legislation enactment." (IP7, pos. 22-23)

In addition, as IP4 and IP8 have found, changes due to innovation, such as new study types or similar, are very difficult or even impossible to accept quickly and at short notice. This and the long waiting times for approvals in the area of clinical trials represent a major hurdle for R&D. In return, the time that companies have to submit a change after a rejection is often very short and a major strategic challenge to overcome.

These statements coincide with several statements and authors in the literature. Pelkmans & Renda (2014), for example, describe more flexible frameworks as being more conducive to innovation, but Heikkinen et al (2023) also name flexibility and adaptability as factors that have a positive influence on R&D and innovation. These factors can be increased through so-called soft laws, for example. The EFPIA also writes in its report about the lack of flexibility in pharmaceutical legislation and calls for this to be changed. Other authors also see the stringency of the European system as hindering innovation.

3.c. Time it takes for approvals

While the long approval times are a consequence of the strict legal framework, it is still cited as a challenge in its own right, due to the frequency of mentions during the interviews. Time is extremely important for pharmaceutical companies, as even a few days later than planned for a product to come onto the market can lead to enormous economic losses, according to IP6. All interviewees stated during the interview that the time required for approvals of clinical trials, for example, and thus the time-to-market, is far too long to be conducive to innovation.

The time factor is frequently associated with issues of flexibility and bureaucracy. Both Pelkman & Renda (2014) and BERR (2008) consider it an important aspect in the innovation process, both for companies and for authorities in terms of compliance times. Generally speaking, long waiting times are always a major issue for individual pharmaceutical companies and thus hinder the R&D process, but also the market authorization and sale of medical products.

3.d. Not enough streamlining within the system

The fact that there is not enough streamlining and coordination between the authorities is the second most frequently cited hurdle for pharmaceutical companies after the rigid and inflexible framework. Often the same process has to be submitted multiple times at different levels, i.e. nationally and at EU level, or the requirements are different, which in turn presents another challenge.

> "It is still very challenging because, despite these efforts to create harmonized conditions and requirements for clinical trial applications for all EU countries, there has recently been an increase in national requirements and this means more work to ensure that you are constantly up to date and not only screen for EU requirements, but also for local requirements." (IP9, Pos. 15)

Similarly, there is often overlap in the area of checking and auditing. According to multiple IPs, for example, a more coordinated solution in which the authorities communicate more with each other would be a great relief and would greatly help research and development. In addition, as IP6 explains, you often get different answers about the same issue from different places. EU regulations are often interpreted differently in individual member states and even within countries. Coming to a harmonized solution here would remove this hurdle.

> "We have submitted a clinical trial authorization in several European countries and we have received five different answers from five authorities. Five different answers that also referred to the relevant regulations and articles. And that shows that Europe is - excuse my poor expression - a patchwork. We ourselves are talking about legislation, a procedure, but then, due to a human factor, it is interpreted very differently by people." (IP6, Pos. 23)

The literature also shows that streamlining plays an important role in promoting innovation and R&D. For example, Blind (2013) points out that streamlining has a positive influence on innovation, but that this also involves clarification of the regulatory framework. Benedek (2012) also agrees, as does the EFPIA (2023), which repeatedly calls for more streamlining and efficiency in its reports.

3.e. Administrative Burden

This challenge is also accompanied by inflexible legislation and inadequate streamlining, but here too the number of mentions was particularly high and will therefore be dealt with

separately. In this area, all interviewees agree that the large bureaucratic apparatus and the resulting bureaucratic burden have a negative impact on R&D.

While this point often coincides with other factors such as streamlining, the administrative burden was often highlighted in interviews. In the literature, for example, Heikkinen et al (2023) or the OECD (1997), but also the European Commission itself, states that bureaucracy and red tape hinder innovation and make it more difficult for companies to carry out effective R&D.

4.1.4. Positive impact of regulatory framework on R&D

Finally, this subchapter deals with the findings of the interviews in the area of the positive impacts of the EU legal framework on pharmaceutical R&D

4.a. Harmonization

Harmonization is the greatest advantage of pharmaceutical regulation in the EU, the interviewees agree. Since adopting the current legislative framework at the beginning of the 2000s, a lot has happened, and things have developed in a positive direction.

> "It really covers everything and there are guidelines. A whole list that you simply follow today and where you know exactly what you have to do. And that is helpful and of course it also leads to more, let's say, equal treatment between pharmaceutical companies. Everyone has the same requirements, let's say. And in that respect, you are aligned and simply regulated." (IP2, Pos. 13)

IP1 notes how complex certain processes were before, when they all had to be clarified individually with national guidelines. Harmonization also makes it easier for companies from outside the EU to come to Europe with innovative products to do research here.

> "[opening up research to outside companies] but of course that gives us the chance to get innovative products that do not come from the EU earlier, so that is definitely the case with this standardization, it will be easier, I would say, it opens things up for us." (IP 10, Pos. 33)

Harmonization therefore has a positive effect on research and development, and it also makes it easier to carry out studies, says IP4. As already mentioned in section 3.d., streamlining and harmonization are essential factors for carrying out successful and effective research and development. In general, the majority of interviewees were in favor of more harmonization and consider the harmonization of the last decades to be positive for the industry.

4.b. Digitalization

Digitalization, for example in the form of electronic databases and programs for submitting documents, is also becoming increasingly important. Even though some processes in the EU have already been converted to digital, the expanded digitalization within the framework of the new pharmaceutical strategy for Europe would offer great added value for R&D. IP4, IP9 and IP10 in particular see this form of digitalization as having a positive impact on Europe's ability to innovate. But other forms of digitalization, such as the digitalization of the package insert, would also lead to great simplifications, according to IP10.

Digitalization enables pharmaceutical companies to work more efficiently, faster and more easily. The European Union is already noticing this and, in the proposals presented, it is also placing emphasis on making the processes in the pharmaceutical industry and the regulatory framework more digital (e.g. European Commission, 2020b).

4.c. Support by authorities

In principle, it can be said that it is possible for pharmaceutical companies in the EU to provide feedback to the authorities and thus to a certain extent to influence current and future legislation. This is can either be done directly or through committees. IP1 and IP6 also make it clear that the EU is trying to support the industry as best as possible, within the scope of its possibilities.

> But then they do have the opportunity to provide feedback to the authorities, so they don't just do something and then everyone is surprised, it is also a process, it is actually a collaboration. Of course, at the end the authority then issues guidelines and that is that. But it is not the case that this is actually a complete surprise for a pharmaceutical company, so there is also the opportunity to provide feedback. (IP2, Pos. 38)

This provides pharmaceutical companies in Europe with the opportunity to communicate their concerns and feedback to the EU. This also highlights the importance of associations such as the EFPIA to properly represent the companies and facilitate cooperation between the companies and the EU. Since the EU always collects feedback from industry players as part of its impact assessments or ex-ante and ex-post evaluations, this is a good opportunity to influence the regulatory framework to a certain extent. The interviewees are therefore aware of the importance of impact assessment feedback and also appreciate the opportunity to give feedback to the authorities.

4.d. Other positive impacts

Other advantages mentioned include, for example, that the current legislation, but also the new pharmaceutical strategy for Europe, focuses on rare diseases and unmet medical needs and tries to provide incentives for R&D, as IP10 mentions. IP10 also shows that communication between the authorities leads to more certainty and that this benefits both patients and companies. IP9 mentions that the regulations lead to more transparency and that the availability of funds for R&D increases, says IP2. Certainty and transparency are also mentioned in the literature as promoters of innovation, as Pelkman & Renda (2014) show.

4.1.5. Summary of the findings

In summary, the expert interviews revealed a complex impact of EU regulations on the pharmaceutical industry's R&D efforts. While the experts acknowledge improvements since the early 2000s, especially through regulatory harmonization across EU member states that has enhanced industry growth by providing a predictable environment for companies across EU member states, they view the framework's advanced rigidity as a hindrance to innovation, often prompting companies to seek more flexible environments like the USA and Switzerland for their R&D activities. Therefore the industry observes closely the developments in the changes of regulatory framework, monitoring the proposed Pharmaceutical Strategy for Europe and it’s possible impacts on the day to day business of the companies operating in Europe. Generally the proposed changes and goals of the EC are welcomed, but there is still a big remaining uncertainty about its potential impact on research and development of medicinal products in the EU. The interview partners especially support further EU-wide harmonization, streamlining and digitalization of the processes, but challenges like the rigid bureaucracy and inflexibility of the system remain. While generally European authorities like the European Medicines Agency are appreciated for their support, concerns about long waiting times and coordination with national authorities are still a big issue for pharmaceutical companies. This leads to the need for faster approval processes and a more flexible legal framework to foster innovation, which in turn would free resources and possibilities for more research within the EU. In general, interactions with authorities like the European Medicines Agency (EMA) are crucial. While the EMA is regarded as supportive, criticisms focus on feedback inefficiencies and insufficient synchronization with national entities, requiring redundant efforts that consume resources. These relationships underscore the need for effective communication channels to assist companies in meeting regulatory demands and incorporating changes. The overarching narrative from these interviews

therefore highlights the nuanced balance between regulatory compliance and innovation, emphasizing the need for the EU to support ongoing R&D endeavors effectively within the regulatory framework. Looking ahead, pharmaceutical companies emphasize the need for faster approval times and greater flexibility within the legislative framework. Speed and agility in regulatory processes are essential to reducing time-to-market and fostering innovation. Companies also advocate for broader collaboration with research institutions to create a more integrated innovation ecosystem. In summary, while European pharmaceutical regulations have laid a solid foundation for industry growth, they also present significant challenges. Balancing the need for safety and compliance with agility and innovation remains a crucial focus for future regulatory improvements.

4.2. Discussion

4.2.1. Combining the existing literature with the new findings

The relationship between regulatory frameworks and research and development in the pharmaceutical industry is a complex interplay of compliance and incentives. In the European Union another factor gets weight in and that is the collection of member states. This makes the situation and the questions of how the regulatory framework for the pharmaceutical industry in the EU does impact the research and development investments of European companies operating within the sector and what the main challenges and opportunities that European companies encounter due to pharmaceutical regulations in the EU are, as well as how do these affect their R&D and innovation initiatives so complicated. The European Union's regulatory framework has a multifaceted impact on pharmaceutical research and development, balancing between enabling innovation and imposing constraints on the companies within the industry. Literature consistently emphasizes the high administrative burden enforced by the EU regulatory framework as a significant inhibitor of pharmaceutical innovation. This complexity and overlap in regulations increase bureaucratic demands on companies, diverting time and resources away from R&D activities (Pelkmans & Renda, 2014; Heikkinen et al, 2023). Interview findings agree with this perspective, highlighting the negative impact the administrative burden has on the companies operating in the European Union. The IPs stated how navigating multiple layers of regulation often leads to resource-intensive procedures, in line with the literature's claims. Specific examples, such as the Clinical Trials Regulation (CTR) causing longer waiting times due to inefficiencies, strongly illustrate these burdens. Obstacles such as long waiting times for answers from the authorities, but also the lack of consultation between government authorities are mentioned. These

inefficiencies, as well as the current inflexible regulatory framework, are some of the biggest problems mentioned in the literature, but also in the interviews, in connection with innovation in the European pharmaceutical industry.

Furthermore, the literature suggests a dual role for compliance stringency: while it can drive investment and strategic shifts towards innovation, excessive stringency can stifle R&D by escalating compliance costs (Pelkmans & Renda, 2014). Interviewees confirmed this view as well, describing how stringent compliance has become an industry standard, justifying its perceived impact on operational efficiency. However, the findings of the interviews found no significant evidence that the stringency per se and compliance really have a positive or negative impact on R&D like Pelkmans and Renda (2014) have suggested. This insight enriches the discourse by suggesting that within certain thresholds, compliance stringency may enforce beneficial operational disciplines but become counterproductive when excessively stringent. Other perspectives from the interviews also show that stringent compliance is particularly important in the health care sector and the pharmaceutical industry. In future studies, it would be possible to find out whether the view of IPs would behave differently in different industries. In the case of the pharmaceutical industry in Europe, compliance does not play a significant role in the productivity of innovation.

Timing is another crucial factor highlighted in the literature, which notes that prolonged regulatory approval times can reduce innovation by slowing time-to-market and potentially leading to lost economic opportunities (BERR, 2008). Interviewees emphasized that the time-intensive nature of regulatory approvals is a significant negative impact, resulting in delayed market entry for new innovations. This perspective directly aligns with the literature's findings, reinforcing the view that regulatory timing is a critical determinant of innovation momentum in the pharmaceutical sector. If the approval times as described in the communication from the European Commission were actually to be greatly reduced, this would be a great advantage for the European pharmaceutical industry.

Flexibility in regulatory frameworks is presented in the literature as essential for fostering innovation. Adaptive regulations that reduce administrative barriers and accommodate new scientific advancements are seen as particularly beneficial (Pelkmans & Renda, 2014). The experts during the interviews stated the need for greater regulatory flexibility, particularly criticizing the constraints of the current rigid system. They suggested that increased adaptability could significantly enhance innovation, supporting literature's emphasis on flexibility. Practical strategies discussed by interviewees, such as using SOPs and fostering

close communication within regulatory affairs units, offer concrete ways companies attempt to inject flexibility into an otherwise stringent system.

Uncertainty within regulatory frameworks has both challenges but also opportunities for companies. While it can stimulate firms to innovate in anticipation of future regulations, excessive uncertainty can destabilize the investment environment, therefore reducing R&D. (Pelkmans & Renda, 2014). Many IPs highlighted regulatory uncertainty as a central challenge, especially when frequent changes or inconsistent implementations across member states create an unpredictable environment. This sentiment aligns closely with existing literature, underscoring the destabilizing effect of regulatory uncertainty on investment decisions and strategic planning.

In summary, the literature and interviewees underscore the significant administrative burdens and compliance costs as critical barriers to innovation. This confirms that the bureaucratic complexities of the EU framework consume significant resources that could otherwise be directed towards research and development. On the other hand, while literature predominantly highlights the negative impact of stringent regulations, interviewees added that structured compliance frameworks might sometimes provide operational consistency, suggesting a nuanced understanding where stringent yet clear guidelines potentially aid operational efficiency. However, this stringency is ultimately only advantageous if the regulatory framework is clearly formulated and there are no ambiguities in the rules.

The findings from the interviews also expand the literature by offering practical insights into strategies employed by companies to navigate the regulatory landscape. These include adopting SOPs, establishing specialized teams within regulatory affairs units, and ongoing training programs.

By providing a comprehensive view that captures the complexity of compliance and innovation dynamics within the EU regulatory framework, this thesis enriches the theoretical foundation for understanding the impact of EU regulations on pharmaceutical R&D and offers practical insights for companies in the pharmaceutical industry, but also for regulators and authorities with the intent to increase innovation activities and support R&D in the pharmaceutical field.

4.2.2. Implications for pharmaceutical companies conducting R&D in the EU

Implement standard procedures and specialized teams

The complex relationship between regulatory frameworks and R&D investment in the pharmaceutical sector requires companies to adopt strategic alignment and adaptation measures. Developing and refining Standard Operating Procedures (SOPs) is essential. Companies should incorporate regulatory requirements into these SOPs in order to streamline processes and ensure compliance. For instance, templates are a good way to standardize document submissions to authorities, enhancing efficiency and consistency. Establishing or strengthening regulatory affairs units is equally crucial. Such departments should monitor legislative changes and provide timely updates. Finally, companies should install teams dedicated to different regulatory aspects to act as coordinators across various research phases, ensuring seamless compliance.

Conduct internal and external trainings to be prepared

Continuous training programs are another critical aspect. Implementing these programs keeps staff informed about regulatory requirements and best practices. Using both internal and external training materials supplies employees with the essential knowledge to maintain compliance effectively. Utilizing the harmonization of regulations within the EU to streamline internal procedures also offers substantial benefits. Uniform guidelines reduce complexity and can enhance operational efficiency. The EU's legislative framework offers harmonized guidelines, and using this clear framework to navigate the company's strategy can be advantageous. In this regards is a clear and structured communication within companies particularly important here. Since not every department is always informed of the latest changes in the EU, it is important that departments such as regulatory affairs keep the research department up to date. On the other hand, however, it is also essential that feedback finds its way through the company structure to the authorities, thus ensuring a constant exchange.

Embrace digitalization

Digitalization presents a significant opportunity for companies. Investing in digital tools and platforms can help manage regulatory submissions and compliance processes more efficiently, streamlining documentation and data management. This allows process steps to be automated, but also allows past activities to be better documented and traced. The SOPs mentioned in the

interview and literature also play an important role here, as digitalization not only makes the authorization process easier, but also allows companies to benefit from it internally.

Establish a long-term coherent strategy

Long-term planning and strategic shifts are vital for staying ahead. Developing a forward-looking regulatory strategy that anticipates future changes and aligns with long-term business goals is imperative. Preparing for potential shifts in therapeutic areas involves staying adaptable and open to adopting new platforms and technologies, ensuring companies remain competitive. Maintaining active engagement with regulatory bodies is equally important. Providing feedback through platforms like EMA and EFPIA helps shape more effective regulations, benefiting both regulators and the industry.

Seeking alternative solutions

Balancing compliance with innovation is a delicate act that requires companies to develop strategies to navigate the rigid aspects of the regulatory framework without stifling innovation. The challenge of complex regulatory procedures for clinical trials necessitates innovative approaches within established frameworks. Seeking alternative solutions and engaging in discussions with authorities can overcome regulatory hurdles and facilitate innovative projects.

In summary, by incorporating these detailed implications, pharmaceutical companies can strategically navigate the complex EU regulatory landscape. Ensuring compliance while fostering innovation through these adjustments and long-term strategies will enable companies to enhance their R&D efficiency, reduce time-to-market, and maintain a competitive position in the evolving pharmaceutical sector.

4.2.3. Implications for European Authorities

Foster Flexibility in Regulatory Frameworks

The regulatory framework for pharmaceutical companies within the EU should embrace greater flexibility in order to promote innovation while maintaining high safety and efficacy standards. Introducing adaptive regulations that accommodate new scientific advancements and reduce administrative barriers is imperative. The regulatory framework must adapt to the rapidly changing regulatory changes and enable companies to carry out the best possible research and development while maintaining high safety standards. By fostering a more agile approach, the EU can support pharmaceutical companies in adapting to evolving technologies

and market demands more easily. Furthermore, proactively involving stakeholders in the legislative process can ensure that regulations remain relevant and supportive of innovation.

Streamline and Harmonize Procedures

Harmonization and standardization of regulatory procedures across the EU can significantly reduce the complexity pharmaceutical companies face. Uniform guidelines and streamlined processes can enhance operational efficiency and reduce administrative burdens. Authorities should focus on consistent implementation and interpretation of regulations across member states, minimizing discrepancies that can lead to compliance challenges. Enhancing coordination between national and EU regulatory bodies will also facilitate smoother processes and reduce redundancy. However, due to discrepancies, harmonization can be seen as a disadvantage, as companies do not have a clear framework within which to operate. Transparency is therefore particularly important for the European Union in this context, so that clear rules do not lead to any ambiguities.

Enhance Approval Processes

Speeding up approval processes for clinical trials and new drug applications is crucial for maintaining the EU's competitive edge in pharmaceutical innovation. Authorities should prioritize the development of more efficient and responsive systems to handle regulatory approvals as well as implementing joint assessments and inspections in order to reduce duplicative efforts and expedite the time-to-market for new pharmaceutical products. Adopting digital tools to manage submissions and reviews can further streamline the approval process, making it more transparent and accessible. Since time to market and fast authorization times are cited as one of the main criteria for research and development, it is particularly important for the EU and thus the EC to take this into account when revising the legislation.

Support Collaboration and Stakeholder Engagement

Maintaining open and continuous dialogue between regulatory authorities and pharmaceutical companies is essential for shaping effective policies. Authorities should encourage feedback from the industry through formal channels such as the European Medicines Agency (EMA) and the European Federation of Pharmaceutical Industries and Associations (EFPIA) before and after the implementation of regulations. This collaboration can help identify potential regulatory barriers and develop solutions that balance compliance with innovation. Additionally, fostering partnerships with research institutions, clinics, and universities can

create a cohesive innovation ecosystem. The impact assessments represent a valuable opportunity for the EC to gather feedback and further incorporate the opinions of stakeholders into the regulatory frameworks. Through the European policy cycle, continuous feedback enables the constant improvement of the legislation and thus also the performance of European companies in the area of research and development.

Promote Comprehensive Risk Management

Developing robust risk management frameworks within the regulatory structure can help mitigate uncertainties and variances that pharmaceutical companies face. Authorities should consider incorporating comprehensive risk management strategies into the regulatory process, ensuring that potential risks are identified and addressed proactively. By integrating risk assessments and mitigation plans, the regulatory framework can support a more stable and predictable environment for pharmaceutical R&D.

Encourage Innovation-Friendly Policies

Authorities should also focus on creating policies that actively promote innovation within the pharmaceutical industry. This includes incentivizing R&D activities through grants, tax benefits, and supportive regulations. Implementing measures that specifically address the needs of start-ups and small biotech companies can drive innovation and enhance the EU's position as a leader in pharmaceutical research. By aligning regulations with the goal of fostering innovation, authorities can ensure that the regulatory framework supports the growth of cutting-edge therapies and medical advancements. But here it is also important not only to work specifically for the pharmaceutical industry, but to expand the innovation opportunities across a broad range of industries and economic sectors and to create a coherent system for carrying out research and development.

In summary, by embedding these implications and suggestions into the regulatory framework, authorities within the EU can create an environment that balances regulatory compliance with the need for pharmaceutical innovation. Greater flexibility, streamlined procedures, faster approval processes, enhanced collaboration, comprehensive risk management, and innovation-friendly policies are crucial for maintaining the EU's competitive edge in the global pharmaceutical industry. Through these targeted improvements, the EU can support pharmaceutical companies in enhancing their R&D efficiency, reducing time-to-market, and pioneering new medical innovations.

4.2.4. Limitations

When conducting research, it is essential to acknowledge its limitations to provide a balanced and thorough understanding of the findings. Below are several limitations that apply to this master's thesis on the impact of EU regulations on the R&D departments of international European pharmaceutical companies:

Firstly, the scope of the expert interviews might not fully represent the diversity of international European pharmaceutical companies. The sample size and selection process could lead to biases, as opinions can vary widely based on geographic location, company size, and specific roles within the organization. Additionally, those who agreed to be interviewed might share similar perspectives, which could influence the findings, while the views of those who declined remain absent. Furthermore, the depth and detail of responses can vary significantly among interviewees, potentially affecting the comprehensiveness of the analysis. Secondly, the generalizability of the case study approach is limited. By focusing on only a few selected companies, this research might not capture the full diversity of the pharmaceutical industry in Europe. Results could differ if additional or different companies were analyzed. Moreover, the financial and yearly reports used in the case study may reflect specific timeframes that do not capture longer-term trends or recent regulatory changes, thereby limiting the temporal relevance of the findings.

The literature review, despite being extensive, might not encompass all relevant studies or reports, particularly newer or less accessible publications. This limitation could result in an incomplete picture of the existing research landscape. Additionally, there may be a citation bias, where emphasis is placed on prominently cited studies, potentially overlooking less cited but equally relevant research. The complexity and dynamic nature of the regulatory framework also present limitations. EU regulations are continually evolving, and the regulatory environment at the time of the study might change by the time of publication, impacting the relevance of the findings over time. Furthermore, while the EU aims for harmonization, there are still significant differences in how member states implement and enforce regulations, making it difficult to generalize findings across all EU countries.

Also, quantitative data limitations must also be considered. The accuracy and completeness of financial and yearly reports can vary, with companies reporting their R&D investments differently. This variability can limit the ability to make direct comparisons or infer broader trends. Additionally, quantifying the impact of regulatory frameworks on R&D investments and innovation is challenging due to the multifactorial nature of innovation, influenced by

numerous internal and external factors beyond regulatory frameworks alone. Methodological constraints also exist. The interpretation of qualitative data from interviews and case studies involves a degree of subjectivity, where different researchers might draw varying conclusions from the same data. Additionally, aligning qualitative insights from interviews with quantitative data from financial reports and literature can be complex and may introduce inconsistencies or interpretation biases.

Lastly, the focus on the EU might overlook the global context in which pharmaceutical companies operate. These companies face multiple overlapping regulatory frameworks, and the specific focus on the EU might miss interactions with non-EU regulations that could significantly impact R&D. By acknowledging these limitations, this master's thesis presents a nuanced and transparent analysis of the impact of EU regulations on pharmaceutical R&D. Awareness of these constraints helps contextualize the findings and suggests areas for future research to further explore this complex relationship.

5. Conclusions

5.1. Summary of Findings

This master's thesis explored the impact of EU pharmaceutical regulations on innovation and R&D and analyzed how these frameworks influence decision-making, strategies alignment, and the overall innovation landscape in the industry. It aimed to evaluate the regulatory environment, uncover challenges and opportunities for firms, and provide actionable insights by integrating perspectives from international business, innovation management, and European studies. Based on an extensive literature analysis, semi-structured expert interviews were conducted with ten employees or managers from eight different pharmaceutical companies to ask them about the current and possible future influence of the EU on the research-based pharmaceutical industry. The results were ultimately evaluated according to Mayring's theory, summarized and linked to the existing literature. The study seeked to inform policymaking and corporate strategies while advancing interdisciplinary knowledge in this critical field. The starting point for this study were therefore the two research questions RQ1 and RQ2, which set the framework for the entire work:

RQ1: How does the regulatory framework for the pharmaceutical industry in the EU impact the research and development investments of European companies operating within the sector?

RQ2: What are the main challenges and opportunities that European companies encounter due to pharmaceutical regulations in the EU, and how do these affect their R&D and innovation initiatives?

Prior to the work, two additional hypotheses were formulated to answer the research questions. The first hypothesis H1 was that European pharmaceutical companies that strategically align their R&D efforts with EU regulatory requirements see higher and more efficient investments in research and development. The second hypothesis H2, to answer RQ2, was that increased regulatory complexity, and administrative burden can negatively impact the time-to-market for new pharmaceutical innovations in the EU and therefore have a hemming impact on innovation and R&D.

The first hypothesis cannot be fully verified. While the European framework, through harmonization and standardization, provides a good basis for pharmaceutical companies to work easily and efficiently in the European Union, the legislation has now progressed so far

that it has become very rigid and inflexible. These inflexibility and lengthy processes make it difficult for pharmaceutical companies to conduct research and development within the EU. For these reasons, many pharmaceutical companies prefer research locations outside the EU, such as the market leader, the USA. However, adapting to European rules has the advantage of being able to participate successfully in the European market, the second largest pharmaceutical market in the world, and to operate more efficiently in this market. It can therefore be said that the European legal framework brings many advantages for pharmaceutical companies, but at the moment it does not offer enough opportunities for R&D and innovation. The Pharmaceutical Strategy for Europe aims to change this. With shorter authorization times and more flexible and simplified processes, the EU wants to make innovation in the EU easier again. The interviews conducted in this work show that this is a good step in the right direction and will certainly promote innovation, but further measures are still needed. While the exact consequences of the change in the regulatory framework cannot yet be precisely estimated, there is already feedback from, for example, the EFPIA, which is of the opinion that the EU would even achieve negative results for the research-based pharmaceutical industry with some changes. The exact changes resulting from the pharmaceutical strategy for Europe will therefore only be seen in a few years, but the experts questioned during the interviews are mostly positive about the changes. In summary, the EU offers a good basis for pharmaceutical companies to operate with a harmonized network of rules, but the network is too rigid for research and development and needs to be more flexible. Pharmaceutical companies in the EU therefore do not gain much advantage if they are compliant with the legislation; as the interviewees confirm, this is more of a neutral situation.

The second research question and hypothesis, on the other hand, are simpler to answer. While there are a multitude of obstacles and opportunities for companies in such a large economic area and regulatory framework as the European Union, the interviewees are largely in agreement with this question. The main obstacle is cited as the EU's rigid and inflexible framework, as well as the slow authorization times caused by the bureaucratic effort. This often leads to long waiting times until medicinal products are approved for the EU market, resulting in enormous costs for companies. The lack of harmonization between the authorities is also a major problem and prevents companies from pursuing innovation. The lack of support for R&D and innovation is not just an isolated problem in the pharmaceutical industry but is a general problem in the European Union. Hypothesis 2 can therefore be confirmed in this master's thesis: administrative burden and the high regulatory complexity in the EU have a negative impact on innovation and inhibit it. On the other hand, the European Union also

offers advantages for companies, with harmonization being cited as the Union's greatest advantage. This enables companies to work more efficiently overall.

In summary, the expert interviews provided a comprehensive insight into the impact of EU regulations on the pharmaceutical industry's research and development activities. Since the early 2000s, the implementation of a harmonized regulatory framework across EU member states has been viewed positively for fostering industry growth and creating a predictable business environment. However, experts also highlight that the framework's rigidity poses significant challenges to innovation, prompting some companies to seek more flexible R&D environments, such as those in the United States and Switzerland. Therefore, the proposed Pharmaceutical Strategy for Europe is being closely monitored by the industry. While the companies are generally welcoming of these changes, uncertainty about its actual impact on research and development still remains. The industry would favor further harmonization, streamlining, and digitalization across EU procedures, but bureaucratic rigidity and inflexibility remain key challenges. Interactions with regulatory bodies, particularly the European Medicines Agency (EMA), are seen as supportive, however, as real life pratice shows is often lengthy and uncoordinated. This often leads to more efforts and higher resource expenditures.

Regarding the possible future, pharmaceutical companies emphasize the need for expedited approval processes and a more flexible legislative framework to enhance innovation. Additionally, they advocate for broader collaboration with research institutions to develop a more integrated innovation ecosystem. Balancing the demands of safety and compliance with the need for agility and innovation will be of crucial focus for future regulatory enhancements.

5.2. Contribution to Knowledge

This master's thesis contributes to expanding the current state of knowledge through its qualitative approach. On the one hand, new knowledge was gathered through the expert interviews and, on other hand, this knowledge was directly linked to existing theories. In this way, existing literature could be strengthened and confirmed, such as the positive impact that standardization and harmonization have on companies, or that overly strict regulations inhibit innovation. But strategies for aligning companies with the regulatory framework could also be confirmed, but also expanded upon in some ways. In addition, strategies for compliance and insights into the future needs of the European pharmaceutical industry were gained. Thus, implications could be drawn for pharmaceutical companies as well as authorities in the

European Union, which can be used in the future both as guidelines and as a starting point for further studies.

5.3. Reflection on research limitations and possibilities for future research

Since this master's thesis is written as part of the completion of a master's degree, there are limitations that may limit the research results. This would be the sample size and diversity, for example. The study may have a limited number of expert interviews, which can restrict the generalizability of the findings. The diversity of expertise and geographic representation among the interviewees may also influence the comprehensiveness of the insights gathered. In addition, the subjectivity of the experts could distort the results. The qualitative nature of interviews means that findings are influenced by the subjective opinions and experiences of the participants. This can introduce bias and may not fully represent the broader perspective industry. The evolving regulatory landscape was also seen as an obstacle in the writing of this work. The regulatory environment is continuously changing, and insights derived from the interviews may quickly become outdated. As regulations evolve, new challenges and opportunities may arise that are not captured in the current study. However, within the scope of possibilities, these limitations are kept as low as possible. On the other hand, they also represent an opportunity for further research. The scope for future research in the area of regulatory frameworks and their influence on innovation within the pharmaceutical industry is still far-reaching and diverse.

One possibility for further research would be to choose a different geographical focus, such as Eastern Europe, East Asia or the USA. By changing the location, cultural differences could be investigated. In addition, the incorporation of quantitative methodologies, such as surveys and economic modeling, presents an opportunity to complement qualitative findings with robust, empirical data. This approach could afford a more comprehensive understanding of how regulatory frameworks affect research and development productivity and innovation capacity in the pharmaceutical sector. Another possibility to tie in with this master's thesis would be, for example, a long-term study. By examining regulatory changes and their impacts over extended periods, researchers could derive insights into the long-term effects of policy decisions on industry innovation and competitiveness. This long-term study would make sense in this case in particular, as the changes in the last decade, as well as in the coming decade, are very distinct.

6. Sources

Abraham, J., & Davis, C. (2007). Interpellative Sociology of Pharmaceuticals: Problems and Challenges for Innovation and Regulation in the 21st Century. Technology Analysis & Strategic Management, 19(3), 387–402. https://doi.org/10.1080/09537320701281607

Abraham, J., & Reed, T. (2002). Progress, Innovation and Regulatory Science in Drug Development: The Politics of International Standard-Setting. Social Studies of Science, 32(3), 337–369. https://doi.org/10.1177/0306312702032003001

BAK Economics AG. (2021). The importance of the pharmaceutical industry for Switzerland. Study on behalf of Interpharma. Retrieved [13.08.2024] from https://www.interpharma.ch/wp-content/uploads/2021/11/BAK_Economics_Interpharma_Volkswirtschaftliche_Bedeutung_Pharmaindustrie_2020_en.pdf

Bénard, L., Bore, J., & Van Keymeulen, E. (2018). Rewarding Innovation: Pharmaceutical Incentives as a Crucial Instrument to Foster Public Health. EPLR, 2, 72

Benedek, P. (2012). Compliance management–A new response to legal and business challenges. Acta Polytechnica Hungarica, 9(3), 135-148.

BERR – Department for Business, Enterprise and Regulatory Reform of the UK Government (2008), “Regulation and Innovation: Evidence and Policy Implications”, BERR Economics Paper No. 4, London.

Blind, K. (2012). The influence of regulations on innovation: A quantitative assessment for OECD countries. Research Policy, 41(2), 391–400. https://doi.org/10.1016/j.respol.2011.08.008

Blind, K. (2016). "Chapter 15: The impact of regulation on innovation". In Handbook of Innovation Policy Impact. Cheltenham, UK: Edward Elgar Publishing. https://doi.org/10.4337/9781784711856.00022

Brooks, E. (2018). Using the Advocacy Coalition Framework to understand EU pharmaceutical policy. European Journal of Public Health, 28(suppl_3), 11–14. https://doi.org/10.1093/eurpub/cky153

Bruton, G. D., Lohrke, F. T., & Lu, J. W. (2004). The evolving definition of what comprises international strategic management research. Journal of International Management, 10(3), 413–429. https://doi.org/10.1016/j.intman.2004.05.003

Chataway, J., Tait, J., & Wield, D. (2006). The governance of agro-and pharmaceutical biotechnology innovation: public policy and industrial strategy. Technology Analysis & Strategic Management, 18(2), 169-185.

Cronin, M. A., & George, E. (2023). The Why and How of the Integrative Review. Organizational Research Methods, 26(1), 168–192. https://doi.org/10.1177/1094428120935507

Denny, E., & Weckesser, A. (2022). How to do qualitative research?: Qualitative research methods. BJOG : An International Journal of Obstetrics and Gynaecology, 129(7), 1166–1167. https://doi.org/10.1111/1471-0528.17150

Efpia. (2022). “The pharmaceutical industry in figures”. [Retrieved on 14.04.2024 from] https://www.efpia.eu/media/637143/the-pharmaceutical-industry-in-figures-2022.pdf

Efpia. (2023a). “Regulations, safety & supply”. [Retrieved on 14.04.2024 from] https://www.efpia.eu/about-medicines/development-of-medicines/regulations-safety-supply/

Efpia. (2023b). “Assessment of main provisions and key EFPIA recommendations on the revision of the pharmaceutical package”. [Retrieved on 25.04.2024 from] https://www.efpia.eu/media/gy5j1nkt/efpia-recommendations-on-the-revision-of-the-pharmaceutical-package.pdf

Egeberg, M. (2022). The European Commission. In European Union Politics. Oxford University Press. https://doi.org/10.1093/hepl/9780198862239.003.0010

EUCOPE. (08.2023). EU Pharmaceutical Package: A more competitive and attractive EU for smaller companies. [Retrieved on 04.11.2024 from] https://www.eucope.org/wp-content/uploads/2023/08/eucope-pharma-package-position-paper-final.pdf

European Commission. (2015). “50 years of Pharmaceutical Legislation in Europe – making a difference in the well-being of patients across Europe”. [Retrieved on 12.02.2024 from] https://ec.europa.eu/commission/presscorner/detail/de/MEMO_15_3960

European Commission. (2017a). “50 years EU Pharmaceutical Regulation Milestones”. [Retrieved on 12.02.2024 from] https://ec.europa.eu/health/human-use/50years/docs/50years_pharma_timeline_v3.pdf

European Commission. (2017b). “50 years of EU pharmaceutical legislation”. [Retrieved on 12.02.2024 from] https://ec.europa.eu/health/human-use/50years/index_en.htm

European Commission. (2020a). “COMMISSION STAFF WORKING DOCUMENT Synopsis report Accompanying the document COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL, THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE AND THE COMMITTEE OF THE REGIONS Pharmaceutical strategy for Europe”. [Retrieved on 20.04.2024 from] https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=SWD:2020:286:FIN

European Commission. (2020b). “COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL, THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE AND THE COMMITTEE OF THE REGIONS Pharmaceutical Strategy for Europe. COM/2020/761 final”. [Retrieved on 21.04.2024 from] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52020DC0761

European Commission k. (2021). “Better Regulation Guidelines. SWD(2021) 305 final”. [Retrieved on 30.03.2024 from] from https://commission.europa.eu/document/download/d0bbd77f-bee5-4ee5-b5c4-6110c7605476_en?filename=swd2021_305_en.pdf

European Commission. (2023a). “A pharmaceutical strategy for Europe”. [Retrieved on 12.02.2024 from] https://health.ec.europa.eu/medicinal-products/pharmaceutical-strategy-europe_en

European Commission. (2023b). “COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL, THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE AND THE COMMITTEE OF THE REGIONS Pharmaceutical Strategy for Europe. COM/2020/761 final”. [Retrieved on 22.04.2024 from] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52023DC0190&qid=1682665765572

European Commission. (2023c). “Directive of the European parliament and of the council”. [Retrieved on 22.02.2024 from] https://eur-lex.europa.eu/resource.html?uri=cellar:bfcb9e00-e437-11ed-a05c-01aa75ed71a1.0001.02/DOC_1&format=PDF

European Commission (2023d) Directorate-General for Research and Innovation, Hollanders: “European Innovation Scoreboard 2023”. Publications Office of the European Union. [Retrieved on 28.09.2024 from] https://data.europa.eu/doi/10.2777/119961

European Commission. (2023e). “Factsheet - Driving innovation for pharmaceutical industry”. [Retrieved on 28.09.2024 from] https://health.ec.europa.eu/publications/factsheet-driving-innovation-pharmaceutical-industry_en

European Commission. (2023f). “Legal framework governing medicinal products for human use in the EU”. [Retrieved on 18.02.2024 from] https://health.ec.europa.eu/medicinal-products/legal-framework-governing-medicinal-products-human-use-eu_en

European Commission. (2023g). “Proposal for a directive of the European Parliament and of the Council”. [Retrieved on 12.02.2024 from] https://eur-lex.europa.eu/resource.html?uri=cellar:bfcb9e00-e437-11ed-a05c-01aa75ed71a1.0001.02/DOC_1&format=PDF

European Commission. (2023h). “Proposal for a regulation of the European Parliament and of the council”. [Retrieved on 12.02.2024 from] https://eur-lex.europa.eu/resource.html?uri=cellar:e3f40e76-e437-11ed-a05c-01aa75ed71a1.0001.02/DOC_1&format=PDF

European Commission. (2023i). “Reform of the EU pharmaceutical legislation”. [Retrieved on 12.02.2024 from] https://health.ec.europa.eu/medicinal-products/pharmaceutical-strategy-europe/reform-eu-pharmaceutical-legislation_en#

European Medicines Agency. (2024a). “What we do”. [Retrieved on 17.02.2024 from] https://www.ema.europa.eu/en/about-us/what-we-do

European Medicines Agency. (2024b). “European medicines regulatory network”. [Retrieved on 17.02.2024 from] https://www.ema.europa.eu/en/about-us/how-we-work/european-medicines-regulatory-network)

European Medicines Agency. (2024c). “The European regulatory system for medicines”. [Retrieved on 17.02.2024 from] https://www.ema.europa.eu/en/documents/leaflet/european-regulatory-system-medicines_en.pdf

European Medicines Agency. (2024d). “Compliance: Overview”. [Retrieved on 17.02.2024 from] https://www.ema.europa.eu/en/human-regulatory-overview/compliance-overview

European Union. (2012). Article 288 of the Treaty on the Functioning of the European Union (TFEU) (ex Article 249 TEC). Official Journal of the European Union, C 326.

European Union. (n.a.). European Medicines Agency (EMA), [Retrieved on 23.03.2024 from] https://european-union.europa.eu/institutions-law-budget/institutions-and-bodies/search-all-eu-institutions-and-bodies/european-medicines-agency-ema_en)

Exadaktylos, T., Graziano, P. R., & Vink, M. P. (2020). Europeanization: Concept, Theory, and Methods. In The Member States of the European Union. Oxford University Press. https://doi.org/10.1093/hepl/9780198737391.003.0003

Flockhart, T. (2010). Europeanization or EU-ization? The Transfer of European Norms across Time and Space. Journal of Common Market Studies, 48(4), 787–810. https://doi.org/10.1111/j.1468-5965.2010.02074.x

Gault, F. (2018). Defining and measuring innovation in all sectors of the economy. Research Policy, 47(3), 617–622. https://doi.org/10.1016/j.respol.2018.01.007

Geoghegan-Quinn, M. (2012). From Innovation Emergency to Economic Growth. Innovation Lecture, The Hague, 26.

Heikkinen, I., Eskola, S., Acha, V., Morrison, A., Walker, C., Weil, C., Bril, A., Wegner, M., Metcalfe, T., Chibout, S.-D., & Chlebus, M. (2023). Role of innovation in pharmaceutical regulation: A proposal for principles to evaluate EU General Pharmaceutical Legislation from the innovator perspective. Drug Discovery Today, 28(5), 103526–103526. https://doi.org/10.1016/j.drudis.2023.103526

Hopia, H., Latvala, E., & Liimatainen, L. (2016). Reviewing the methodology of an integrative review. Scandinavian Journal of Caring Sciences, 30(4), 662–669. https://doi.org/10.1111/scs.12327

Howlett, M. (2019). Moving policy implementation theory forward: A multiple streams/critical juncture approach. Public Policy and Administration, 34(4), 405–430. https://doi.org/10.1177/0952076718775791

Interpharma. (n.a.). Agreements between Switzerland and the EU. Retrieved [13.08.2024] from https://www.interpharma.ch/themen/starke-wirtschaftliche-rahmenbedingungen/zugang-zu-exportmaerkten-sichern/institutionelles-rahmenabkommen/?lang=en

Jagun, C. (2018). Strategies for Compliance with Government Regulation in a Pharmaceutical Company. ProQuest Dissertations & Theses.

Kirchhoff, Jasmina. (2022). “Das Branchenportrait. Die pharmazeutische Industrie in Deutschland, Gutachten im Auftrag des Verbands der forschenden Pharma-Unternehmen”. [Retrieved on 10.09.2024] from https://www.iwkoeln.de/studien/jasmina-kirchhoff-die-pharmazeutische-industrie-in-deutschland-1.html

Knill, C., & Lehmkuhl, D. (2002). The national impact of European Union regulatory policy: Three Europeanization mechanisms. European Journal of Political Research, 41(2), 255–280. https://doi.org/10.1111/1475-6765.00012

Listorti, G., Basyte-Ferrari, E., Acs, S., & Smits, P. (2020). Towards an Evidence-Based and Integrated Policy Cycle in the EU: A Review of the Debate on the Better Regulation Agenda. Journal of Common Market Studies, 58(6), 1558–1577. https://doi.org/10.1111/jcms.13053

Luchetta, G. (2013). Antitrust and regulation in the European Union: selected topics.

Mayring, P. (2002). Einführung in die qualitative Sozialforschung (5. Aufl.). Weinheim: Beltz Verlagsgruppe.

Mayring, P. (2010). Qualitative Inhaltsanalyse : Grundlagen und Techniken (11., aktualisierte und überarb. Aufl.). Beltz.

Mazzucato, M. (2018). Mission-oriented research & innovation in the European Union. European Commission, 36.

Mellein, C., & Schwarze, J. (2021). Targeted Review of EU Pharmaceutical Legislation-The Community Code on Medicinal Products Needs to Remain a Directive. EPLR, 5, 4.

Misoch, S. (2019). Qualitative Interviews (2., erweiterte und aktualisierte Auflage). München ; Wien : De Gruyter Oldenbourg.

Nayroles, G., Frybourg, S., Gabriel, S., Kornfeld, Å., Antoñanzas-Villar, F., Espín, J., Jommi, C., Martini, N., de Pouvourville, G., Tolley, K., Wasem, J., & Toumi, M. (2017). Unlocking the potential of established products: toward new incentives rewarding innovation in Europe. Journal of Market Access & Health Policy, 5(1), 1298190–15. https://doi.org/10.1080/20016689.2017.1298190

Organisation for Economic Co-operation Development. (1997). The OECD Report on Regulatory Reform : Synthesis Report (1st ed.). OECD Publishing.

Better regulation and institutional oversight across the European Union. (2019). In Better Regulation Practices across the European Union. OECD Publishing. https://doi.org/10.1787/590a1394-en

Pelkmans, J., & Renda, A. (2014). Does EU regulation hinder or stimulate innovation? CEPS Special Report No. 96, 19 November 2014.

Pharma Deutschland. (2023). “Der Arzneimittelmarkt - Pharmadaten Deutschland 2023”. [Retrieved on 09.09.2024 from] https://www.pharmadeutschland.de/redakteur_filesystem/public/Weitere_oeffentliche_Dateien/202407xx_Pharma_Daten_Deutschland_2023.pdf

Pharmig. (2021). Facts & Figures 2021 - Medicinal Products and Health Care in Austria. [Retrieved on 13.08.2024 from] https://www.pharmig.at/media/4049/pharmig_facts_figures-2021_e.pdf

Pharmig. (2023). “Rund um die Pharmaindustrie”. [Retrieved on 13.08.2024 from] https://www.pharmig.at/pharmaindustrie/rund-um-die-pharmaindustrie/

Pignatti, F., Gravanis, I., Herold, R., Vamvakas, S., Jonsson, B., & Marty, M. (2011). The European medicines agency: An overview of its mission, responsibilities, and recent initiatives in cancer drug regulation. Clinical Cancer Research, 17(16), 5220–5225. https://doi.org/10.1158/1078-0432.CCR-11-0623

Publications Office of the European Union. (2022a). “European Union Regulations”. Eur-Lex. [Retrieved on 12.08.2024 from] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=LEGISSUM:l14522

Publications Office of the European Union. (2022b). “European Union Directives”. Eur-Lex. [Retrieved on 12.08.2024 from] https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=legissum:l14527

Reillon, V. (2016). EU Innovation Policy–Part II: EU policies and instruments supporting innovation.

Rossi, C. L., & McNutt, P. A. (2010). Compliance: an over-looked business strategy. International Journal of Social Economics, 37(10), 816–831. https://doi.org/10.1108/03068291011070471

Russell, C. (2005). An overview of the integrative research review. Progress in Transplantation (Aliso Viejo, Calif.), 15(1), 8–13. https://doi.org/10.7182/prtr.15.1.0n13660r26g725kj

Saltelli, A., Kuc-Czarnecka, M., Piano, S. L., Lőrincz, M. J., Olczyk, M., Puy, A., Reinert, E. S., Smith, S. T., & van der Sluijs, J. P. (2023). Impact assessment culture in the European Union. Time for something new?

Switzerland Global Enterprise. (2020). “Switzerland as a Pharma Hub”. [Retrieved on 13.08.2024 from] https://www.s-ge.com/sites/default/files/publication/free/factsheet-pharma-switzerland-s-ge-en-2020_0.pdf

Tomaszewski, L. E., Zarestky, J., & Gonzalez, E. (2020). Planning Qualitative Research: Design and Decision Making for New Researchers. International Journal of Qualitative Methods, 19. https://doi.org/10.1177/1609406920967174

Torraco, R. J. (2016). Writing Integrative Literature Reviews: Using the Past and Present to Explore the Future. Human Resource Development Review, 15(4), 404–428. https://doi.org/10.1177/1534484316671606

VFA. (03.01.2019). “Germany as a location for pharmaceutical research and development”. [Retrieved on 12.08.2024 from] https://www.vfa.de/de/englische-inhalte/en-amf-standortfaktoren.html

VFA. (18.07.2023). “Stellungnahmen zur Reform des EU-Arzneimittelsrechts”. [Retrieved on 12.08.2024 from] https://www.vfa.de/download/stellungnahme-eu-pharma-paket.pdf

Vogler, S., Paris, V., & Panteli, D. (2018). Ensuring access to medicines: How to redesign pricing, reimbursement and procurement? (p. 30272895). Copenhagen: World Health Organization, Regional Office for Europe.

Yin, R. K. (2018). Case study research and applications : design and methods (Sixth edition). Los Angeles London New Delhi Singapore Washington, DC Melbourne: SAGE.

Appendix

A. Standard questions for semi-structured interviews

1: Regulatory impact on R&D in general

- What is your overall opinion on the influence of EU regulatory frameworks on the pharmaceutical industry?
- What is your experience with EMA?
- General Influence: How has the current framework impacted the pharmaceutical industry?
- Recent Changes: Have recent regulatory changes influenced your R&D activities? Is the new pharmaceutical strategy for Europe going to have an important impact on your company?

2: Strategic Alignment with regulatory requirements

- Strategic Alignment: What strategies does your company employ to align its R&D efforts with EU regulatory requirements?
- How is the intertwining with other EU strategies and initiatives going? Green deal, industry strategy …
- Impact on Efficiency: How has aligning R&D efforts with regulatory requirements impacted your project efficiency and success rates?
- Balancing Compliance and Innovation: How does your company balance the stringend regulatory compliance with the need to innovate?

3: Challenges and Opportunities

- Challenges: What are the main challenges your R&D department faces due to EU pharmaceutical regulations?
- Opportunities: Are there any opportunities presented by the EU regulatory framework that have benefited your R&D activities? If so, which ones?
- Navigation: Can you share any examples of how your company has successfully navigated regulatory challenges?

- Expectation: What are your expectations regarding future EU regulatory changes and their potential impact on R&D?
- Long-Term Impact: What long-term impacts do you anticipate from the new Pharmaceutical Strategy for Europe on your R&D investments (and the legislative proposals)?
- Do you think in general that the European Pharmacy Regulatory Framework is helping the companies, or would it be better to only have national regulations?
- What do you think the EU should change in terms of legislation to create better conditions for innovation and R&D?

B. Quantitative Content Analysis – Codes

Categorie	**Definition**
General Statements	
1.a. General Improvement since 2000	Segments of the content that describe improvements in the pharmaceutical industry due to the regulatory framework implemented since the early 2000s.
1.b. General Awareness and planning for New Pharmaceutical Strategy	Segments of the content that discuss the awareness and preparatory actions of companies regarding the upcoming Pharmaceutical Strategy for Europe.
1.c. General support for more centralized/ decentralized procedures	Segments of the content that examine the industry's support for either more centralized or decentralized regulatory procedures within the EU.
1.d. General Relationship with Authorities	egments of the content that explore the nature of the relationship between pharmaceutical companies and regulatory authorities, including the European Medicines Agency (EMA).
1.e. General Outcome of Compliance of	Segments of the content that address how

efficiency	compliance with regulatory frameworks impacts the efficiency of companies.
1.f. General Expectations and needs for future	Segments of the content that outline the expectations and future needs of pharmaceutical companies regarding regulatory frameworks.
Strategies to cope with requirements	
2.a. SOP and checklists	Segments of the content that describe the use of Standard Operating Procedures (SOPs) and checklists to meet regulatory requirements.
2.b. Good general strategy	Segments of the content that discuss the importance of having a coherent overall strategy aligned with regulatory frameworks.
2.c. Training	Segments of the content that emphasize the role of continuous training programs to keep employees informed about regulatory requirements.
2.d. Communication	Segments of the content that highlight the significance of good internal and external communication in ensuring compliance with regulations.
2.e. Regulatory Affairs Unit	Segments of the content that examine the role of regulatory affairs units in monitoring changes in legislation and ensuring compliance.
2.f. Teams	Segments of the content that describe the formation of specialized teams to handle specific regulatory challenges and requirements.
2.g Alternative Ways	Segments of the content that discuss alternative approaches and solutions when

	standard R&D cannot proceed due to regulatory constraints.
2.h. Strict compliance with reg. framework	Strict Compliance with Regulatory Framework**: Segments of the content that emphasize the necessity of strict adherence to the regulatory framework and its implications.
1. Negative Impact of reg. framework on companies (Challenges)	
3.a. External factors	Segments of the content that address external factors not directly part of the EU regulatory framework but pose challenges to pharmaceutical companies.
3.b. Too rigid and unflexible framework	Segments of the content that describe how a rigid and inflexible regulatory framework hinders innovation and adaptability.
3.c. Not enough streamlining within the system	Segments of the content that highlight the lack of streamlining and coordination within the regulatory system, leading to inefficiencies.
3.d. Administrative Burden	Segments of the content that explore the extensive administrative burden imposed by the regulatory framework.
3.e. Time it takes for approvals	Segments of the content that discuss the lengthy approval processes and their adverse impact on time-to-market for new innovations.
Positive impact of reg. framework on companies (Opportunities)	
4.a. Harmonization	Segments of the content that describe how harmonization of regulations across the EU benefits pharmaceutical companies.
4.b. Digitalization	Segments of the content that discuss the positive impact of digital tools and

	platforms on managing regulatory submissions and compliance.
4.c. Support by authorities	Segments of the content that highlight the supportive role of regulatory authorities and the feedback mechanisms for pharmaceutical companies.
4.d. Strategies to cope with	Segments of the content that explore additional benefits brought about by the regulatory framework, such as incentives for unmet medical needs and rare diseases, and the overall transparency and availability of R&D funds.