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Data-Driven Solutions for Medicine Shortages in the European Union: The Role of Collaborative Governance

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Abbreviations

AMG	Arzneimittelgesetz
API	Active pharmaceutical ingredient
ATC	Anatomical Therapeutic Chemical
B2G	Business-to-government
BMG	Bundesministerium für Gesundheit
EAHP	European Association of Hospital Pharmacists
EMA	European Medicines Agency
ESMP	European Shortages Monitoring Platform
EU	European Union
FMD	Falsified Medicines Directive
MAH	Marketing Authorisation Holder
NCA	National Competent Authority
NESA	National Emergency Supply Agency
PGEU	Pharmaceutical Group of the European Union
PZN	Pharmacy Central Number

1 Introduction

Almost all European Union (EU) Member States are experiencing medicine shortages, as reported by the European Medicines Agency (EMA) in December 2022 (Louloudi et al., 2023). Particularly, the Pharmaceutical Group of the European Union (PGEU) and the European Association of Hospital Pharmacists (EAHP) underline its severity in 2024. Their studies highlight the ongoing and increasingly tense situation regarding medicine shortages in 2023 (EAHP, 2024; PGEU, 2024). Furthermore, European hospitals report that the shortages negatively impact the quality of patient care (Bochenek et al., 2018). The shortages affect all categories of medicines, from commonly used to lifesaving ones (Shukar et al., 2021). Accordingly, Huss et al. (2023, p. 1) describe medicine shortages as a "growing problem for Europe's national health systems". Thus, medicine shortages pose a serious threat to the public health (Shukar et al., 2021). Therefore, this thesis explores how the EU and its Member States address medicine shortages.

The significance of medicine shortages became particularly evident during the COVID-19 pandemic in 2020 when medicine shortages turned into a global concern (Badreldin & Atallah, 2021; Romano et al., 2021). The shortage of critical medicines, such as propofol, a common anaesthetic, was exacerbated by the high number of patients with COVID-19 infections requiring intensive care (Choo & Rajkumar, 2020). Simultaneously, the availability of common medicines, such as painkillers, decreased due to high demand (Romano et al., 2021). Medicine shortages during the COVID-19 pandemic were primarily caused by disruptions in the global supply chain of active pharmaceutical ingredients (APIs) and medicines (Shukar et al., 2021). Consequently, countries that produce APIs, such as India, China, and the United States, implemented export bans, leading to a global shortage of various medicines (Shukar et al., 2021). Furthermore, several other issues, including shortages of packaging materials, transportation disruptions, delivery delays, and delayed customer clearance, limited the import and export of APIs and medicines worldwide (Shukar et al., 2021). Moreover, the situation exacerbated through the reliance on a sole supplier for certain critical ingredients, making the supply chain more vulnerable (Shukar et al., 2021).

Despite the end of the pandemic, medicine shortages remain a significant challenge. The reasons for medicine shortages are diverse and multifaceted. They can be broadly categorised into issues related to supply, demand, and regulatory factors (Shukar et al., 2021). Acosta et al. (2019) provide a more detailed classification, identifying the most frequent causes of medicine shortages within four key categories: market dynamics, supply chain management, manufacturing issues, and political factors.

To ensure public health and safety, the public sector enforces strict regulations within the pharmaceutical industry (Handoo et al., 2012). National governments fulfil their duty to protect citizens through National Competent Authorities (NCAs), which enforce and monitor stringent guidelines for quality assurance and medicine regulation (Handoo et al., 2012). Medicine shortages significantly affect the capacity of national healthcare systems to maintain continuity of health care (Musazzi et al., 2020). Consequently, these regulatory bodies are also responsible for maintaining the integrity and safety of the medicine supply chain.

The experiences from the COVID-19 pandemic highlight the urgency of better preparedness for public health emergencies and medicine shortages (Assefa et al., 2022). Specifically, the pandemic has shown that the medicine shortages can significantly disrupt the continuity of care in national healthcare systems, emphasising the importance of effective public sector measures (Musazzi et al., 2020). Moreover, the pandemic has shown the far-reaching impact of medicine shortages on a global scale (Badreldin & Atallah, 2021).

While many medicine shortages are managed and resolved at the national level, certain critical shortages, require coordinated action at the European level with the close involvement of the EMA and Member States (European Commission, n.d.-a). The European Commission emphasises that “everyone must have timely and equal access to critical medicine”, identifying the mitigation of medicine shortages and the strengthening of supply security as key policy priorities (European Commission, n.d.-a).

Accordingly, the European Parliament enacted Regulation (EU) 2022/123, which enhances the EMA’s role in crisis preparedness and management for medicines and medical devices. As part of this regulation, the EMA is developing the European Shortages Monitoring Platform (ESMP), which will be implemented by February 2025 (Ferreira, n.d.). The ESMP focuses on information sharing about medicine supply and demand as a tool to prevent, detect, and manage medicine shortages within the EU (Regulation (EU) 2022/123). Although the majority of Member States have already implemented national registers of medicine shortages, the EMA aims to establish a single, standardised database to streamline and enhance data harmonisation across the EU (EMA, n.d.). Moreover, the regulation imposes a legal obligation on marketing authorisation holders (MAHs) to report information on critical medicines at the request of the EMA (Regulation (EU) 2022/123). In addition, the European Commission is working on a reform of the EU pharmaceutical legislation (European Commission, n.d.-b).

1.1 Research Problem

Despite the regulatory efforts of the EU, certain NCAs report significant challenges in effectively managing medicine shortages (Experts, personal communication, June 28, 2023). A primary challenge faced by NCAs is the lack of transparency and insufficient data sharing from the private sector regarding these shortages (Experts, personal communication, June 28, 2023). The Experts are involved in the EU-co-funded CHESSMEN (Coordination and Harmonisation of the Existing Systems against Shortages of Medicines – European Network) project that aims to harmonise operational processes across Member States to reduce the risk of medicine shortages (Fimea, 2023). The legal mandate requiring MAHs to notify NCAs of incoming shortages results in an excessive oversharing of data, as reported in Sweden (Kleja, 2023). This over-reporting is driven by concerns over substantial penalties for failing to submit the required data on time (Kleja, 2023). As a result, huge amounts of data are shared including data on medicines that do not result in shortages (Kleja, 2023).

The study by Shusha et al. (2022) highlights the private sector's reluctance to share data with the public sector. Shusha et al. (2022, p. 1) conclude that "while there is a strong push from the public sector for more private sector data, the private sector is less enthusiastic about (…) mandatory B2G [business-to-government] data sharing". However, it appears that the resistance of the private sector is lower regarding emergencies (Susha et al., 2022).

Legislative mandates requiring the industry to share data with the NCAs appear to be inadequate for effectively addressing medicine shortages. Instead, scholars argue that addressing the challenge of medicine shortages requires a focused and dedicated collaboration among relevant stakeholders (Bochenek et al., 2018). Efficient communication between stakeholders at both national and international levels is crucial for the management of medicine shortages (De Weerdt et al., 2017). Proactive and effective communication strategies can mitigate the impacts of these shortages (De Weerdt et al., 2017; Shukar et al., 2021). Alongside this, harmonisation and openness among all involved parties are necessary to support these efforts (Shukar et al., 2021).

1.2 Research Gap

Although the critical role of collaboration and communication in managing medicine shortages is recognised (AlAzmi & AlRashidi, 2019; De Weerdt et al., 2017; Dill & Ahn, 2014; Jovanović Lješković et al., 2021; Musazzi et al., 2020), there remains a significant gap in the literature concerning the effective implementation of public-private collaboration to address these shortages Current regulatory instruments of the EU and its

Member States mandate data sharing. However, these initiatives often meet resistance from the private sector, resulting in an overload of data that fails to improve the quality of information on medicine shortages.

This resistance underscores the need to explore alternative methods that the public sector can implement to enhance information sharing on medicine shortages. Scholars argue that effective collaboration could mitigate medicine shortages, but there is a lack of clarity on how this can be achieved in practice. While existing research on collaborative efforts predominantly focuses on healthcare institutions and professionals (Chen et al., 2021; Clark et al., 2020; Zovi et al., 2021), the role of governmental entities is less explored. This indicates a potential area for further research into how collaboration could enhance current governmental strategies to address medicine shortages.

Collaboration between organisations and information sharing to address common challenges has long been explored in the literature and administrative practice (Susha & Gil-Garcia, 2019). However, Susha and Gil-Garcia (2019) identify a significant research gap regarding the impact of increased data availability on collaborative efforts, particularly in addressing complex and urgent social issues requiring joint action. Reflecting the problem outlined at the beginning of this thesis, the private sector's reluctance to share data (Susha et al., 2022) suggests the need for targeted research to better understand and utilise data-driven opportunities effectively.

This thesis adopts a qualitative approach to address the research gap concerning public-private collaboration as an instrument to effectively manage medicine shortages. Specifically, it focuses on assessing the receptivity and effectiveness of existing collaborative strategies among various stakeholders, with an emphasis on the role of the private sector. Through an in-depth examination of public-private collaboration and data-sharing practices to address medicine shortages, this thesis highlights key factors to enhance public-private collaboration. By exploring these aspects, this thesis does not aim to directly solve the problem of medicine shortages. Instead, it offers perspectives on how to address the issue through enhanced public-private collaboration.

1.3 Research Questions

In response to the urgent need for collaboration in mitigating the challenge of medicine shortages, and given the reluctance of the private sector, the thesis aims to investigate the following research questions:

RQ: How can public-private collaboration be enhanced to facilitate information sharing about medicine shortages within the European Union?

Sub-RQ1: How do different EU Member States and EU-level initiatives approach public-private collaboration and information sharing to address medicine shortages?

Sub-RQ2: What are the key factors influencing effective public-private collaboration and information sharing in mitigating medicine shortages?

To address the research questions, a comprehensive literature review is conducted. The literature review aims to collect relevant literature to explain the main concepts of medicine shortages, information sharing and collaboration. Subsequently, an in-depth analysis through semi-structured interviews is carried out. The objective is to identify the key factors that enhance public-private collaboration to gain deeper insights into the processes of information sharing among public and private stakeholders. In addition, the following sections outline the theoretical framework of Data Collaborative Governance and the qualitative methodology employed in this thesis.

This thesis investigates the approaches of different EU Member States and EU-level initiatives in fostering public-private collaboration and information sharing to address medicine shortages. Specifically, it examines the national strategies employed by Italy, Germany, and Finland, as well as the overarching EU initiatives like the European Shortages Monitoring Platform (ESMP) and the Joint Action CHESSMEN. Furthermore, key factors of public-private collaboration are identified through semi-structured interviews. These factors include shared understanding, trust, mutual recognition, stakeholder engagement, data handling, perceived impact, motivation, root cause analysis, and external communication, and are analysed to provide a comprehensive view of the issue.

However, this thesis does not encompass all initiatives focusing on medicine shortages, either at the national or EU level. While it offers insights into the collaborative efforts within the EU, it does not provide a holistic evaluation of all possible factors influencing medicine shortages. Instead, it presents a selection based on the findings from the conducted interviews. The analysis is limited to publicly available data, academic literature, expert interviews from selected countries and EU initiatives. Due to the uneven distribution of experts, this is not a comprehensive case study of collaborations. In Italy, qualitative evidence is collected from private sector participants in the national collaboration, while evidence from Germany and Finland, includes participants from NCAs leading the public-private collaborations. In Germany, this perspective is expanded by the inclusion of external experts from the private sector. However, there is a lack of evidence from private sector experts from Finland. Accordingly, this thesis cannot be considered a comprehensive case study of the different collaboration approaches.

Additionally, the list of stakeholders involved is extensive and cannot be fully covered in this thesis. The scope of the 'private sector' is limited to the pharmaceutical industry and pharmacies. Other stakeholders, such as wholesalers or health insurance companies, are not considered. The public sector in this thesis is mainly limited to regulatory authorities such as NCAs and the EMA. Nevertheless, certain key factors can be drawn from this thesis to enhance public-private collaboration.

Firstly, the thesis continues with a comprehensive literature review in Section 2. This section examines the existing literature on medicine shortages in the EU. It explores the causes and potential strategies to address these shortages, the role of data and information sharing, and the concept of collaboration. Secondly, Section 3 presents the theoretical framework of Data Collaborative Governance, providing a basis for analysing the public-private collaboration in addressing medicine shortages. Following this, Section 4 details the methodology, describing the research design, data collection methods, data analysis and its limitations. Next, Section 5 presents the results. It includes an examination of national collaborations in Italy, Germany, and Finland, highlighting each country's approach to address medicine shortages. Furthermore, EU-level initiatives such as the ESMP and the Joint Action CHESSMEN are presented. Additionally, it outlines key factors of public-private collaboration to address medicine shortages, including shared understanding, trust, mutual recognition, genuine stakeholder engagement, trust in data handling, perceived impact, motivation, root cause analysis, and external communication. In Section 6, the discussion interprets the results in the context of the research questions, theoretical framework, and existing literature. It highlights the implications for managing medicine shortages and the limitations of public-private collaboration. Finally, Section 7 concludes the thesis by summarising the key findings and offering suggestions for future research.

2 Literature Review

The literature review explores the multifaceted issue of medicine shortages within the EU. It explores the diverse causes contributing to this challenge, assesses the existing governmental strategies aimed at mitigating its impact, and evaluates the role of collaborative governance in effectively addressing these shortages. This literature review aims to provide a thorough understanding of the current landscape and identify relevant theories and frameworks (Mertens, 2010).

Section 2.1 introduces the issue by outlining the scale and impact of medicine shortages, drawing insights from the survey of the PGEU and EAHP. Furthermore, the underlying factors contributing to these shortages, such as production interruptions, regulatory challenges, and demand fluctuations are discussed. Section 2.2 considers governmental strategies that address these shortages, emphasising the need for advanced forecasting systems, regulatory reforms, and enhanced stakeholder collaboration. In Section 2.3, the critical role of data and information sharing is examined, particularly how these practices are supported or hindered by current EU legislative frameworks. Finally, Section 2.4 discusses the concept of collaboration in resolving complex health issues, exploring different collaborative models and their effectiveness.

The literature review is conducted through a systematic search of academic databases, including PubMed, Scopus, and Google Scholar, as well as grey literature from relevant industry reports and organisational publications. Key search terms include “medicine shortages” or “drug shortages”, “EU”, “collaborative governance”, “public-private collaboration”, “data sharing”, and “information sharing”. The search is confined to publications from the last decade to ensure contemporary relevance. Additionally, references from identified articles are reviewed to uncover further pertinent studies. Only literature that is open access or available through the libraries of KU Leuven, the University of Münster, or TalTech is considered. The selected literature is then categorised based on themes such as causes of shortages, mitigation strategies, and collaborative efforts. This methodical approach ensures a comprehensive and balanced overview of the topic.

2.1 Current Situation of Medicine Shortages in the European Union

The annual survey conducted by the PGEU, which represents community pharmacists at the European level, highlights the increasing difficulties posed by medicine shortages across numerous countries in 2023 (PGEU, 2024). The PGEU survey, designed to assess the current situation of medicine shortages from the perspective of European pharmacies, collected responses from 26 member countries. The findings of the 2023 survey highlight

persistent and worsening challenges across the majority of member countries compared to the previous year. Figure 1 shows the result of the PGEU 2023 report, where member countries evaluated the medicine shortages situation in comparison to the previous 12 months. The situation in 2023 worsened in 17 out of the 26 responding countries, accounting for 65% of the total. In six countries, constituting 23% of the respondents, the situation remained the same. Only three countries, Cyprus, Greece, and North Macedonia, recorded improvements compared to the preceding year (PGEU, 2024, p. 4).

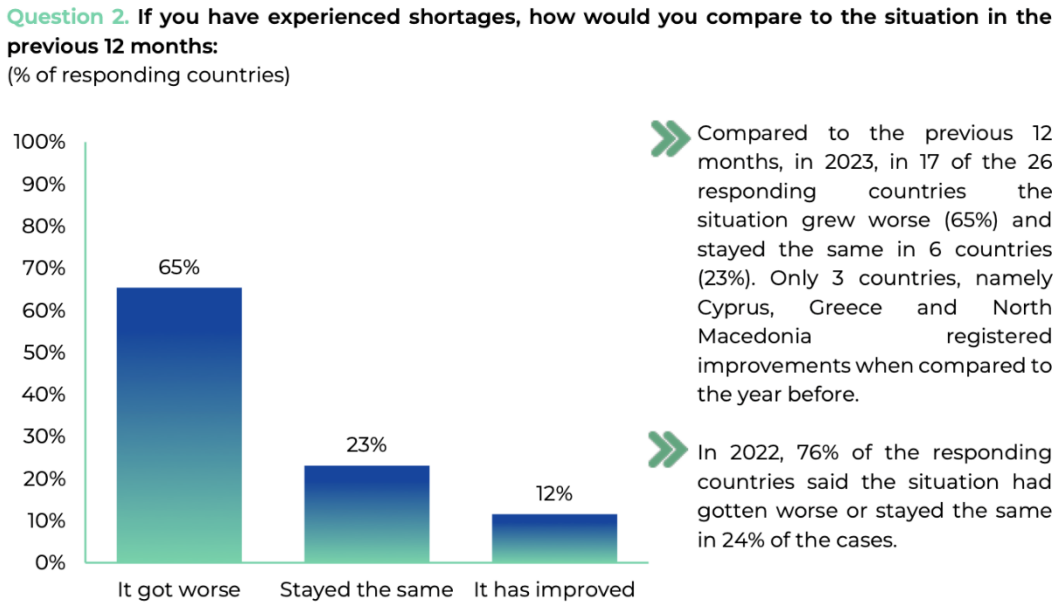


Figure 1 Survey Data on Medicine Shortages: Country Responses to Changes in Medicine Shortages Over 12 Months. Source: PGEU, 2024.

Greece reports improvements in its medicine supply situation in 2023 due to new government regulations and an increase in local production for national distribution (PGEU, 2024). In a subsequent question regarding the expansion of the legal scope of pharmacy practice to address shortages, Greece emphasises the enforcement of a regulation that temporarily prohibits the export of critical medicines during periods of shortages. North Macedonia notes better forecasting and supply of medicines compared to 2022, attributed to enhanced organisation and improved management along the supply chain (PGEU, 2024).

According to the PGEU 2023 report, Spain, the Netherlands, Ireland, and Sweden have reported an increase in medicine shortages. However, Sweden mentions that it is “due to increased reporting from pharmaceutical companies” (PGEU, 2024, p. 5). Specifically, Ireland has expressed concerns that its pharmacists are not sufficiently warned in advance about these shortages (PGEU, 2024).

Furthermore, the PGEU 2023 report requested information on the number of medicines that are short in supply. The findings, illustrated in Figure 2, are categorised by the number of medicines short in supply, ranging from 50-100 to over 600. Additionally, there is a category for respondents who were uncertain about the extent of the shortages. A small fraction (4%) reported shortages of 50-100 medicines, while 8% of countries reported 100-200 medicines short in supply. The percentages remains consistent at 12% for both the 200-300 and 300-400 medicine shortage categories. A notable decrease is observed in the 400-500 category, where only 8% of countries reported shortages. However, the highest reported shortages are in the category of over 600 medicines, with 27% of countries indicating such extensive shortages. Concurrently, 15% of the respondents were unsure of the number of medicines short in supply. This distribution suggests a significant variation in the medicine shortage severity, with a substantial proportion of countries experiencing high levels of shortages.

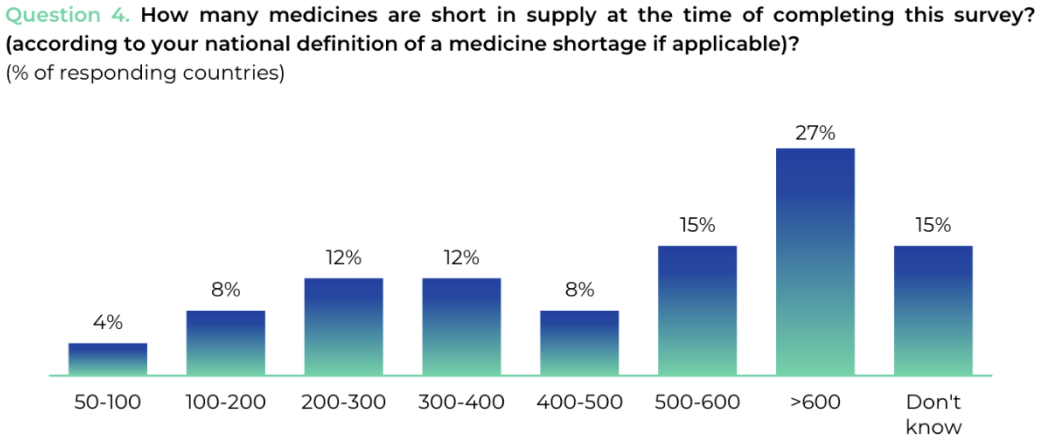


Figure 2 Survey Data on Medicine Shortages: Percentages of Countries by Number of Medicines in Short Supply. Source: PGEU, 2024.

Pharmacists report that the primary causes of medicine shortages are the suspension or interruption of production processes (65%), national pricing and procurement strategies, such as tendering policies (62%), and sudden or significant increases in demand for medicines (50%). Less significant but still notable causes of medicine shortages include quotas imposed by manufacturers (31%), inefficiencies in the logistics supply chain (27%), market withdrawals (27%), and parallel exports from the country (23%). These findings reflect the multifaceted nature of the medicine shortage, which identifies both supply-side disruptions and political factors as the main causes of the problem (Acosta et al., 2019; Shukar et al., 2021).

The EAHP Shortage Survey 2023 draws comparable conclusions within the hospital sector (EAHP, 2024). The EAHP represents hospital pharmacists at both European and international levels, with over 27,000 members across 36 European countries. In the survey, 1497 hospital pharmacists from all 36 member countries participated, along with other healthcare professionals, including nurses, physicians, and patients and their carers (EAHP, 2024). The results confirm a growing shortage of medicines in Europe, which poses a threat to public health (Miljković et al., 2024). According to the survey, the main causes of this shortage are a global shortage of active pharmaceutical ingredients (APIs), manufacturing and supply chain issues, and regulatory challenges (Miljković et al., 2024).

The causes reported in the PGEU 2023 report and the EAHP Shortages Survey 2023 are consistent with a strain of literature on medicine shortages. The reasons for medicine shortages are diverse and multifaceted, yet they can be broadly categorised into issues related to supply, demand, and regulatory factors (Shukar et al., 2021). According to Shukar et al. (2021), supply issues arise when manufacturers cannot or choose not to meet the demand for medicines. These issues encompass manufacturing difficulties, shortage of raw materials, logistical challenges within the supply chain and economic factors. Economic factors include insufficient profit margins or small market sizes, increased costs of raw materials, capacity limitations, and logistical challenges. Demand-related issues that contribute to medicine shortages include just-in-time inventory practices, increased marketing efforts, and fluctuations in demand due to average growth, outbreaks, epidemics, and seasonal variations (Shukar et al., 2021). While some demand-related issues can be predicted and managed through effective systems, others such as epidemics and unforeseen disasters are less predictable and more difficult to manage.

In addition, regulatory factors significantly contribute to medicine shortages. Shukar et al. (2021) highlight that changes in government guidelines for medicine use or therapy management can affect supply and demand dynamics, resulting in shortages. For instance, the EU's Falsified Medicines Directive (FMD), while effective in preventing the distribution of counterfeit and low-quality medicines, has led to temporary shortages as the system needs time to adjusts to the new standards (Shukar et al., 2021). Furthermore, regulatory authorities face the primary challenge of the absence of a uniform definition of medicine shortages (Bochenek et al., 2018; De Weerdt et al., 2015, 2017; Mulcahy et al., 2021; Musazzi et al., 2020; Shukar et al., 2021; Vassal et al., 2021). In their study, De Weerdt et al. (2015) identified a total of 26 different definitions of medicine shortages, distinguishing between general and reporting definitions. The definitions originate from different legislations, governmental and professional organisations, and scientific articles (De Weerdt et al., 2015). The lack of a uniform definition leads to gaps in the assessment of the severity of the problem and affects mitigation strategies. The European

Commission attempts to address this issue by defining a medicine shortage as a situation where “the supply of a medicine does not meet the demand for that medicine” (European Commission, n.d.-a).

Acosta et al. (2019, pp. 7–8) offer a more detailed classification, breaking down the most frequent causes of medicine shortages into four key categories: market dynamics, supply chain management, manufacturing issues, and political factors. Market dynamics encompass increases in sales, pricing issues, voluntary product withdrawal, unexpected demand changes, parallel or grey market activities, loss of market interest, production relocation, speculation in international markets, and mergers of manufacturing entities. Supply chain management involves structural issues within the country's supply chain and the availability of raw materials and excipients contributing to shortages. Manufacturing processes are affected by quality issues, alterations in product formulations, industrial development capacities, and general production challenges. Lastly, political and ethical issues, including regulatory barriers, public policy decisions, societal conflicts, and adjustments in the legal and normative frameworks for medicine manufacturing, are significant contributors to the shortage of medicines.

These findings indicate that medicine shortages result from a complex interplay of various factors. Each category represents a critical area where disruptions or changes can significantly affect medicine availability. According to the PGEU, the increasing burden of medicine shortages negatively impacts both patients and pharmacies, eroding trust in the pharmaceutical supply chain (PGEU, 2024). Accordingly, comprehensive strategies are needed to mitigate medicine shortages and improve the resilience of the pharmaceutical supply chain across Europe. The next section examines strategies proposed in the literature to address these medicine shortages.

2.2 Strategies to Address Medicine Shortages

The literature on medicine shortages not only explores the causes but also provides recommendations and suggestions for addressing them. Proposed technical interventions include the establishment of early warning systems (Badreldin & Atallah, 2021) and the adoption of algorithms for assessing the impact of medicine shortages on clinical demand across European countries (Musazzi et al., 2020). Moreover, there are recommendations for strengthening legislative and regulatory frameworks by establishing early notification requirements and standardising the reporting procedures for medicine shortages (De Weerdt et al., 2017; Vassal et al., 2021). To implement these strategies effectively, scholars emphasise the importance of collaboration and communication among all relevant stakeholders (Bogaert et al., 2015; De Weerdt et al., 2017; Miljković et al., 2020; Musazzi et al., 2020; Shukar et al., 2021).

Addressing medicine shortages is a complex challenge due to the involvement of various stakeholders and the significant variation in the causes (Acosta et al., 2019; Gray & Manasse, 2012). Bochenek et al. (2018) emphasise the necessity to establish a structured and coordinated collaboration among stakeholders, irrespective of the cause. Furthermore, effectively addressing medicine shortages involves enhanced monitoring (Badreldin & Atallah, 2021; Miljković et al., 2020; Musazzi et al., 2020). Key organisational requirements for improved monitoring include a shared understanding of the problem through a common definition (De Weerdt et al., 2015) as well as increased collaboration among stakeholders involved (Bochenek et al., 2018). Researchers emphasise the critical role of information sharing in enhancing monitoring, promoting transparency, and providing a more comprehensive overview (Bade et al., 2023; Dill & Ahn, 2014; Miljković et al., 2020). This collaborative effort demands active participation from all stakeholders, who should contribute their knowledge and information to better address the complexities of medicine shortages (Dill & Ahn, 2014).

Effective management of medicine shortages requires collaboration among various stakeholders, including policymakers, manufacturers, healthcare providers, and regulatory agencies (Badreldin & Atallah, 2021; Dill & Ahn, 2014). According to De Weerdt et al. (2017), policy measures must be formulated in partnership with all relevant stakeholders to ensure they are effective and supported by thorough research. Dill & Ahn (2014) emphasise the potential benefits of strong communication channels and sustained collaboration throughout the medicine supply chain. This involves sharing information on alternative medicine supplies at an international level and adapting regulatory frameworks to address shortages more promptly. Furthermore, Dill & Ahn (2014) highlight the value of proactive strategies over reactive ones to effectively manage medicine shortages. Additionally, the authors emphasise the role of international collaboration among regulatory authorities, given the global concern of medicine shortages. This approach could facilitate a deeper understanding of the causes, enhance prevention strategies, and foster the establishment of partnerships for effective information sharing (Dill & Ahn, 2014). Accordingly, AlAzmi & AlRashidi (2019) advocate for the creation of new communication platforms that enhance the efficiency of information exchange. Jovanović Lješković et al. (2021) suggest that improving the transparency and organisation of communications among stakeholders, through the integration of data from various sources, can improve the anticipation and management of potential medicine shortages. Musazzi et al. (2020) recommend that regulators closely coordinate with all stakeholders when modifying information sharing or reporting requirements to fully consider the potential impacts on the medicine supply chain. Overall, scholars emphasise the importance of a proactive, collaborative, and strategic approach for effectively addressing the complexities of medicine shortages.

While there is a consensus on the necessity of collaboration and improved sharing of data and information, methods for implementing these strategies remain undefined. Before exploring existing collaborative approaches, the following section discusses the role of data and information sharing between the public and private sectors as a strategy to address medicine shortages.

2.3 The Role of Data and Information Sharing

To address medicine shortages, the public sector is promoting data and information sharing with the private sector. In this context, the terms 'data sharing' and 'information sharing' are often used interchangeably. Particularly, in the interactions between the private and public sectors, the concept of B2G data sharing, is frequently referenced (European Commission, 2022; Susha et al., 2022). However, differences can be identified.

To clarify these terms, Bellinger et al. (2004) differentiate between data, information, and knowledge. Data is described as raw and unprocessed, representing isolated facts. Information, on the other hand, reflects organised and processed data to give it meaning. Knowledge is the accumulation of information. However, Bellinger et al. (2004) note that knowledge alone does not enable integration from which further knowledge can be derived. To summarise, data sharing refers to the exchange of raw facts, whereas information sharing involves the communication of processed and meaningful insights derived from data. However, definitions of information sharing also focus on the exchange of data. Praditya & Janssen (2015, p. 247) describe information sharing as "exchanging or giving other involved users access to explicit data in any forms through ICT system."

Scholars argue that information sharing enhances transparency and enables earlier notifications on medicine shortages (Bade et al., 2023; Dill & Ahn, 2014; Miljković et al., 2020). Thus far, the primary mechanism for promoting information sharing at both the national and EU levels is legislation, specifically EU regulations and their implementation into national laws. Regulation (EU) 2022/123, requires MAHs to share their available stock information with the EMA. Furthermore, most European countries have implemented national regulations requiring MAHs to report medicine shortages with the NCAs (Vogler, 2024). For instance, in Sweden, pharmaceutical companies must inform the NCA of potential shortages at least two months in advance (Kleja, 2023). However, this requirement has not been adequately followed, prompting Sweden to consider imposing high fines for non-compliance. Critics warn that over-reporting could occur as companies seek to minimize the risk of fines (Kleja, 2023). Consequently, the regulation's measures appear insufficient to address medicine shortages more effectively.

The European Commission has noted that current incentives are inadequate to encourage companies to share data with the public sector for the common good (European Commission, 2022).

Information sharing is a key element of collaboration (Thomson & Perry, 2006). However, it is not the key to success: “Without mutual benefits, information sharing will not lead to collaboration” (Thomson & Perry, 2006, p. 27). Although information sharing can help address medicine shortages, it is not sufficient on its own. A collaborative approach that benefits all stakeholders involved is necessary. Therefore, the next section explores the concept of collaboration.

2.4 The Concept of Collaboration

The issue of medicine shortages is complex, involving a wide array of stakeholders across multiple levels. These stakeholders include European organisations, national competent authorities, pharmaceutical companies, healthcare providers, and the public. Given the multidimensional nature of medicine shortages, scholars argue that collaboration can lead to more effective policy measures (Badreldin & Atallah, 2021; De Weerdt et al., 2017; Dill & Ahn, 2014). Collaboration emphasises the importance of involving diverse stakeholders and integrating their various perspectives and resources in the policymaking process (McNamara, 2012). This section explores the concept of collaboration and its necessity in the context of medicine shortages. The selection of this concept is based on a comprehensive review of existing literature, highlighting its significance in addressing the complex issue of medicine shortages.

To provide a clear understanding, it is essential to distinguish collaboration from similar concepts such as cooperation and coordination. According to McNamara (2012, p. 391), collaboration is “an interaction between participants who work together to pursue complex goals based on shared interests and a collective responsibility for interconnected tasks which cannot be accomplished individually”. Compared to cooperation and coordination, it involves much closer relationships, shared connections, and resources (Castañer & Oliveira, 2020; McNamara, 2012). A detailed comparison of these three concepts is provided in Table 1. This comparison highlights several key differences in collaboration, including the importance of trust, shared power arrangements, open and frequent communication, and participative decision-making.

Element	Cooperation	Coordination	Collaboration
Design	Work within existing organizational structures	Centralized control through hierarchical structures	Shared power arrangements
Formality of the Agreement	Informal agreement	Formalized agreements	Informal and formal agreements
Organizational Autonomy	Fully autonomous; policies to govern the collective arrangement are not developed	Semi-autonomous; policies to govern the collective arrangement may be developed by higher authorities	Not autonomous; policies to govern the collective arrangement are developed jointly by participants
Key Personnel	Implementation of the partnership occurs at the lowest levels; leaders are not involved	Implementation of the partnership is based on a higher authority; a boundary spanner may be used to foster linkages	Implementation of the partnership is based on the participants; a convener may help bring participants together
Information Sharing	Basic information shared through informal channels	Information is exchanged through more formal channels	Open and frequent communications through formal and informal channels
Decision Making	Independent decision making	Centralized decision making	Participative decision making
Resolution of Turf Issues	Conflicts avoided through independence	A neutral facilitator may help resolve conflicts	Participants work together to resolve conflicts
Resource Allocation	Information is exchanged	Physical and nonphysical resources are exchanged to achieve individual goals	Physical and nonphysical resources are pooled in support of collective goals
Systems Thinking	System integration does not occur	System integration may occur to better achieve individual goals	System integration does occur to better achieve collective goals
Trust	Trust relationships are not required but may develop	Leaders work closely to create relationships based on trust	Trust between participants is needed to sustain relationships

Table 1 Elements Distinguishing among Cooperation, Coordination, and Collaboration. Source: McNamara, 2012.

The existing literature and government practices have explored inter-organisational collaboration and information sharing to address complex challenges (Susha & Gil-Garcia, 2019). Collaboration in public administration can take various forms, as outlined by Bianchi et al. (2021): collaborative governance, new public governance, policy networks, network governance, cross-sector collaboration, public value governance, participatory governance, holistic governance, integrated governance, and interactive governance. Although they address different aspects in detail, all these forms emphasise multi-actor collaboration. Typically initiated by public sector organisations, collaboration aims to foster consensus among stakeholders to formulate and implement policies that create public value.

This thesis focuses on collaborative governance due to its broad and well-established framework in public administration and policy analysis (Ansell & Gash, 2008; Bryson et al., 2015; Emerson et al., 2012; Provan & Kenis, 2007). Collaborative governance is particularly suitable for assessing the varied collaborative efforts aimed at addressing medicine shortages. Rather than concentrating on a specific form of collaboration, this approach facilitates a more comprehensive analysis of the general collaborative landscape within the context of medicine shortages. Furthermore, the concept of collaborative governance is expanded to include data collaborative governance, which incorporates elements of data processing and sharing (Klievink et al., 2018; Ruijer, 2021; Susha & Gil-Garcia, 2019). Data collaborative governance is particularly significant in understanding how data integration influences collaborative strategies to address medicine shortages.

Another perspective is obtained by examination of Public-Private Partnerships (PPP), as this concept is increasingly gaining attention in both research and policy. However, Ansell & Gash (2008) argue that although PPPs require collaboration to function, they primarily focus on coordination rather than achieving consensus in decision-making, unlike collaborative governance. The authors define collaborative governance as "a governing arrangement where one or more public agencies directly engage non-state stakeholders in a collective decision-making process that is formal, consensus-oriented, and deliberative and that aims to make or implement public policy or manage public programs or assets" (Ansell & Gash, 2008, p. 544). Following this definition Ansell & Gash define six criteria:

> *"(1) the forum is initiated by public agencies or institutions, (2) participants in the forum include nonstate actors, (3) participants engage directly in decision making and are not merely ''consulted'' by public agencies, (4) the forum is formally organized and meets collectively, (5) the forum aims to make decisions by consensus (even if consensus is not achieved in practice), and (6) the focus of collaboration is on public policy or public management." (Ansell & Gash, 2008, pp. 544–545)*

The COVID-19 pandemic highlighted the potential for effective public-private collaboration in the health sector. The partnership between the multinational pharmaceutical and biotechnology company AstraZeneca and universities in the UK played a crucial role in effectively managing the pandemic by contributing to the development of a vaccine (Rezaei & Kamali, 2022). Furthermore, aggregated mobility data was shared to aid research into the spread of COVID-19 (Oliver et al., 2020). This underscores the importance of collaboration and data sharing across sectors in solving complex public problems. It is evident that data generated by businesses holds significant value in addressing public issues. This is the primary focus of data collaboratives, which specifically aim to tackle public problems through collaborative data sharing (Ruijer, 2021; Susha et al., 2017; Verhulst et al., n.d.). For instance, the Data4COVID19 initiative is a network that comprises over 300 data collaboratives, which have been established to address the pandemic, according to The GovLab (2020).

By incorporating these concepts, this thesis aims to provide a comprehensive analysis of public-private collaboration strategies and their effectiveness in addressing medicine shortages, thereby answering the research questions. The growing importance of data in addressing complex public issues highlights the necessity of understanding how data sharing and integration can influence public-private collaboration. Accordingly, the Data Collaborative Governance by Ruijer (2021) will serve as the theoretical framework for

this thesis. Therefore, its elements will be discussed in further detail in the following section.

3 Theoretical Framework

The theoretical framework for this thesis is based on the concept of Data Collaborative Governance, which integrates established theories of collaborative governance with data-sharing practices (Klievink et al., 2018; Ruijer, 2021; Susha & Gil-Garcia, 2019). Notably, while extensive research exists on collaborative governance and information sharing, these studies do not address how data inclusion can change collaboration dynamics. Therefore, Data Collaborative Governance highlights how data integration reshapes collaboration among public agencies, private entities, and civic organizations. Consequently, the framework introduces new dimensions to collaborative governance through the use of data sharing. Given the current EU regulations that promote data sharing to address medicine shortages, the application of this framework is particularly relevant for this thesis.

According to Ruijer (2021), data collaboratives introduce additional socio-technical complexities into collaboration processes, making it essential to reevaluate traditional governance models to address these new challenges. Effectively, the Data Collaborative Governance framework merges the principles of collaborative governance with the dynamic realm of data sharing. Thus, it provides a robust analytical tool to explore the evolving landscape of data collaboratives. Data collaboratives aim to address complex public issues through data sharing across various sectors (Verhulst et al., n.d.). This innovative approach leverages collaborative efforts to share and analyse data, enhancing decision-making processes and policy development to address societal challenges (Klievink et al., 2018; Ruijer, 2021; Verhulst et al., n.d.).

Consequently, the concept of data collaboratives appears well-suited to address the issue of medicine shortages. However, the collaborations analysed in this thesis are not estbalished data collaboratives. Given the growing importance of data sharing in regulations designed to address medicine shortages, Data Collaborative Governance remains a suitable framework. Consequently, this thesis utilises ideas, elements, and challenges from the Data Collaborative Governance framework to understnad the role of data sharing in collaborations. The framework supports investigating how public-private sector collaboration can be enhanced, examining current approaches by EU Member States and initiatives, and identifying key factors influencing effective collaboration. The framework of Data Collaborative Governance will be elaborated in the following section.

The literature on collaborative governance presents multiple frameworks (Ansell & Gash, 2008; Emerson et al., 2012; Provan & Kenis, 2007). While these frameworks provide valuable concepts for understanding collaborative governance, they do not specifically address the role of technology. Ruijer (2021) employs the collaborative governance

framework developed by Bryson et al. (2015). Bryson et al. (2015) place governance and technology at the core of their framework while also integrating the key elements from various collaborative governance frameworks (Ansell & Gash, 2008; Emerson et al., 2012; Provan & Kenis, 2007). These elements include the (external) institutional environment, (internal) initial conditions and drivers, collaborative structures, processes, leadership, outcomes, and tensions. Ruijer (2021) extends this model by incorporating the dimension of data, thereby enhancing the framework's applicability to scenarios where data plays a critical role in governance processes. The Data Collaborative Governance framework aims to address the challenges of data collaboratives including "legal barriers, silos, proprietary nature of data, fear of misuse as well as privacy, ethical, and fairness issues" (Ruijer, 2021).

Extending the collaborative governance definition by Emerson et al. (2012), Ruijer (2021, p. 2) defines Data Collaborative Governance "as the processes and structures of decision-making and management that engage people constructively in data-driven activities across the boundaries of public agencies, levels of government, and/or the public, private and civic spheres for a societal purpose that could not otherwise be accomplished." Accordingly, Data Collaborative Governance refers to a governance structure that focuses on collaborative efforts centered around data. It emphasises decision-making processes and management structures that are influenced by data and involve various stakeholders. Therefore, various sectors such as government agencies, private businesses, and civic organisations, as well as different levels of government (local, regional, national) are being included. Such collaborations often address complex problems that are beyond the scope of any single entity.

The framework, illustrated in Figure 3, identifies three key factors influencing the structure and process of data collaboratives. Ruijer (2021) acknowledges that initial conditions and shared motivations significantly affect the collaborative's structure and process, with leadership and tensions acting as additional influential factor. The 'structure' refers to the norms, rules, and practices of engagement, while the 'process' involves trust, communication, a shared understanding of the problem, and the actual usage of data. The outcome of the data collaborative is based on these three factors. Furthermore, the incorporation of technology as an integral part of the collaborative data process is emphasised. The following section describes each element of the framework in more detail.

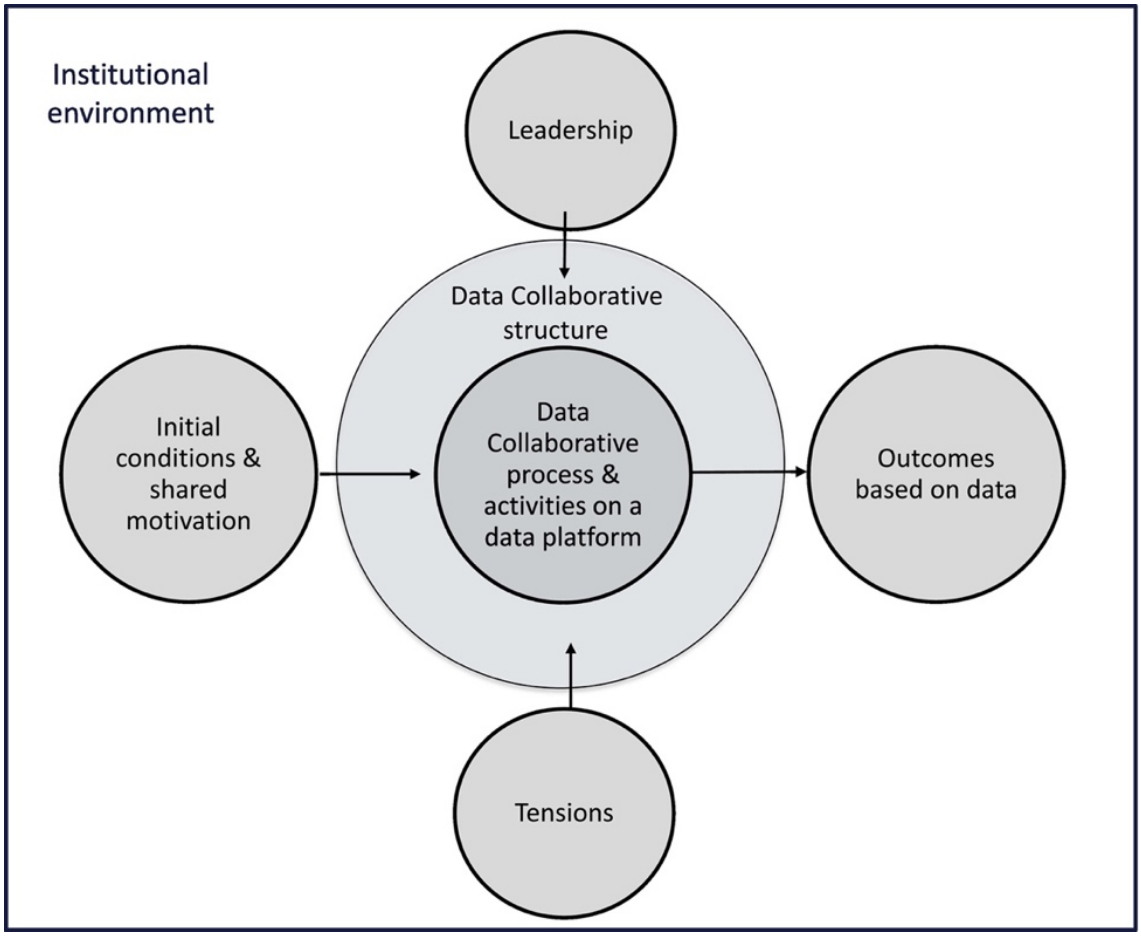


Figure 3 Data Collaborative Governance by Ruijer (2021)

The **institutional environment** describes the broader context that affects collaborative action (Ruijer, 2021). It is shaped by policies, legal frameworks, and political dynamics that might influence collaborations (Ruijer, 2021). Furthermore, this context encompasses various factors such as the mandatory or voluntary nature of the collaboration, the existence of a favourable opportunity, and the acknowledgement that the government alone is insufficient to resolve the issue (Ruijer, 2021).

Moreover, the **initial conditions and shared motivation** are crucial elements. Even when the aforementioned institutional environment conditions are established, it is essential for there to be a consensus on the preliminary objective of the collaboration (Ruijer, 2021). This includes recognising mutual dependencies and ensuring a shared commitment. Additionally, motivation significantly influences the success of these collaborative efforts (Ruijer, 2021).

Collaborative structures, composed of resources, norms, and engagement practices, fundamentally shape the behaviour, decision-making processes, and activities within collaboratives (Ruijer, 2021). In the context of data collaboratives, these structures

delineate the roles and responsibilities of participants, specifically their engagement in data collection (Ruijer, 2021). Critical elements of these collaborations include the free distribution of data, potential incentives for sharing, and the duration of data usage, be it long-term or temporary (Ruijer, 2021). Moreover, legal, and ethical considerations are pivotal in the process of information sharing. Here, responsible data governance emerges as a crucial factor (Ruijer, 2021).

Building trust and establishing a shared understanding of the problem are essential for effective **collaborative processes and activities** (Ruijer, 2021). To thoroughly comprehend complex public problems, it is necessary to break them down into manageable questions and action-oriented tasks (Ruijer, 2021). Activities in data collaborations typically involve standardised data collection, as well as facilitating data access, data sharing and data integration (Ruijer, 2021). Moreover, collaboratively creating value and deriving insights from data play a crucial role in addressing and solving public issues (Ruijer, 2021).

Technology can enhance collaborative structures, processes, and activities by offering innovative solutions that include tools designed to facilitate collaboration (Ruijer, 2021). Beyond just supporting activities, technology also enables efficient data sharing and fosters the co-creation of value based on this data (Ruijer, 2021). This not only streamlines collaboration but also amplifies the potential for meaningful outcomes from these engagements (Ruijer, 2021).

Leadership is essential for the effectiveness of collaborative efforts. The presence of individuals with formal authority can significantly influence the structures, processes, and outcomes of collaboration (Ruijer, 2021). Leaders should ensure that there is alignment among the initial conditions, structures, and processes (Ruijer, 2021). Additionally, they need the capability to work across various boundaries, engage stakeholders in addressing public issues, and coordinate the necessary expertise (Ruijer, 2021). In data collaboratives, leaders often act as mediators, helping to resolve tensions and ensure equitable participation among all stakeholders (Ruijer, 2021).

In collaborative settings, **tensions** frequently arise from disparities in power and divergent institutional logics (Ruijer, 2021). Common conflicts emerge between flexibility and stability, autonomy and interdependence, as well as inclusivity and efficiency (Ruijer, 2021). Within collaborations involving data, concerns regarding data control and worries over potential misuse of shared data by others can impede the sharing process (Ruijer, 2021). Consequently, it is essential to manage these tensions throughout the collaborative process (Ruijer, 2021).

The full impact and **outcomes** of data collaborations have yet to be fully evaluated (Ruijer, 2021). These collaborations hold the potential to generate public value by fostering shared learning, encouraging innovative strategies, and facilitating new partnerships at the organisational level (Ruijer, 2021).

In complementing the collaborative governance framework established by Bryson et al. (2015), Ruijer (2021) focuses on the unique aspects of data collaboratives that are integrated into the existing framework. Ruijer identifies various factors within each component of the framework that could either enable or hinder the governance of data collaboratives. The author organises these factors into three interconnected levels: organisational, political and policy, and data and technical aspects. By enhancing the framework, Ruijer provides a robust theoretical base for stakeholders to derive data-driven insights and develop solutions for societal challenges. Thereby the author extends the applicability and depth of the collaborative governance framework by Bryson et al. (2015). It demonstrates that incorporating data and technical aspects adds a new layer of complexity to existing frameworks on collaborative governance and information sharing.

Ruijer's (2021) framework for Data Collaborative Governance applies to both theory and practice. Its purpose is to aid the analysis of current collaborations by offering insights into the key factors that impact collaboration and the acceptance of data collaborative efforts between the public and private sectors. However, Ruijer (2021) points out that private parties are not included in this study, which may impact the results. Consequently, this thesis examines how the involvement of private parties affects the Data Collaborative Framework, particularly in the context of addressing medicine shortages.

The selection of Ruijer (2021) framework is based on several criteria. First, it explicitly incorporates data sharing and integration, crucial for understanding collaborative efforts in addressing medicine shortages. Second, the framework builds on established collaborative governance models (Ansell & Gash, 2008; Bryson et al., 2015; Emerson et al., 2012; Provan & Kenis, 2007), ensuring a robust theoretical foundation. Third, Ruijer's framework extends traditional models by addressing socio-technical complexities through the use of data, making it suitable for analysing current governance challenges. Finally, its emphasis on data collaboratives to solve complex public issues aligns well with the context of medicine shortages.

However, while serving as a theoretical framework for this thesis, the concept of data collaboratives is critically assessed in the context of medicine shortages. Although data collaboratives effectively tackle the challenges of data sharing and focus on solving complex public problems, the current collaborative efforts in addressing medicine shortages are not classified as data collaboratives. Accordingly, the aim of this thesis is

to evaluate the current collaborations, analyse existing challenges and shortcomings, and explore key factors to enhance these efforts. Furthermore, data collaboratives often engage in less obvious forms of data sharing. For instance, during the COVID-19 pandemic, they enabled inter-sectoral data sharing in unexpected ways (Oliver et al., 2020). This thesis focuses specifically on data related to the availability and stock levels of medicines, as well as information on supply shortages, which are directly pertinent to addressing the issue of medicine shortages.

Based on this theoretical framework, the following section discusses the methodology used to analyse the public-private collaboration to mitigate medicine shortages.

4 Methodology

This section outlines the research design and methodology to investigate how to enhance public-private collaboration to address medicine shortages in the EU through information sharing. A qualitative research approach is adopted to address the main research question and its sub-questions, using semi-structured interviews as the primary data collection method. The data collection and analysis are described in detail. Additionally, the limitations of the methodology are acknowledged.

4.1 Research Design

The thesis adopts a qualitative approach due to the complexity of addressing medicine shortages and the limited availability of information on collaborative efforts in the EU. VanderStoep and Johnston (2009, p. 8) recommend qualitative research when a "detailed narrative account of a particular subgroup is desired". It provides a more detailed and comprehensive insight into the population being studied. Hale and Brown (2014) highlight that qualitative research is particularly effective at observing, describing, and analysing complex political and social phenomena. Although qualitative data may not be generalisable, Alsaawi (2014) points out that it can be exceptionally rich and deep. This qualitative approach allows an in-depth exploration of public-private collaboration. Hence it provides a comprehensive perspective of the key factors influencing effective collaboration and information sharing to address medicine shortages. Furthermore, this method is well-suited to explore the necessary factors for effective collaborations. The approach allows for an in-depth analysis of the nuances and dynamics that quantitative data alone cannot provide (Mahoney & Goertz, 2006).

Semi-structured interviews are chosen as the primary data collection method for this thesis This method is ideal for addressing the research questions because it offers flexibility, allowing interviewers to delve deeper into specific areas of interest while maintaining a consistent framework across interviews (Adams, 2015; Adeoye-Olatunde & Olenik, 2021; Bryman, 2012; Magnusson & Marecek, 2015). Specifically, Adeoye-Olatunde & Olenik (2021) note that semi-structured interviews are useful for capturing the individual perspectives of participants, rather than aiming for a generalised understanding of a phenomenon. Accordingly, the insights gained from in-depth interviews are invaluable for exploring the dynamics of public-private collaborations in addressing medicine shortages.

The thesis follows a deductive approach, where the theoretical framework guides the formulation of interview questions and data analysis (Van Thiel, 2021). This approach

helps in systematically exploring and validating the theoretical concepts related to collaborative efforts and information sharing between the public and private sectors.

To address the research questions, primary qualitative data is collected through semi-structured interviews with key stakeholders from both the public and private sectors involved in managing medicine shortages within the European Union. The interviewees are carefully selected to provide a broad and informed perspective on the multifaceted issue of medicine shortages. This selection ensures a diverse representation of views and experiences, enriching the research findings.

Given the scope of the thesis, not all EU Member States can be analysed. Therefore, three countries are selected: Italy, Germany, and Finland. These Member States are part of the CHESSMEN project, and each has taken responsibility for one of the eight work packages that support the implementation of the Joint Action objectives (CHESSMEN, 2023). Italy's AIFA oversees work package 1 (coordination, management, and evaluation), Germany's BfArM is responsible for work package 7 (facilitating digital information exchange for the monitoring and reporting of medicine shortages), and Finland's Fimea handles work package 8 (reducing the likelihood of medicine shortages via preventive and mitigation strategies). These selections are based on the overlap between the work packages and the research questions, as well as the representation of both large (Germany, Italy) and smaller (Finland) pharmaceutical markets within the EU. Additionally, the EU perspective is included to provide a broader overview.

A targeted research approach is used to identify key stakeholders in the field of medicine shortages. Email correspondence is utilised to recruit these experts for interviews. Additionally, the snowball sampling method is employed, wherein interviewed experts recommend further contacts, thereby expanding the pool of potential interviewees and enriching the research data (Naderifar et al., 2017).

While qualitative research provides a deeper and more nuanced understanding of complex issues, it also has limitations (Alsaawi, 2014; Alshenqeeti, 2014; Dorussen et al., 2005). One significant disadvantage is the reliance on small, non-random sample sizes, which can restrict the external validity and generalisability of the findings (VanderStoep & Johnston, 2009).

Overall, this research design enables a thorough investigation of the collaboration dynamics between the public and private sectors. It provides valuable insights into enhancing information sharing to address medicine shortages in the EU. The following section will provide further details on the data collection and analysis processes.

4.2 Data Collection

In total, eleven experts are interviewed for this thesis. Among these, seven experts are from the private sector and four from the public sector, covering four location based scopes: Italy, Germany, Finland, and the EU. In the private sector, four associations and two pharmacists are interviewed. The associations represent the pharmaceutical industry and private pharmacies. Ten interviews are conducted with one expert each, while one interview involves two experts. From the public sector, interviews are conducted with representatives from three regulatory authorities and one from a Joint Action. A detailed overview can be seen in Table 2.

Expert	Sector	Location	Organisation
1	Private Sector	Italy	National Association of Pharmaceutical Industry
2	Private Sector	Italy	National Association of Pharmaceutical Industry
3	Private Sector	Italy	National Association of Private Pharmacies
4	Private Sector	Italy	National Association of Private Pharmacies
5	Private Sector	Germany	National Association of Pharmaceutical Industry
6	Private Sector	Germany	Private Pharmacy
7	Private Sector	Germany	Pharmaceutical Industry
8	Public Sector	Germany	Federal Institute for Drugs and Medical Devices
9	Public Sector	Finland	Finnish Medicines Agency
10	Public Sector	EU	European Medicines Agency
11	Public Sector	EU	Joint Action CHESSMEN

Table 2 Overview of the Interviewed Experts

In Italy, four experts are interviewed from the private sector, with two representing two national associations of the pharmaceutical industry and two from a national association of private pharmacies. In Germany, three private sector experts are interviewed, one from a national association of pharmaceutical industry, one from a private pharmacy, and one from the pharmaceutical industry. Additionally, one expert from Germany's Federal Institute for Drugs and Medical Devices, one from the Finnish Medicines Agency, and two from the EU, representing the European Medicines Agency and Joint Action CHESSMEN, are interviewed from the public sector.

The interviews are guided by specific guidelines. The interview guidelines are developed based on existing literature, the theoretical framework and previous research on the respective organisations. Moreover, the guidelines are customised for each interviewee to accommodate the specificities of their organisations and the various levels at which they operate. Nevertheless, all guides adhere to a consistent structure, starting with an introduction, followed by discussions on data sharing and management, then examining collaborative efforts and stakeholder engagement, and concluding with further

considerations. The thesis aims to explore how different EU Member States and EU-level initiatives approach collaboration and information sharing between public and private sectors to address medicine shortages. Ultimately, the goal is to identify key factors that enhance effective collaboration and facilitate information sharing about medicine shortages. Accordingly, the interview questions are designed to gain comprehensive insights into current collaborative mechanisms and challenges in the EU. These questions explore organisational culture, data sharing tools, trust between public and private sectors, legal and regulatory challenges, and previous collaboration experiences. The theoretical framework of Data Collaborative Governance guides the design of these questions. The detailed interview guidelines for each expert can be found in Appendix B. The interviewed experts receive the interview guides a few days in advance.

The interviews are conducted online via Teams Meetings between March and May 2024, each lasting between 45 and 60 minutes. Interviews with German experts are conducted in German and subsequently translated to English using DeepL Translator to facilitate the data analysis, while interviews with experts from other locations are conducted in English.

While the sample provides a broad perspective through experts from both the private and public sectors across multiple countries, potential biases cannot be entirely avoided. In the sample, the perspectives from Germany and Italy are represented more strongly. Thus the findings can be skewed towards the experiences and viewpoints prevalent in these countries. Additionally, the inclusion of only four public sector experts compared to seven from the private sector might result in a slight imbalance in the shared perspectives. Consequently, private sector viewpoints may be emphasised more prominently.

To address these potential biases, efforts are made to ensure diverse representation within the chosen sectors and organisations. The selected experts can share their experiences from different roles within their organisations, providing a comprehensive view of the pharmaceutical industry. However, it is important to acknowledge that the sample may not fully represent all possible viewpoints within the broader European pharmaceutical landscape. There are many other participants in the collaborations studied, that are not included in the sample, such as scientific associations, ministries, health insurance organisations and patient advocacy groups.

Despite these limitations, the sample is considered reasonably comprehensive for the thesis' objectives. It includes key stakeholders from significant regulatory bodies and industry associations, as well as private pharmacies ensuring that critical insights into both regulatory and industry practices are captured. By incorporating a diverse range of experts from public and private sectors and locations, the study aims to present a holistic

view of the pharmaceutical industry's landscape and regulatory environment across the EU.

4.3 Data Analysis

To analyse qualitative data, coding is a fundamental method supported by extensive literature (Corbin & Strauss, 2014; Kuckartz, 2016; Saldaña, 2016). In this thesis, the interviews will be analysed using the coding method described by Saldaña (2016), which offers a structured approach to extract valuable insights from qualitative data. Saldaña's manual is widely recognised in academia for its clear, practical guidance and its adaptability to various research questions and disciplines. By utilising Saldaña's coding strategies, this thesis aims to adhere to established academic standards, enhancing the credibility and robustness of the analysis, thereby supporting the validity of the research findings. To facilitate the coding process the software MAXQDA 2022 is used.

The purpose of coding is to identify patterns within the interview transcripts that help to interpret the qualitative data efficiently. The coding process unfolds over several cycles. In this thesis a combination of in vivo and descriptive codes is used. In vivo codes are directly extracted from the exact wording used in the interview transcripts, capturing the participants' own language (Saldaña, 2016). Descriptive codes, summarise specific themes into a single word or a brief phrase, simplifying and categorising the data for easier analysis (Saldaña, 2016).

To extract findings from the conducted interviews, several coding cycles are conducted. Initially, the aim is to align the codes with elements of the theoretical framework: institutional environment, initial conditions and drivers, collaborative structures, collaborative processes, leadership, outcomes, and tensions. Moreover, in the early stages of coding, in vivo codes are used to stay as close to the original data as possible. Subsequently, after coding three interviews, the codes are sorted thematically and divided into different categories aligning with the research questions, using descriptive codes. These categories include elements from the framework, other key factors that could not be directly assigned to the framework and background information such as the causes of medicine shortages or potential tools to address these shortages. This process is repeated for the subsequent interviews.

During the coding of the initial interviews, it becomes evident that the results cannot be neatly categorised according to the elements of the theoretical framework. This is primarily because data sharing does not play a significant role in the assessed collaborations. Although data sharing between industry and government is discussed, it does not emerge as the main tool for addressing medicine shortages within public-private

collaborations. Nonetheless, the analysis of the interviews provides valuable insights into key factors of public-private collaborations. However, the qualitative approach using semi-structured interviews has several limitations, which are addressed in the following section.

4.4 Limitations

The qualitative research methodology employed in this thesis has inherent limitations. While semi-structured interviews allow for in-depth exploration of complex issues, they can also lead to inconsistencies in the data collection process. The qualitative nature of these interviews means that findings are based on subjective interpretations, which may be influenced by the interviewer's perspectives and biases. This subjectivity can impact the reliability and reproducibility of the results.

Furthermore**,** the study primarily focuses on the pharmaceutical industry and regulatory authorities, as indicated by the expert profiles. The interview sample does not include other important stakeholders, such as scientific associations, ministries, health insurance organisations, wholesalers and patient advocacy groups. Effectively, critical perspectives and contributions from other stakeholders are potentially neglected. These would be essential for a comprehensive understanding of the public-private collaboration needed to address medicine shortages.

Moreover, the external validity of this study is limited due to the focus on interviewees from only three EU Member States. This may introduce a bias, limiting the generalisability of the findings to other EU Member States with different regulatory and cultural contexts. Consequently, the geographical concentration of the interviewees does not fully capture the diversity of approaches and challenges faced by other countries within the EU.

5 Results

In this section, the findings from eleven interviews are presented to understand national and EU approaches to address medicine shortages. Firstly, the national strategies employed by Italy, Germany, and Finland are examined. This is followed by an exploration of EU-level initiatives, including the ESMP and the Joint Action CHESSMEN. This analysis highlights existing public-private collaborations and their data-sharing initiatives. Secondly, the key factors influencing public-private collaboration are presented.

5.1 National Public-Private Collaborations in Italy, Germany, and Finland

This section explores the national strategies employed by Italy, Germany, and Finland to foster public-private collaboration in addressing medicine shortages. Through insights from various experts, the approaches taken by these Member States highlight the importance of structured dialogues, coordinated efforts, and regulatory frameworks in mitigating the risks associated with medicine shortages. Each country's strategy reflects its unique challenges and how stakeholders from the public and private sectors work together to ensure a stable supply of medicines. The following subsections provide a detailed examination of the collaborative frameworks in place, illustrating the effectiveness and ongoing challenges faced by these collaborations.

5.1.1 Technical Table of Shortages in Italy

Italy's Technical Table of Shortages (“Tavolo Tecnico Indisponibilità” or TTI) represents a national collaboration to address medicine shortages through coordinated efforts between the public and private sectors. Established in 2015, the TTI is coordinated by the AIFA. The TTI involves a wide range of stakeholders, including AIFA, the Ministry of Health, regional authorities, police forces, technical administrations, marketing authorisation holder associations, pharmacy associations, wholesalers, logistic-technical services associations, manufacturing associations, and scientific societies. Participation in the TTI requires a formal request to join, which is sent to the coordinator. Once approved, each organisation appoints a reference contact who is consistently present at the meetings, ensuring consistent representation and communication among stakeholders.

The establishment of the TTI was supported by various stakeholders, including the Italian Association represented by Experts 1, 3, and 4. The Experts emphasise the importance of a platform where pharmacies, wholesalers, and industry representatives could directly communicate with regulatory authorities such as AIFA. According to the Experts, the TTI functions as a formal mechanism to bring together different stakeholders in the

pharmaceutical supply chain to discuss and address specific issues related to medicine shortages.

The TTI conducts regular meetings, allowing stakeholders to report shortages, discuss their causes, and propose solutions. This ensures that all parties are aware of current and potential shortages, enabling a proactive response (Expert 4). Accordingly, the TTI is instrumental in addressing shortages through genuine stakeholder engagement. Expert 4 describes how face-to-face interactions within the TTI facilitate more rapid and effective solutions, such as discussing alternative therapies when specific medicines are unavailable. This does not always involve medicine shortages throughout Italy but can also be specific to individual regions (Expert 4). For instance, Expert 3 references an event from approximately a year ago in Sardinia, where a shortage of oxygen cylinders was reported. Through the TTI, they discussed the issue with industry representatives and ultimately found a solution for this local problem. The TTI's ability to bring all stakeholders to the table and foster a collaborative spirit has been seen as a significant achievement by all Experts. Expert 4 states that the table is a very useful tool, as it allows all stakeholders to come together and find solutions directly when problems arise.

While the dynamism of the TTI is conceived as a strength by its participants, it faces several challenges, primarily related to the harmonisation of its stakeholders (Expert 2, Expert 4). The stakeholders often have different approaches, rules, and perspectives, making coordination difficult. The different priorities of stakeholders, including technical and political perspectives, create potential conflicts of interest (Expert 2). Despite these challenges, the Experts recognise the TTI's strength in bringing all stakeholders together to collaboratively find solutions and reach compromises, facilitated and coordinated by AIFA.

Overall, the four Experts from Italy agree upon the accomplishment of significant improvements in mitigating medicine shortages through the TTI. These achievements encompass the distribution of medicines for acute shortages, the dissemination of information, and the development of guidelines (Di Giorgio & Scrofina, 2021). Specific examples of these initiatives include the reinforcement of traceability and verification of stocks for critical medicines, achieved through partnerships with IT services and distributors. The TTI also established an IT platform to signal issues in hospital medicine availability, collaborating closely with the Hospital Pharmacists Association. Furthermore, the TTI developed and disseminated guidelines to assist pharmacists in effectively managing shortages. Lastly, the TTI created a webpage, in cooperation with relevant clinics, to provide patients with information on managing epilepsy medicine shortages.

Furthermore, AIFA is also responsible for collecting data on medicine shortages in Italy and publishes this information for the public (AIFA, n.d.). According to AIFA, a medicine shortage occurs when a medicine is temporarily unavailable in the national territory because the MAH cannot ensure a continuous supply to meet patients' therapeutic needs. However, AIFA notes that not all shortages cause significant problems, as many can be managed by using equivalent medicines, prescribing alternatives, or importing the medicine from abroad (AIFA, n.d.). To prevent or limit shortages, AIFA may temporarily block the export of certain medicines.

AIFA lists a variety of causes for medicine shortages, such as the unavailability of active ingredients, production issues, regulatory measures, unexpected increases in demand, and public health emergencies. When a shortage occurs, the MA holder reports it to AIFA. Subsequently, AIFA is responsible for including the shortage on the official shortages list. In Italy, pharmaceutical companies are required to notify AIFA four months in advance of potential shortages (Expert 1). Failure to comply results in fines, which vary significantly (Expert 1).

AIFA provides several lists to inform the public about medicines currently in shortage and the available alternatives:

1. **Medicines with Equivalent Medicines Available:** Lists medicines in shortage or no longer marketed for which equivalent medicines are available on the Italian market.

2. **Medicines with Alternative Treatments Available:** Lists medicines in shortage or no longer marketed for which no equivalents are available, but therapeutic alternatives exist.

3. **Medicines Authorised for Import:** Lists medicines in shortage for which neither equivalents nor therapeutic alternatives are available domestically.

4. **Medicines with Temporary Export Bans:** Lists medicines that cannot be exported to ensure a sufficient supply to meet treatment needs throughout the national territory.

5. **Six-Monthly List of Import Requests:** Shows medicines lacking in the national market for which AIFA has authorised importation from abroad in the last six months.

6. **Historical Shortages List:** Provides a complete list of medicines in shortage since 2010 due to reasons such as production or regulatory problems, ceased marketing, or suspension.

The lists are available in Excel format. Due to the extensive size of the data, the illustration in Figure 4 may be difficult to read as it contains a substantial amount of information with many columns. To ensure readability and provide detailed insights, an excerpt of the list, showing medicines with their equivalent alternatives, is included in Appendix A.

NB: I medicinali, per i quali il Titolare AIC non abbia provveduto a comunicare la data effettiva di fine carenza, continueranno ad essere mantenuti nel presente elenco anche oltre la "data di fine presunta" precedentemente comunicata e qui indicata.

Elenco dei farmaci carenti per i quali sono disponibili equivalenti aggiornato al 31/05/2024

Nome medicinale	Codice AIC	Principio attivo	Forma farmaceutica e dosaggio	Titolare AIC	Data inizio	Fine presunta	Equivalente	Motivazioni	Suggerimenti/indicazioni AIFA	Nota AIFA	Classe di rimborsabilità
ABIMONO	025318645	ISOCONAZOLO NITRATO	"1 % CREMA VAGINALE" 1 TUBO DA 30 G + 6 APPLICATORI MONOUSO	FARMITALIA INDUSTRIA CHIMICO FARMACEUTICA S.R.L.	01.02.2019		SI	Cessata commercializzazione definitiva	Per trattamento alternativo si consiglia di rivolgersi allo specialista o al M.M.G		A TOTALE CARICO DELL'ASSISTITO
ABIOCLAV	037350028	ACIDO CLAVULANICO + AMOXICILLINA	" 400 MG + 57 MG/5 ML POLVERE PER SOSPENSIONE ORALE " FLACONE DA 70 ML CON CUCCHIAIO DOSATORE	AESCULAPIUS FARMACEUTICI SRL	15.12.2023		SI	Elevata richiesta	Per trattamento alternativo si consiglia di rivolgersi allo specialista o al M.M.G		A TOTALE CARICO DEL SSN.
ABIRATERONE DR. REDDY'S	049397021		"500 MG COMPRESSE RIVESTITE CON FILM" 56X1 COMPRESSE IN BLISTER PVC/PVDC/AL	DR. REDDY'S S.R.L.	15.07.2023		SI	Cessata commercializzazione definitiva	Per trattamento alternativo si consiglia di rivolgersi allo specialista o al M.M.G		A CARICO DEL SSN AMBITO OSPED.
ABIRATERONE EG	049473344	ABIRATERONE ACETATO	"500 MG COMPRESSE RIVESTITE CON FILM" 56X1 COMPRESSE IN BLISTER OPA/Al/PVC/Al DOSE UNITARIA AL PVC/PE/PVDC	EG S.P.A.	26.01.2023		SI	Cessata commercializzazione definitiva	Per trattamento alternativo si consiglia di rivolgersi allo specialista o al M.M.G		A CARICO DEL SSN AMBITO OSPED.
ABIRATERONE MYLAN	049686852	ABIRATERONE ACETATO	500 MG - COMPRESSA RIVESTITA CON FILM - USO ORALE - BLISTER (ALU-PVC/PE/PVDC) - 56 COMPRESSE	MYLAN IRELAND LIMITED	30.06.2024		SI	Cessata commercializzazione definitiva	Per trattamento alternativo si consiglia di rivolgersi allo specialista o al M.M.G		A CARICO DEL SSN AMBITO OSPED.
ACARBOSIO AUROBINDO	047612027	ACARBOSIO	"50 MG COMPRESSE" 40 COMPRESSE IN BLISTER PVC/PE/PVDC/AL	AUROBINDO PHARMA (ITALIA) S.R.L.	19.03.2024		SI	Elevata richiesta: distribuzione contingentata (vendita relativa solo al canale retail)	Per trattamento alternativo si consiglia di rivolgersi allo specialista o al M.M.G		A TOTALE CARICO DEL SSN.
ACARBOSIO DOC GENERICI	044155012	ACARBOSIO	"50 MG COMPRESSE" 40 COMPRESSE IN BLISTER PVC/PE/PVDC AL	DOC GENERICI SRL	08.04.2024		SI	Elevata richiesta	Per trattamento alternativo si consiglia di rivolgersi allo specialista o al M.M.G		A TOTALE CARICO DEL SSN.
ACARBOSIO DOC GENERICI	044155024	ACARBOSIO	"100 MG COMPRESSE" 40 COMPRESSE IN BLISTER PVC/PE/PVDC AL	DOC GENERICI SRL	11.04.2024		SI	Elevata richiesta	Per trattamento alternativo si consiglia di rivolgersi allo specialista o al M.M.G		A TOTALE CARICO DEL SSN.
ACC FLUIDIFICANTE E ANTIDOTO	032819031	ACETILCISTEINA	"300 MG/3 ML SOLUZIONE INIETTABILE, DA NEBULIZZARE E PER INSTILLAZIONE ENDOTRACHEOBRONCHIALE" 5 FIALE DA 3 ML	SANDOZ S.P.A.	30.05.2022		SI	Cessata commercializzazione definitiva	Per trattamento alternativo si consiglia di rivolgersi allo specialista o al M.M.G		A TOTALE CARICO DELL'ASSISTITO
ACCARIZAX	043755038	Estratto di allergeni di acari della polvere domestica-Dermatophagoides farinae + Estratto di allergeni di acari della polvere domestica-Dermatophagoides pteronyssinus	"12 SQ-HDM LIOFILIZZATO ORALE" 90 LIOFILIZZATI ORALI IN BLISTER AL/AL	ALK-ABELLÓ A/S	15.05.2020		SI	Cessata commercializzazione definitiva	Per trattamento alternativo si consiglia di rivolgersi allo specialista o al M.M.G		A TOTALE CARICO DELL'ASSISTITO

Figure 4 Excerpt of the List of Medicines with Equivalent Medicines Available from 01.06.2024. Source: AIFA, n.d.

The list contains detailed information about each medicine in shortage, including the trade name, active ingredient, pharmaceutical form, packaging, and the name of the MAH. It also specifies the start date and presumed end date of the shortage, the availability of equivalent medicines on the national market, the reasons for the shortage, and any suggestions or measures adopted by AIFA. Additionally, the list includes relevant notes to provide further context or information

In summary, AIFA addresses medicine shortages through a structured and collaborative approach that involves regular stakeholder engagement and comprehensive data collection shared with the public.

5.1.2 Advisory Board for Medicine Shortages in Germany

Germany's strategy for managing medicine shortages includes the establishment of the Advisory Board for Medicine Shortages (original: “Beirat zu Liefer- und Versorgungsengpässen”), regulated by law (§ 52b Absatz 3b AMG). The Advisory Board serves as a national collaboration framework, engaging multiple stakeholders to ensure a coordinated response to shortages (Expert 8). The Advisory Board, established in July 2020 under German law, brings together representatives from medical and scientific associations, pharmaceutical commissions, federal health and defense ministries, regulatory and research institutes, pharmaceutical industry associations, healthcare provider associations, health insurance organisations, patient advocacy groups, and

federal states (BfArM, n.d.). The members are appointed by the Federal Ministry of Health (BMG). The BfArM handles the management of the Advisory Board. Operating under a legal mandate, the board facilitates structured dialogues aimed at mitigating medicine shortages.

According to Expert 8, the Advisory Board conducts regular meetings three times a year, with one in-person meeting and the others conducted online. Special meetings can be convened to address significant situations, such as the antibiotic shortages during the winter seasons of 2022 and 2023 (Expert 8). These meetings are organised and moderated by the BfArM. The meeting agenda is primarily generated by the BfArM, but members can propose additional items (Expert 8). The agendas and meeting minutes are available online on the BfArM website. Decision-making focuses on building consensus and finding practical solutions for medicine shortages through transparent and constructive dialogue among members (Expert 8). Expert 8 states, that the primary aim of the Advisory Board is to ensure a coordinated response to medicine shortages through structured dialogues and information sharing among stakeholders.

The BfArM performs criticality assessments to determine whether a shortage is critical or less severe (Expert 8). These assessments help the BfArM communicate their judgements regarding medicine shortages, determining whether Germany's supply is stable enough to assist other European countries. Although the BfArM does not directly manage the distribution of medicines, it provides evaluations and recommendations to manufacturers and other stakeholders (Expert 8). Expert 8 highlights the structured approach taken by the BfArM at both national and EU levels to manage critical medicine shortages. This involves close collaboration with the EMA and other Member States, focusing on criticality assessments and strategic information sharing to mitigate shortages across the EU.

As emphasised by Expert 8, in Germany, numerous legal and regulatory frameworks must be adhered to. Due to the federal system in Germany, the national authority does not have jurisdiction over the entire area. Accordingly, many regulations are implemented at the state level. The advisory board lacks the authority to overrule or nullify these state regulations (Expert 8). As depicted by Expert 8, this presents the challenge of finding feasible and implementable solutions that comply with all legal and regulatory requirements. Furthermore, while discussions typically involve all stakeholders, each brings their own perspective, creating additional challenges. Therfore, Expert 8 emphasises that developing a mutual understanding during discussions and acknowledging the need for temporary adjustments to standards requires considerable effort and persuasive energy. Navigating regulatory complexities and persuading diverse

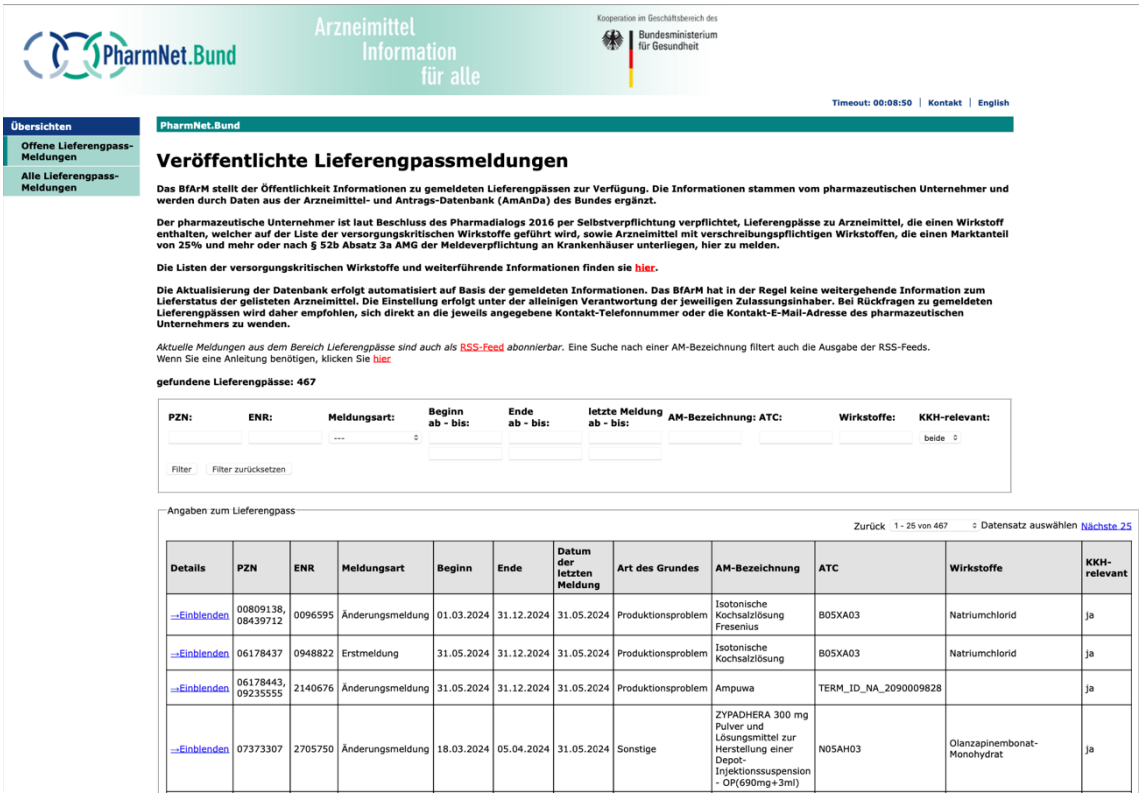
stakeholders to agree on common actions are significant challenges. Expert 8 states that the collaborative spirit fostered by the advisory board is essential for solving complex issues like medicine shortages, balancing interests, complying with legal frameworks, and maintaining transparent and constructive dialogue among members.

The role of the Advisory Board is to continuously oversee and evaluate the availability of medicines for human use (BfArM, n.d.). This involves aiding federal authorities in assessing the impact of supply shortages, considering alternative therapies, and formulating recommendations to enhance the supply situation (BfArM, n.d.). Furthermore, the BfArM can employ legal measures, including permissions to market medicines with non-German labelling if necessary to ensure supply (BfArM, n.d.).

The BfArM provides an overview of current supply shortages for human medicines (excluding vaccines) in Germany on the "Supply Shortage Online Portal" (orig.: “Lieferengpass Online Portal”) for the public (PharmNet.Bund, n.d.). The BfArM implements a system that includes lists of supply-relevant and supply-critical active substances, agreed upon with the Advisory Board (Expert 8). The database is automatically updated.

Pharmaceutical companies are required to report supply shortages of medicines that contain a supply-critical active ingredient, prescription-only medicines with a market share of 25% or more, or medicines that are subject to the reporting obligation to hospitals under § 52b Absatz 3a AMG (PharmNet.Bund, n.d.). Pharmaceutical companies submit these reports based on a self-commitment declared in the Pharma Dialogue in 2016 (Expert 8). Pharmaceutical companies are required to report a supply shortage to the relevant authorities if they anticipate being unable to maintain their usual delivery quantities for a period exceeding two weeks (Expert 8). Additionally, they must report any significant increase in demand that cannot be adequately met. Reports are submitted via the portal, for which pharmaceutical companies can log in using access credentials.

While primarily a national tool, this data can inform broader assessments if questions arise beyond national concerns (Expert 8). Figure 5 illustrates the layout of this database.



PharmNet.Bund

Arzneimittel Information für alle

Kooperation im Geschäftsbereich des Bundesministerium für Gesundheit

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Übersichten

Offene Lieferengpass-Meldungen

Alle Lieferengpass-Meldungen

PharmNet.Bund

Veröffentlichte Lieferengpassmeldungen

Das BfArM stellt der Öffentlichkeit Informationen zu gemeldeten Lieferengpässen zur Verfügung. Die Informationen stammen vom pharmazeutischen Unternehmer und werden durch Daten aus der Arzneimittel- und Antrags-Datenbank (AmAnDa) des Bundes ergänzt.

Der pharmazeutische Unternehmer ist laut Beschluss des Pharmadialogs 2016 per Selbstverpflichtung verpflichtet, Lieferengpässe zu Arzneimittel, die einen Wirkstoff enthalten, welcher auf der Liste der versorgungskritischen Wirkstoffe geführt wird, sowie Arzneimittel mit verschreibungspflichtigen Wirkstoffen, die einen Marktanteil von 25% und mehr oder nach § 52b Absatz 3a AMG der Meldeverpflichtung an Krankenhäuser unterliegen, hier zu melden.

Die Listen der versorgungskritischen Wirkstoffe und weiterführende Informationen finden sie hier.

Die Aktualisierung der Datenbank erfolgt automatisiert auf Basis der gemeldeten Informationen. Das BfArM hat in der Regel keine weitergehende Information zum Lieferstatus der gelisteten Arzneimittel. Die Einstellung erfolgt unter der alleinigen Verantwortung der jeweiligen Zulassungsinhaber. Bei Rückfragen zu gemeldeten Lieferengpässen wird daher empfohlen, sich direkt an die jeweils angegebene Kontakt-Telefonnummer oder die Kontakt-E-Mail-Adresse des pharmazeutischen Unternehmers zu wenden.

Aktuelle Meldungen aus dem Bereich Lieferengpässe sind auch als RSS-Feed abonnierbar. Eine Suche nach einer AM-Bezeichnung filtert auch die Ausgabe der RSS-Feeds.
Wenn Sie eine Anleitung benötigen, klicken Sie hier

gefundene Lieferengpässe: 467

PZN: | ENR: | Meldungsart: | Beginn ab - bis: | Ende ab - bis: | letzte Meldung ab - bis: | AM-Bezeichnung: ATC: | Wirkstoffe: | KKH-relevant: (beide)

Filter | Filter zurücksetzen

Angaben zum Lieferengpass

Zurück 1 - 25 von 467 Datensatz auswählen Nächste 25

Details	PZN	ENR	Meldungsart	Beginn	Ende	Datum der letzten Meldung	Art des Grundes	AM-Bezeichnung	ATC	Wirkstoffe	KKH-relevant
→Einblenden	00809138, 08439712	0096595	Änderungsmeldung	01.03.2024	31.12.2024	31.05.2024	Produktionsproblem	Isotonische Kochsalzlösung Fresenius	B05XA03	Natriumchlorid	ja
→Einblenden	06178437	0948822	Erstmeldung	31.05.2024	31.12.2024	31.05.2024	Produktionsproblem	Isotonische Kochsalzlösung	B05XA03	Natriumchlorid	ja
→Einblenden	06178443, 09235555	2140676	Änderungsmeldung	31.05.2024	31.12.2024	31.05.2024	Produktionsproblem	Ampuwa	TERM_ID_NA_2090009828		ja
→Einblenden	07373307	2705750	Änderungsmeldung	18.03.2024	05.04.2024	31.05.2024	Sonstige	ZYPADHERA 300 mg Pulver und Lösungsmittel zur Herstellung einer Depot-Injektionssuspension - OP(690mg+3ml)	N05AH03	Olanzapinembonat-Monohydrat	ja

Figure 5 Excerpt of the Supply Shortage Online Portal from 01.06.2024. Source: PharmNet.Bund, n.d.

The Supply Shortage Online Portal provides detailed information on supply shortages. Each entry contains the Pharmacy Central Number (PZN), a unique identifier for each medicine, and another specific identifier or reference number (ENR). It specifies the type of report, the start and anticipated end dates of the supply shortage, and the date of the last submitted report. Additionally, the list categorises the type of reason for the shortage and includes the name of the affected medicine. The Anatomical Therapeutic Chemical (ATC) classification code is provided to classify the medicine, and it lists the active ingredients. The list also indicates whether the shortage is relevant to hospitals.

Furthermore, additional information for each medicine can be shown, including the MAH and their contact details, the specific reason for the supply shortage, and further explanations about the shortage. This can cover details such as partial availability, mitigation efforts with substitute products, and issues with suppliers. The additional information also includes the date of the first report, plans for informing professional circles, and the affected dosage form. In addition, the database is also equipped with a filter function.

In summary, Germany addresses medicine shortages through a coordinated approach managed by BfArM. Explicitly, the BfArM emphasises collaboration and information exchange between public and private sectors via the Advisory Board for Medicine

Shortages. The Advisory Board meets regularly to discuss and address shortages, focusing on practical actions, criticality assessments, and making recommended actions. Furthermore, the BfArM maintains the Supply Shortage Online Portal, providing public access to detailed information on shortages.

5.1.3 Fimea's Approach to Managing Medicine Shortages in Finland

Fimea, the Finnish Medicines Agency, is responsible for managing medicine shortages in Finland, with responsibilities defined by the Finnish Medicines Act (Expert 9). According to Expert 9, Fimea's mandate includes compiling, evaluating, and conveying information about medicine shortages to the public and healthcare professionals. Expert 9 provides insights into Fimea's strategies to manage medicine shortages. Firstly, obligatory medicine storage ensures a buffer of essential medicines for crisis situations. Secondly, Fimea can issue special licences and permit the importation of medicines from abroad to address shortages. Furthermore, Fimea maintains an ongoing dialogue with supply chain stakeholders through regular situational meetings and newsletters to ensure all parties are informed and can collaborate effectively.

Fimea's efforts to mitigate medicine shortages centre around patient organisations, supply chain entities, and government bodies (Expert 9). By implementing the aforementioned strategies and by maintaining open lines of communication, Fimea aims to manage and mitigate the impact of medicine shortages in Finland (Expert 9). The Patient Advisory Board, which meets twice a year, is complemented by newsletters targeted at patients (Expert 9). Monthly situational meetings with supply chain stakeholders, including pharmaceutical companies, hospital pharmacists, pharmacies, and the National Emergency Supply Agency (NESA), focus on medicine availability (Expert 9). Regular updates are provided to the Ministry of Social Welfare and Health regarding availability and shortages (Expert 9). An annual educational day for GDP-license holders (wholesalers) include sessions on medicine availability (Expert 9). Additionally, ad hoc and follow-up meetings with stakeholders are convened as necessary to address specific shortages (Expert 9).

Furthermore, data collection and analysis are central to Fimea's approach. The agency collects sales data from wholesalers and stock data from pharmacies, which are manually analysed to assess demand and stock levels (Expert 9). In the future, Fimea aims to develop better analytical tools, such as the use of AI (Expert 9). The MAH is required to inform Fimea of any temporary withdrawal of a medicinal product intended for human use, as specified under section 27 of the Medicines Act (395/1987). This notification must be submitted at least two months prior to the withdrawal. In principle, failure to notify about a shortage can result in sanctions for the MAH (Expert 9). However, Expert 9

reports that no penalties have ever been imposed, even though MAHs often fail to meet the two-month deadline. Expert 9 explains, that the process of imposing sanctions is very bureaucratic, requiring Fimea to go through legal proceedings.

Fimea's primary objective in collecting and sharing data is to facilitate information sharing with various stakeholders (Expert 9). This ensures that all relevant parties are aware of the current situation and can make informed decisions. Despite efforts to ensure comprehensive data, Expert 9 reveals, that some shortages are identified by patients or hospitals rather than reported by companies. These unreported cases are followed up with companies to ensure proper notifications (Expert 9). Expert 9 explains, that companies often find it challenging to predict shortages two months in advance due to delivery uncertainties, leading to unforeseen shortages.

To prevent hoarding, Fimea publishes shortage notifications two weeks before the shortage begins (Expert 9). These notifications include the medicine name, start and end dates, and company contact details, but not the reasons for the shortage due to confidentiality (Expert 9). The database is illustrated in Figure 6.

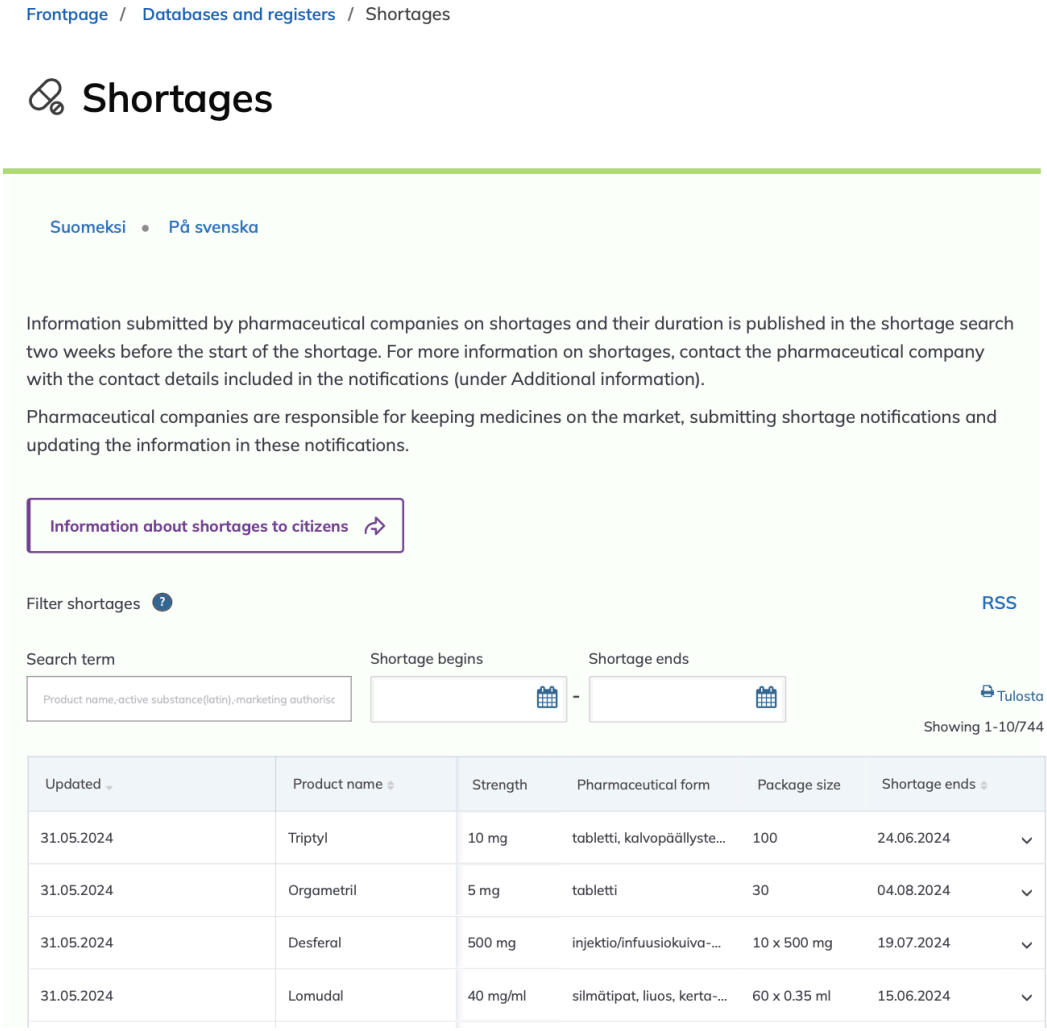

Figure 6 Excerpt of the Shortages Database from 01.06.2024. Source: Fimea, n.d.

The shortages database includes comprehensive details on medicine shortages. These include the date when the information was last updated, the product name, the strength of the medicine, the pharmaceutical form, the package size, and the anticipated end date of the shortage. Additionally, the database is equipped with a filter function to facilitate easier navigation and access to specific information. Furthermore, additional information for each medicine can be displayed, such as the ATC classification, active substances, MAH and their contact details, and more information regarding the shortage. Other details may include the date of the notification, whether it is the first notification, the VNR, type of medicine, and whether it is a mandatory stored medicinal product.

Companies with a Finnish business ID submit shortage notifications through an e-service. The e-service requires a Finnish social security number as foreign identification methods are not enabled (Expert 9). According to Expert 9, the e-service allows users to submit, view, and update their own shortage notifications and view all current or future shortages

reported to Fimea. Foreign companies without a Finnish business ID or personnel with a Finnish social security number submit their shortage notifications using a PDF form, which should be emailed to the registry office of Fimea (Expert 9). Accordingly, only companies with a Finnish Business ID have full access to the database to monitor competitors' shortages and prepare accordingly, which is seen as a limitation by Expert 8.

As depicted by Expert 9, Fimea faces several challenges in managing medicine shortages. Inconsistent compliance with the two-month notification requirement complicates shortage management. Despite these challenges, Fimea engages in regular meetings with patient organisations, supply chain stakeholders, and government bodies to address shortages effectively. Another challenge is the management of media and public perception. Fimea balances public information dissemination to prevent panic-induced hoarding (Expert 9)

Taken together, Fimea plays a crucial role in managing medicine shortages in Finland through its legal mandate, strategic data collection, and extensive stakeholder collaboration. Despite challenges such as inconsistent notification compliance and managing public perception, Fimea's proactive approach and open communication channels aim to ensure the stability of medicine supply within Finland. By fostering collaboration among diverse stakeholders and maintaining transparency, Fimea aims to mitigate the impact of medicine shortages and ensure patient access to necessary medicines.

5.2 EU Approaches to Managing Medicine Shortages

The EU establishes several collaborative frameworks and regulatory measures to manage and prevent medicine shortages across its Member States. In the following sections, the ESMP by the EMA and the Joint Action CHESSMEN are presented as key initiatives in the collaborative efforts. The EMA plays a central role in coordinating medicine shortages, supported by legislation such as Regulation (EU) 2022/123. The CHESSMEN project aims to address medicine shortages across Europe by utilising existing resources and knowledge from Member States.

5.2.1 European Shortages Monitoring Platform

The ESMP is a tool developed by the EMA to manage medicine shortages which will be implemented in February 2025 (Ferreira, n.d.). It aims to consolidate data from various sources into a single platform, allowing the EMA to monitor supply and demand and address shortages. Expert 10 explains that the ESMP handles supply and demand data to

facilitate a matching exercise, ensuring that if supply does not meet demand, measures can be taken to either increase supply or adjust demand.

Under Regulation (EU) 2022/123, the EMA is responsible for establishing governance structures, processes, and tools such manage and prevent medicine shortages. This regulation enhances the EMA's ability to require companies to provide specific data, thereby improving the overall management of shortages. According to Expert 10, this regulation significantly enhances the consistency and information sharing among EU Member States. Effectively the regulation allows for faster collective responses to shortages (Expert 10). As depicted by Expert 10, the EMA's centralised communication facilitates the process and fosters relationships with stakeholders across the supply chain, thereby enhancing the overall situation for patients.

The ESMP integrates disparate data sources and includes a public portal to improve awareness and understanding of medicine availability management across Europe (Expert 10). The platform aims to standardise and harmonise data reporting, allowing for trend analysis and historical data searches (Expert 10). Expert 10 highlights the future vision of the ESMP, noting that its role will expand with the new pharmaceutical legislation, enhancing its capability to manage and prevent shortages more effectively across Europe.

Furthermore, the ESMP serves as the main tool for companies to report shortages of centrally authorised products, transitioning from an interim email process to a standardised system (Expert 10). Expert 10 emphasises that the ESMP is intended to be the primary tool for preventing, managing, and mitigating shortages by centralising all relevant information. According to Expert 10, the ESMP features three distinct views to meet the needs of different stakeholders:

1. **Regulator View:** Allows the EMA to have a comprehensive overview of supply and demand in each Member State, thereby monitoring and managing supply chain issues and facilitating a coordinated response to shortages.

2. **Industry View:** Enables pharmaceutical companies to report shortages helping them anticipate and address potential issues. However, access to other companies' data is restricted to protect commercial confidentiality.

3. **Public View:** Provides the public with information about medicine availability, helping to ensure transparency.

The ESMP's public portal aims to improve awareness and understanding of medicine availability management across the EU (Expert 10). By standardising and harmonising

data reporting, the platform enables trend analysis and historical data searches, facilitating better-informed decision-making (Expert 10).

The biggest challenge identified by Expert 10 is the variability in data sets and formats across Member States, especially for nationally authorised, older products like antibiotics. Accordingly, this complicates the integration of all the data into a single interoperable system (Expert 10). While the concept of a unified data system is widely accepted, its practical implementation is complex and requires significant effort from Member States (Expert 10).

In summary, the ESMP is a comprehensive tool designed to enhance the EU's ability to manage medicine shortages by centralising data, facilitating collaboration, and improving communication among all relevant parties. This approach aims to reduce the severity and duration of shortages to ensure a more resilient pharmaceutical supply chain across Europe. The ESMP's integration of disparate data sources and its tailored views for different stakeholders make it a critical component of the EU's strategy to prevent and manage medicine shortages effectively.

5.2.2 Joint Action CHESSMEN

The Joint Action CHESSMEN is a collaborative initiative aimed at addressing medicine shortages across Europe by leveraging existing resources and knowledge (Expert 11). Coordinated by Italy, the CHESSMEN project focuses on harmonising efforts among Member States, avoiding duplication, and creating a cohesive strategy for managing and preventing medicine shortages (Expert 11).

According to Expert 11, the primary goal of the CHESSMEN project is to collect, classify, and share existing tools and practices developed at the Member State level. The project seeks to rationalise and optimise existing resources rather than creating new frameworks. Expert 11 explains, “the project aims to harmonise efforts without adding extra burden on Member States.”

The CHESSMEN project engages with relevant stakeholders by facilitating national-level dialogue with private stakeholders, participating in European-level discussions, and ensuring transparency and collaboration with pharmaceutical companies through existing platforms and models (Expert 11). By integrating activities across different administrative levels and managing these challenges effectively, the CHESSMEN project aims to support the overall EU effort in a harmonised manner (Expert 11). As highlighted by Expert 11, the CHESSMEN project produces various deliverables and studies that contribute to understanding and managing medicine shortages, such as mitigation

strategies and communication tools. As depicted by Expert 11, these efforts have been instrumental in discussions with the EMA, influencing the development of the ESMP.

According to Expert 11, one of the significant challenges the project faces is integrating activities across different administrative levels and engaging stakeholders effectively. Expert 11 highlights the importance of creating a common vision and language for addressing potential crises. The project aims to foster continuous dialogue between central and national administrations to achieve this (Expert 11).

As depicted by Expert 11, the project's impact includes facilitating discussions that inform EMA initiatives and creating a platform for continuous dialogue. Expert 11 concludes, "the project's efforts to classify shortages and share good practices aim to enhance the collective response to medicine shortages across Member States." By learning from existing experiences and effectively using resources, the CHESSMEN project avoids reinventing the wheel, spreading, sharing, and classifying knowledge to create a common vision among Member States on managing shortages, mitigation, and prevention (Expert 11). Moreover, the CHESSMEN project focuses on aligning with ongoing European activities, such as those coordinated by the EMA, to create a cohesive strategy without adding unnecessary complexity (Expert 11). Expert 11 highlights, that this ensures the efforts to be streamlined and effective, avoiding the creation of redundant networks.

The CHESSMEN project aims to identify and promote good practices for monitoring, reporting, and managing medicine shortages (Expert 11). This process involves learning from the experiences of various Member States and sharing effective strategies. Good practices are identified through examining and classifying project deliverables, providing valuable insights for Member States (Expert 11). One example is Italy's development of guidance on the use of plasma-derived products during shortages, which was shared with the CHESSMEN network, enabling other Member States to adopt similar strategies (Expert 11).

Expert 11 envisions a harmonised response to medicine shortages across EU Member States through collaboration and shared learning. To ensure sustainability beyond the three-year duration of the CHESSMEN project, a sustainability work package focuses on building lasting frameworks and relationships (Expert 11). This aims to make the collaborative approach a standard practice, ensuring that the harmonised efforts continue effectively.

In summary, the CHESSMEN project focuses on leveraging existing resources and knowledge to address medicine shortages across the EU. The project aims to harmonise

efforts, avoid duplication, and create a common vision among Member States through the classification and sharing of good practices. The project's activities, particularly those related to IT platforms, have been instrumental in discussions with the EMA, influencing the development of the ESMP and the creation of the list of critical medicines published by the EMA. This continuous dialogue helps create a common vision and language for addressing potential crises, facilitating a more coordinated approach across Europe.

5.3 Key Factors of Collaboration to Address Medicine Shortages

Based on the conducted interviews, several key factors emerged for effective collaboration and information sharing between public and private sectors in mitigating medicine shortages. Based on the qualitative evidence from the interviewed Experts, these factors are highlighted and evaluated according to their significance in addressing medicine shortages. The key factors are depicted in Table 3. The conclusions drawn from national collaborations and efforts at the EU level illustrate these key factors. The unequal distribution of representatives across collaborations prevents direct comparisons between national initiatives. Instead, the focus is on mutual learning by highlighting both effective and less effective measures. Accordingly, the analysis encompasses perspectives from both national and European levels, as the factors influencing medicine shortages and their mitigation often overlap across these scales.

Key Factor	Description
Shared Understanding	Heightened awareness and urgency due to the COVID-19 pandemic have significantly improved collaboration and prompted regulatory reforms. The pandemic served as a catalyst, highlighting the need for collaboration and a shared understanding of the urgency of addressing medicine shortages.
Trust and Open Dialogue	Trust and clear communication facilitate better compliance and proactive management of shortages through continuous stakeholder engagement. Building relationships based on trust and transparency is crucial.
Trust in Data Handling	Ensuring that data is managed securely and used appropriately is essential to prevent the fear of data misuse and maintain stakeholder confidence. Addressing data security and confidentiality concerns is vital for effective data sharing and collaboration.
Mutual Recognition	Recognising the stakeholders as partners fosters better collaboration and management of shortages. Open communication and mutual recognition enhance this collaboration.
Genuine Stakeholder Engagement	Genuine involvement of stakeholders in decision-making and evaluation processes leads to practical and impactful collaborative efforts. Effective engagement requires considering and valuing stakeholders' input.
Perceived Impact and Motivation	Tangible outcomes from collaborative efforts reinforce stakeholders' commitment and motivation. Seeing their contributions lead to real changes encourages continued participation.
Root Cause Analysis	Identifying and addressing the underlying causes of medicine shortages to develop effective long-term solutions.
External Communication	Strategic communication with the public and media helps manage perceptions and prevent panic-induced shortages. Proper timing and tailored information release are key to effective external communication.

Table 3 Key Factors of Public-Private Collaboration in Addressing Medicine Shortages

The key factors provide a comprehensive understanding of the elements necessary for effective collaboration and information sharing to address medicine shortages. The following sections will explore each of these factors, drawing on insights from the Expert interviews. Experts from both the private and public sectors provide extensive insights into the challenges and strategies related to collaborations and information sharing in the context of medicine shortages. In the private sector, Experts 1, 2, 3, 4, 5, 6, and 7, offer

perspectives from various roles within pharmaceutical associations and industries. Experts 8, 9, 10, and 11 represent the public sector, sharing their experiences from regulatory authorities. By examining these key factors, a comprehensive understanding of the essential components for effective collaboration and data sharing in the context of medicine shortages can be achieved.

5.3.1 Shared Understanding

The ongoing medicine shortages are primarily attributed to the COVID-19 pandemic, as noted by all Experts. The pandemic, along with other geopolitical and economic factors, has complicated pharmaceutical manufacturing processes by disrupting supply chains and increasing demand for certain medicines. However, the COVID-19 pandemic has also significantly raised awareness of these shortages, serving as a catalyst for enhanced collaboration and regulatory reforms. The public sector recognised the critical importance of addressing medicine shortages due to their substantial impact on public health. Simultaneously, the private sector gained a deeper understanding of the necessity for collaborative solutions. Experts from both sectors consistently emphasise the profound impact of the pandemic on their efforts to improve the resilience of medicine supplies through better collaboration, data sharing, and regulatory updates.

In Italy, the pandemic was particularly impactful, prompting improved collaboration among stakeholders according to the experts. Italy, being one of the first countries severely affected by COVID-19, had to act promptly to overcome medicine shortages. This situation underscored the necessity for closer collaboration between the industry and regulatory bodies and highlighted the need for a comprehensive view of the global supply chain. According to Expert 4, while medicine shortages were not new, the pandemic exacerbated the problem, leading to more regulatory measures at both national and European levels.

At the national level, for instance, Germany's Advisory Board for Medicine Shortages was legally mandated under the German Medicinal Products Act (AMG). At the European level, Expert 10 highlights the adoption of Regulation (EU) 2022/123 as a pivotal change for the European Medicines Agency (EMA), providing it with a formal legal mandate. This regulation transformed the EMA's role from informal, policy-driven efforts to a legally structured approach, making the agency responsible for implementing various measures, setting up groups, and requesting specific data from companies to manage shortages more effectively. Expert 11 notes that while efforts to address medicine shortages through structured dialogues with the industry were already underway by 2016 or 2017, the pandemic significantly accelerated these initiatives, bringing them to a more practical level. Additionally, the European Commission is working to reform EU

pharmaceutical legislation to overcome systemic medicine shortages and ensure the uninterrupted availability of critical medicines.

Despite these advancements, there is scepticism about whether these measures have been fully utilised. Experts from the private sector question the effectiveness of the new regulatory measures at the EU level. Expert 4 refers to the EMA's efforts during past winters, highlighting a perceived lack of decisiveness and calling for more proactive approaches. Similarly, Expert 10 notes that Member States find Regulation (EU) 2022/123 insufficient in some areas, pointing to a lack of adequate responsibility and legal authority for the EMA and Member States. Ongoing reforms in pharmaceutical legislation aim to address these gaps, enhancing the capabilities of the EMA and Member States in managing medicine shortages more effectively.

Overall, the interviews indicate that the pandemic has significantly raised awareness and prompted action regarding medicine shortages. In this context, the COVID-19 pandemic served as a catalyst for enhanced collaboration. It underscored the importance of structured communication channels, shared understanding, trust, and cooperation at both national and European levels. The lessons learned and measures implemented during this period continue to shape strategies for addressing medicine shortages, emphasising the need for ongoing cooperation and proactive management.

5.3.2 Trust and Open Dialogue

Trust and open dialogue are essential for managing medicine shortages collaboratively. Interviews with public sector experts highlight that trust is a crucial factor enabling collaboration with the private sector. Without sufficient trust, public sector initiatives often face rejection and scepticism from private stakeholders.

In Germany, the notification of medicine shortages is not legally mandated but is based on a voluntary commitment from the pharmaceutical industry. Despite this, compliance rates are notably high, exceeding 80%. Expert 8 attributes this high level of participation to the BfArM's ongoing efforts to build trust and communicate effectively with companies. The BfArM actively engages with companies to clarify criteria and discuss measures to prevent or minimise potential shortages, ensuring comprehensive reporting.

In Finland, Fimea aims to foster open discussions and a collaborative atmosphere through extensive stakeholder dialogue with supply chain stakeholders, the Ministry of Health, patient organisations, and hospital pharmacies. Expert 9 emphasises that creating an environment where stakeholders feel comfortable contacting Fimea early is crucial for continuous communication. This open dialogue is particularly important for maintaining

good relationships and ensuring medicine availability. A significant objective of Fimea's collaborative efforts is to shift from a reactive to a preventive approach in managing medicine shortages. While there is a legal mandate for notifying Fimea two months in advance of a medicine shortage, Fimea does not sanction the industry for non-compliance. They still receive many notifications, although not always two months in advance. By encouraging stakeholders to share information openly and early, Fimea hopes to address potential shortages before they become critical. Building relationships based on trust and transparency is vital to achieving this preventive stance. However, a challenge remains with varying levels of openness among companies. Some are not as forthcoming with information, hindering effective collaboration. During inspections, Fimea tries to reach out to these companies personally. Expert 9 notes that the openness of companies to collaboration may also be influenced by their corporate culture, affecting how willing they are to engage in open communication and share information. In critical cases, Fimea finds support from the EMA through the SPOC network. This collaborative network of EU Member States helps address issues with marketing authorisation holders more effectively, providing additional leverage and support in problematic cases.

Expert 10 shares similar experiences with trust-building. The EMA's collaborative approach involves explaining their role and how they can help companies, ensuring that they are seen as partners rather than just regulators. This involves initial calls to explain their support and assistance, helping companies connect with the right people at both the EMA and NCAs in Member States. Expert 10 notes that the EMA continues to seek new ways to collaborate with the industry, emphasising the value and purpose of their work and ensuring companies understand their actions.

Expert 10 reports positive feedback from companies regarding the EMA's involvement, particularly for critical shortages. The EMA's support helps companies manage shortages by guiding them on potential solutions and assisting with product allocation and prioritisation. This support enables better internal decision-making and planning, as companies appreciate having someone to consult when encountering problems. However, engaging companies not yet involved with the EMA can be challenging and often depends on individual perspectives within companies. Companies that have had direct discussions and worked closely with the EMA find it easier to engage. This direct contact fosters a more proactive relationship, with companies reaching out for guidance and advice. The EMA aims to expand these close working relationships to all MAHs, ensuring they know they can contact the agency anytime for help and guidance. Expert 10 acknowledges that changing behaviours and mindsets is a long-term process, particularly since the EMA has only recently started engaging with shortages outside of public health emergencies. Expert 1 from the pharmaceutical industry confirms the importance of this approach for

the industry. Expert 1 wants the public sector to see the industry "as a partner to get pharmacy drugs to patients and not as an enemy whose only role is to make money."

Building trust and maintaining effective communication are crucial for collaborative efforts in managing medicine shortages. Regulatory bodies like BfArM, Fimea, and the EMA emphasise the importance of open dialogue, preventive approaches, and clear communication of their roles and support to foster trust and effective collaboration with industry stakeholders.

5.3.3 Trust in Data Handling

In collaborations where data sharing plays a role, the interviews revealed that trust in data handling is a crucial factor. Although data sharing was not a primary concern within the collaborations themselves, it remains a prominent topic due to current efforts at both national and EU levels to tackle medicine shortages using data on medicine stocks and demand.

In the German Advisory Board, data security is a significant concern. Expert 8 explains that members must submit signed confidentiality documents, and the latest legislation includes personal liability for breaches of confidentiality. The BfArM operates under strict legal guidelines to protect trade and business secrets, ensuring that internal data related to medicine shortages is not shared publicly. An external service provider gathers market movement and availability data, which is treated with high sensitivity and communicated only in anonymised form. When companies report shortages, the document clearly indicates which information is made public and which is not.

In contrast, fear of data misuse can be a significant barrier to effective collaboration, as demonstrated by an example from Italy. Experts 3 and 4 describe an initiative to create a shared database between pharmacists and wholesalers to monitor shortages. Despite the potential benefits, wholesalers were reluctant to participate, fearing accusations of facilitating parallel exports. This concern undermined the project, resulting in a missed opportunity to establish a comprehensive monitoring system for medicine shortages in Italy. Expert 4 laments that while other Member States have successfully implemented similar systems, Italy could not achieve this due to these fears.

Expert 5 discusses the transparency of data sharing. They believe that if data is kept confidential and used solely by authorities to solve problems, there are no issues. However, making such data public could pose geopolitical risks, revealing the sources of essential medicines and potentially being exploited by other countries. Therefore, careful consideration is necessary to avoid unintended consequences while sharing data.

The EMA recognises these concerns. Expert 10 highlights the importance of understanding the specific needs of each stakeholder and the risks of incorrect data access. Ensuring that the right data is available to appropriate users is crucial, highlighting the complexity of the IT requirements for the ESMP. By providing tailored access while maintaining data security and confidentiality, the ESMP aims to enhance transparency and collaboration across Europe. Expert 10 notes the stringent security measures in place for the ESMP, ensuring that data sharing is heavily protected and access is strictly controlled. The ESMP portal will provide tailored information to different stakeholders without including the full data set due to confidentiality and security concerns. The portal is designed with three distinct views: a regulator view, an industry view, and a public view. Each group sees different information, reflecting their specific needs and ensuring commercial confidentiality.

Upcoming pharmaceutical legislation is expected to provide the EMA with additional powers and responsibilities, clarifying the legal basis for their involvement in managing shortages. This legal clarity is crucial for gaining the trust of companies, as it ensures that the EMA's data requests are aimed at resolving shortages rather than for commercial use. This new framework aims to enhance trust and collaboration between public and private sectors in managing medicine shortages effectively.

Trust in data handling is essential for effective collaboration in addressing medicine shortages. While data security and confidentiality are major concerns, careful management and tailored access can facilitate better cooperation and transparency.

5.3.4 Mutual Recognition

However, trust alone is not sufficient. Trust should not only be established unilaterally but should also lead to mutual recognition to enable effective collaboration. Expert 1 emphasises the positive impact of collaboration through the TTI, highlighting the mutual benefits and the continuous link between the public and private sectors. The focus is on fostering dialogues and collaborations to find solutions to medicine shortages. Furthermore, Expert 1 confirms that dialogues with other stakeholders sharing similar interests can be facilitated through the TTI. This results in increased collaborations, allowing stakeholders to come together, compare their positions, and present unified suggestions to AIFA or the government. Expert 1 has a positive outlook on collaborations, noting that people prefer to work together to find solutions rather than insisting on their own positions. This collaborative spirit is seen as essential for effectively addressing medicine shortages. The TTI simplifies the process while ensuring that the entire sector can voice its concerns and suggestions, thereby earning more influence and power through collective collaboration.

Fimea acknowledges its reliance on shared information from private stakeholders. Expert 9 notes that Fimea aims to be transparent about this dependency, highlighting the importance of mutual cooperation and information sharing to manage and prevent medicine shortages effectively. Open communication between Fimea and pharmaceutical companies in Finland has facilitated productive discussions and collaborations, proving very helpful in managing medicine shortages. While Fimea, as an authority, cannot directly procure medicines, they play a crucial role in supporting and facilitating companies in addressing shortages and coordinating solutions within their regulatory capacity.

Meanwhile, experts from the private sector report encountering a certain prejudice that the industry is primarily profit-driven and not seen as a partner. Expert 7 points out that the pharmaceutical industry often has a reputation for high profits, which can obscure the reality of the generics market. While blockbuster drugs can generate enormous revenues, the generics industry operates on much lower margins and often faces negative contribution margins. This misperception can affect policy decisions and collaboration efforts, as the industry's financial struggles are not always recognised.

Mutual recognition through open dialogues and collaborations is vital in managing medicine shortages. Stakeholders working together through platforms like the TTI can more effectively influence policy and regulatory decisions, leading to better management and prevention of shortages.

5.3.5 Genuine Stakeholder Engagement

In addition to trust and mutual recognition, the stakeholders should ultimately be properly included in the decision-making and evaluation processes. While national-level collaborations are generally depicted in a highly positive light, the situation at the EU level appears to be more complex and challenging.

On the EU level, Expert 5 points out that structured dialogue often feels like a formality rather than a genuine collaborative effort. There is a perception that the process is consultative but pre-determined by political will, leading to frustration among stakeholders. Companies feel that their input is not genuinely considered, creating a sense of disillusionment with the process. Expert 5 argues for a shift towards an industrial policy perspective when addressing medicine shortages, emphasising the importance of listening to companies. In general, Expert 5 expresses uncertainty about whether "collaboration" is the appropriate term, suggesting it sometimes feels more like "occupational therapy" rather than genuine partnership.

Expert 10 emphasises the importance of explaining the benefits of the ESMP to stakeholders, ensuring that companies understand the platform aims to help them manage shortages more effectively. This involves familiarising companies with the EU-level management of shortages, which is often less familiar to them compared to national-level management. The EMA's collaborative approach, through initial calls and continuous support, aims to show that they are partners rather than just regulators.

Greater collaboration at the EU level is desirable and could be more effective if approached in a genuinely collaborative manner. EU-level initiatives often lack effective collaboration with industry stakeholders. The new EU pharmaceutical legislation, which includes measures for managing medicine shortages, is viewed as problematic by the Experts from the private sector. Companies feel excluded from the decision-making process and question the usefulness of the established critical list of medicines. Expert 5 highlights that companies have a vested interest in delivering medicines, contradicting the notion that they might withhold information about shortages.

Genuine stakeholder engagement is crucial for addressing medicine shortages effectively. Structured dialogues at the EU level often feel like formalities, leading to frustration among stakeholders. There is a need for a more meaningful approach that includes listening to companies, simplifying processes, and ensuring that collaboration efforts are genuinely collaborative rather than perceived as "occupational therapy." This involves fostering open communication, explaining the benefits of used instruments, and addressing the capacity limitations of smaller stakeholders like pharmacies.

5.3.6 Perceived Impact and Motivation

The perceived impact of collaboration on participants is a key factor in sustaining ongoing efforts. Stakeholders' motivation plays a crucial role in effectively addressing medicine shortages. Within the TTI, experts recognise that their collaborative work has significant external impacts. Participants are motivated by tangible results, seeing the TTI as a platform where their contributions lead to real changes, such as influencing decisions by the Ministry of Health.

Experts from the private sector are particularly motivated to participate in the TTI because it allows them to incorporate their industry's perspective into decision-making processes to proactively solve the problem of medicine shortages. The industry aims to avoid shortages, as they can lead to significant financial losses. Expert 1 reports that TTI participants evaluated various measures to prevent medicine shortages, concluding that stockpiling is unsuitable since it causes shortages in other countries. Following discussions between the pharmaceutical industry and the Ministry of Health, it was

determined that stockpiling should no longer be employed as a measure to address medicine shortages. This gives Expert 1 "good hope" for a dialogue that brings solutions, emphasising that this decision was based on mutual understanding developed from industry input, not solely on industry influence. Expert 1 highlights the importance of these achievements and notes that the association's contributions within the TTI extend beyond discussions and are actively communicated to the Ministry of Health.

This perceived impact motivates participants to engage more intensively, believing their efforts can lead to significant change. Expert 1 highlights another example: the long history of price cuts in Italy, which has resulted in production costs often exceeding revenues, causing manufacturers to halt production of less profitable medicines. In response, the government is now considering implementing a price threshold to address this issue. Expert 1 views this as “one of the biggest victories in recent years,” as it has successfully drawn government attention to price-related problems in the pharmaceutical industry. Through the TTI, participants can effectively signal the government, which serves as a key motivator for their continued involvement.

Expert 2 underscores the TTI's role in fostering continuous dialogue and harmonising efforts among diverse stakeholders, including industry associations, pharmacists, wholesalers, and regulatory authorities. The TTI's ability to align different perspectives and create a unified approach is vital for effective collaboration. It allows private representatives to voice their perspectives and advocate for practical solutions, fostering a sense of partnership rather than adversarial relationships with regulatory bodies. This collaborative environment is essential for maintaining high levels of motivation and engagement.

Expert 8 views this motivation as an incentive to participate in the Advisory Board for Medicine Shortages, highlighting that this participation offers stakeholders the opportunity to directly influence decision-making processes. However, not all stakeholders share this perception, particularly at the EU level, where there is concern about a lack of genuine stakeholder engagement. Expert 1 believes that European policy “brings more problems than benefits” and often goes “in an opposite direction, that is not to solve shortages but to create” them. When collaborative efforts do not yield effective outcomes, frustration arises. This frustration can undermine motivation if participants feel their input is not genuinely considered or does not lead to tangible benefits. Expert 5 notes that one of the main challenges to collaboration is ensuring the association's participation results in meaningful outcomes. They stress the importance of considering proposed solutions and ensuring the collaborative process is not merely symbolic but leads to tangible benefits for addressing medicine shortages. Expert 5 describes that companies

have the feeling that their input is not genuinely considered, leading to a sense of disillusionment with the process. Expert 5 even hesitates when it comes to the word ‘collaboration’, as this is not always perceived as such at EU level.

At the EU level, initiatives like the Critical Medicines Alliance face practical effectiveness issues. Expert 5 describes initial optimism followed by disappointment due to reduced working groups and limited membership, which they believe undermines meaningful participation and outcomes. They highlight that structured dialogue at the EU level often feels like a formality rather than a genuine collaborative effort. There is a perception that the process is consultative but pre-determined by political will, leading to frustration among stakeholders.

Expert 5 notes that while structured dialogues and platforms exist to facilitate collaboration, their effectiveness varies. In Germany, such efforts are perceived more positively, whereas at the EU level, structured dialogues often result in the creation of multiple papers without clear outcomes. Expert 5 emphasises the importance of approaching these issues from an industrial policy perspective, suggesting that a more focused approach could be more effective in addressing the complexities of medicine shortages.

While there is some acknowledgment of public-private collaboration, private sector experts express concerns that these efforts are insufficient to overcome medicine shortages. Their primary criticism is that these collaborations are reactive and do not represent long-term solutions. Expert 5 expresses mixed feelings about the effectiveness of platforms that facilitate public-private collaboration in reducing medicine shortages. They acknowledge that while these platforms can be effective during acute shortages, significant long-term structural challenges remain. Private sector stakeholders express concerns that, despite increased collaboration, the measures taken are sometimes insufficient to address the root causes of medicine shortages

The perceived impact and motivation of stakeholders are enhanced by tangible outcomes from collaborative efforts, the ability to influence decision-making, and the creation of a partnership between public and private sectors. However, maintaining this motivation requires genuine engagement, recognition of contributions, and effective communication strategies to ensure that collaborative efforts lead to meaningful and practical solutions.

5.3.7 Root Cause Analysis

Experts from the private sector agree that the root causes of medicine shortages must be addressed for effective mitigation. While collaborations between public and private

sectors are beneficial for acute shortages, a comprehensive long-term approach is necessary.

The root causes of medicine shortages are complex. Expert 1 highlight significant challenges in pharmaceutical production due to its inherent inflexibility. Changes in production are slow and costly, requiring new infrastructure and considerable time. Expert 2 identifies several root causes for medicine shortages over the past five years, including geopolitical situations such as the COVID-19 pandemic, the war in Ukraine, and increases in energy, packaging materials, API costs, and excipient costs, that hinder manufacturing. Outdated guidelines exacerbate these issues, as they do not align with current geopolitical realities and market conditions. Expert 2 points out that the supply chains have become much longer and more fragile, necessitating a shift to shorter, more flexible supply chains with multiple sources to mitigate risks. Current long and unstable supply chains are easily disrupted. These issues do not necessarily arise from a lack of API; they can also result from packaging or colouring agent problems. If a colouring agent is unavailable, the resulting medicine no longer complies with the marketing authorisation and cannot be placed on the market (Expert 7).

According to the Experts from the private sector, a major factor driving medicine shortages are depressed prices. In Italy, prolonged price reductions have led to production costs frequently exceeding revenues, prompting manufacturers to cease production of less profitable pharmaceuticals. In Germany, reference prices for medicines represent the maximum amount statutory health insurers will cover. If the medication's selling price exceeds this reference price, patients must pay the difference themselves or receive an equivalent alternative at no additional cost. These reference prices aim to prevent burdening statutory health insurance with high costs when affordable, equivalent alternatives are available, reference prices for medications have been in place since 1989, protecting against excessive prices. Expert 6 criticises the reference prices for medicines, which do not adjust with inflation or rising costs. For example, despite significant increases in energy costs since 2022, there has been no mechanism to increase the fixed amounts for pharmaceuticals. Expert 6 argues that this lack of adjustment makes it uneconomical for manufacturers to continue producing certain medicines.

Furthermore, in Germany, experts see the causes of pharmaceutical supply issues in discount contracts ("Arzneimittel-Rabattverträge") between manufacturers and statutory health insurers. Initially aimed at lowering prices by securing large batches through tenders, these contracts reduced the number of suppliers over time, leading to fewer bids and market participants. Smaller companies often won tenders but failed to meet demand, causing disruptions. Consequently, the number of suppliers decreased, exacerbating

supply shortages. According to the Experts, health insurance funds' pursuit of discount agreements and reference pricing has significantly disrupted the market, often resulting in a "winner takes all" scenario where a few companies win contracts, and many others are left without sales for the duration of the contracts. This has driven many companies out of the generics market, jeopardizing supply security.

Expert 7 highlights that the bundling of discount agreements has led to the involuntary exit of small players from the market. As these smaller companies leave, opportunistic players, often Indian generics companies, fill the gaps. These companies may not have a stable presence in the market, further destabilizing supply chains. They tend to deliver only as long as it suits them and then withdraw, adding to supply chain instability.

Expert 6 emphasises the importance of having a diverse range of suppliers to manage shortages effectively. They explain that the market needs a variety of suppliers to ensure resilience against shortages. Instead of one company dominating the market with an 80% share and others with minimal shares, a more balanced distribution would allow the market to absorb the impact if one supplier fails. Expert 6 shared an example of a tamoxifen shortage, an API that is mainly used to treat breast cancer, to illustrate the complexity of medicine shortages. Company A, holding 75% of the market share, continued to supply tamoxifen while Companies B and C, with 20% and 5% shares respectively, could not due to a discontinued excipient. This situation underscores the necessity of transparency and the need for a diverse supplier base to prevent shortages and maintain stability in the pharmaceutical supply chain.

Expert 5 calls for a complete reorganization of pharmaceutical reimbursement and supply markets to increase supplier diversity and ensure stable medicine supply. They argue for a shift towards an industrial policy perspective when addressing these issues, suggesting that procurement processes should consider factors beyond just price, such as the geographical diversity of suppliers. This approach would ensure a more resilient supply chain by having multiple suppliers share contracts rather than relying on a single lowest bidder.

Experts from the private sector share the impression that EU policies are often counterproductive and fail to address the root causes of shortages. The new pharmaceutical legislation is seen as overly bureaucratic, resulting in data overload without practical benefits. The current early notification periods for shortages of six months as outlined in the draft of the new pharmaceutical legislation, would lead to inaccurate predictions and unnecessary administrative burdens. In Italy, extended notification periods of four months instead of two months have led to uncertainties, as anticipated shortages might not occur or may be less severe than predicted. Expert 3

suggests changing the law, while Expert 4 notes that over-reporting due to fear of fines results in inflated shortage lists, which likely overstate the problem.

Expert 7 points out that the industry also faces a lack of transparency, hindering early information sharing about medicine shortages. This lack of transparency within pharmaceutical supply chains is primarily due to their inherent complexity. The production of pharmaceuticals involves multiple stages, from raw material extraction to the final product. For example, in organic chemistry, this process can trace back to petroleum and solvents, many of which are unregulated and not required to be documented in regulatory dossiers. Another significant factor is market dynamics, especially within the generic drug industry. The generic market is highly price-sensitive. Companies prefer not to disclose their sources, especially if they have found a cheap and reliable supplier, as it provides them with a competitive advantage. Even if there were attempts to enforce disclosure by law, the generic drug industry would likely resist, valuing their competitive edge over transparency.

Addressing the root causes of medicine shortages requires a multifaceted approach involving better information exchange, flexible supply chains, updated guidelines, and diversified procurement processes. This holistic approach is necessary to create a resilient and adaptable pharmaceutical market capable of withstanding various geopolitical and economic challenges.

5.3.8 External Communication

In addition to the internal factors relevant for effective collaboration, all experts emphasise the importance of external communication. Proper media communication is critical in managing public perception and preventing panic-induced shortages. Accurate and timely information dissemination to the public is essential.

The public sector aims to communicate shortages in advance to ensure better preparedness and response, while the private sector remains cautious about early notifications due to concerns that they may lead to hoarding behaviours. The right information through the media can prevent panic among patients, which can lead to impulsive purchases and create new shortages. Ensuring that the right medicines reach the right patients is vital, and spreading incorrect messages can exacerbate the problem. Expert 1 sees poor communication as one of the biggest causes of medicine shortages, particularly once the issue has already arisen. Therefore, Expert 1 highlights that correct external communication is crucial in addressing medicine shortages.

Expert 6 points out that this issue does not only affect patients. When discussing the main challenges in overcoming medicine shortages, Expert 6 emphasises the importance of effective external communication to prevent panic. This is also the reason why early warning systems can be viewed critically. Expert 6 believes that early warning systems can be beneficial but only if the correct countermeasures are defined and implemented. For example, if the BfArM is aware of an impending shortage of a certain medicine, it could prompt another manufacturer to increase production preemptively. However, if this information leaks to doctors or pharmacists, it could lead to over-prescribing or hoarding, worsening the situation. Effective management involves early detection and ensuring that information is used constructively to mitigate shortages rather than exacerbate them.

Expert 8 stresses the importance of timing and confidentiality in communication. Revealing information too early can trigger negative behaviours and make it difficult to manage the situation effectively. According to Expert 8, a blanket approach to public communication is ineffective. Tailored communication that considers specific contexts and timing is necessary to prevent unnecessary panic and ensure equitable distribution of available supplies: "A one-size-fits-all approach, where we tell everything that reaches us, is not expedient."

Publishing information about shortages is delicate due to potential media reactions and public hoarding. Therefore, cautious consideration is required. The primary aim of medicine shortage databases is to create transparency regarding the availability of critical medicines. This transparency is crucial for all stakeholders, including citizens, companies, patients, doctors, and pharmacists. However, Expert 5 criticises the Commission's proposal for long reporting deadlines, arguing that early reporting could lead to hoarding and self-fulfilling prophecies. Furthermore, Expert 5 expresses concerns about making such data public, as it could lead to geopolitical problems by revealing the sources of essential medicines. This could be exploited by other countries, posing a significant risk to supply security. Expert 5 suggests that confidential data handling by authorities could mitigate these risks while still addressing shortages effectively.

To avoid hoarding, Fimea publishes public information on medicine shortages no earlier than two weeks before the shortage begins. Publicly shared information includes the medicine name, shortage start and end dates, and company contact details, but not the reasons for the shortage due to confidentiality. However, Expert 9 mentions that it would be helpful to publish the reason for the shortage because this is often the first question from the media and patients.

Effective management of medicine shortages hinges on strategic communication to prevent hoarding, appropriate timing of information release, and maintaining

confidentiality. These factors help minimise negative impacts and ensure a balanced distribution of medicines during shortages.

The following section presents a discussion of the results obtained from the interviews, placing them within the context of the theoretical framework and further relevant literature.

6 Discussion

The following discussion explores various approaches and key factors that influence public-private collaborations, focusing on data sharing, mutual recognition, trust-building, and the identification of root causes. The COVID-19 pandemic has acted as a catalyst, reinforcing the urgency to strengthen public-private collaboration. Through structured forums, early warning systems, and regulatory frameworks, both national and EU-level initiatives aim to address medicine shortages. Effectively, this discussion will analyse the key findings, challenges, and strategies necessary for enhancing public-private partnerships to ensure the continuous availability of essential medicines. The Data Collaborative Governance Framework provides a solid foundation for analysing public-private collaborations. However, the interviews revealed several additional factors that are essential to address medicine shortages effectively.

6.1 Approaches for Data Sharing

The interviews reveal that both national and EU-level efforts aim to foster public-private collaboration to address medicine shortages. National public-private collaborations typically occur through structured forums: Italy implements a technical table, Germany an advisory board, and Finland conducts regular situational meetings focused on information exchange. This section examines the role of data sharing and the implementation of an early warning system at the European level.

The EU and the three Member States legally mandate data sharing on medicine shortages of the pharmaceutical industry. Italy requires notifications four months in advance of a shortage, with penalties for non-compliance. Germany mandates notifications for shortages lasting more than two weeks. Finland requires notifications within two months, though penalties are not enforced, despite being legally possible. Under the proposed new pharmaceutical legislation at the EU level, shortages would need to be reported six months in advance. Consequently, according to Expert 10, the main challenges in establishing a single European platform are the differences in the timing of data provision and the absence of a uniform operational definition of medicine shortages. As described in the results section, each Member State has distinct definitions and implementations of medicine shortages, complicating the establishment of a unified European platform. Therefore, harmonising definitions and reporting procedures is critical. A unified definition would enable manufacturers to report shortages more effectively. Consequently, the study by De Weerdt et al. (2017) suggests that harmonised reporting templates across EU Member States could improve data accuracy and utility.

The European Commission's Regulation (EU) 2022/123 defines a shortage as a situation where the supply of medicine does not meet demand at a national level. The regulation's definition applies to all Member States. However, its application varies significantly across Member States which complicates data comparison. As Expert 10 explains, “If you define a shortage as supply does not equal demand, the immediate question is, at what point in the supply chain are you making that decision?” The differences in operational definitions of shortage data impede their comparison across countries. Thus, there is a risk of creating a misleading picture of the actual shortage situation as highlighted by the Experts. Accordingly, the data variability hinders the effective management of shortages (Expert 10). Consistent definitions and reporting practices are crucial for understanding and addressing shortages across the EU (De Weerdt et al., 2015). Ensuring that all Member States agree on basic principles is essential for improving collaboration and ensuring better access to medicines.

Furthermore, the early notification period is a much-discussed topic among the interviewed Experts. A study by Ravela et al. (2023) finds low compliance with early notification requirements across eight European countries. Only 5.2% of 17,250 temporary shortage notifications were reported 60 days in advance as required. The Experts from the pharmaceutical industry view the current data sharing legislation as burdensome, leading to data overload without addressing the root problems of shortages. Oftentimes, the cause for the data overload lies in the fact that the industry itself does not know about a shortage at an early stage. The industry faces a certain lack of transparency in the supply chain. While the early medicine shortage notifications aim to improve stakeholder’s preparation, private sector experts have stated that these notifications do not help them to adequately prepare. Consequently, the pharmaceutical industries share every potential shortage, while pharmacists see the risk of panic-induced hoarding.

A study by Ravela et al. (2023) highlights the benefits of progressive notification fees in Finland. The analysis of Finnish data revealed notable improvements during their implementation (June 2021–May 2022). The median notification time improved by 17 days, and the share of notifications made at least 60 days in advance increased from 3% to 20%. However, Expert 9 notes that Fimea does not impose sanctions on companies due to the complexities involved in bureaucratic procedures. Contrarily, the pharmaceutical industry opposes such sanctions, arguing that avoiding shortages is out of their scope. According to Expert 1, the public sector should regard the industry "as a partner to get pharmacy drugs to patients and not as an enemy that only aims to make money." Furthermore, criticism raised by private sector Experts highlights that long reporting deadlines and multiple reporting requirements can be counterproductive. For instance, Italy's requirement for companies to notify AIFA of shortages four months in advance

has led to over-reporting and data overload, without effectively solving the underlying problem of medicine shortages (Expert 2).

In comparison, the BfArM's approach to managing medicine shortages relies on a voluntary reporting system established through extensive dialogue and consensus among stakeholders (Expert 8). Furthermore, the voluntary reporting system does not apply to all medicines authorised in Germany. Instead, it focuses on supply-relevant and supply-critical medicines with a market share exceeding 25%, prescription-only medicines, and those on the substitution exclusion list. This targeted approach can ensure that the most critical medicines are monitored without overburdening companies with reporting requirements for less essential products, as depicted by Expert 5. Public-private collaboration can help to address these concerns to enable more effective data sharing.

None of the interviewed experts are entirely opposed to an early warning system for medicine shortages. However, they maintain a critical perspective on its effectiveness. The general idea is considered as useful, but there are concerns about harmonisation, uniformity, and geopolitical situations. Expert 6 emphasises that it is important not only to possess the data but also to know how to handle the situations the data reveals. Effective data sharing requires high-quality, standardised data and a coordinated approach to address the underlying causes of shortages. Data shared by the pharmaceutical industry can help to get an overview of the situation but does not necessarily address the problem. In general, early warning systems can optimise distribution but cannot solve actual shortages if the total supply is insufficient. Instead, sharing the information beyond the data, such as the reasons for medicine shortages, could help to address the problem. This can be achieved through establishing public-private collaboration. However, public-private collaborations are limited in mitigating medicine shortages and will be discussed in the following sections.

In general, it can be said that collaboration is a desired outcome for all involved stakeholders. However, before collaboration can become effective, certain aspects need to be considered. In conclusion, while data sharing is essential for optimising distribution and improving transparency, it cannot fully address the fundamental issue of insufficient supply. Collaborative efforts must focus on improving data quality, standardising reporting requirements, and addressing the root causes of shortages. Enhanced communication and stakeholder engagement is crucial for timely updates and coordinated actions to mitigate the impact of medicine shortages. The key factors that can have an impact on public-private collaboration are discussed in the following.

6.2 Shared Understanding

Ruijer (2021) discusses the institutional environment for collaboration, including the existence of favourable opportunities for joint efforts. In the context of the medicine shortage, COVID-19 has served as a catalyst that has significantly improved public-private collaboration.

Especially in Italy, COVID-19 acted as a catalyst for enhanced public-private collaboration (Expert 1, Expert 2). Underscoring the findings of Shusha et al. (2022) that resistance decreases in emergencies, the willingness to collaborate in times of crisis increases significantly. Italy, which was hit early and hard by the pandemic, all Experts see heightened awareness through the crisis. Accordingly, the pandemic has emphasised the need for collaborative efforts to overcome the issue of medicine shortages. Consequently, several regulations have been introduced to address medicine shortages. Although initially well-intentioned, not all introduced regulations appear to be effective and may need to be adapted in consultation with stakeholders.

Overall, this increased awareness led to a shared understanding of the urgency of tackling medicine shortages. The Expert interviews have shown that the existence of favourable opportunities, in this case, the COVID-19 pandemic as a catalyst, enhance the importance and acceptance of public-private collaboration. However, it is crucial that this acceptance continues, and that the existence of favourable opportunities is utilised to maintain sustainable collaborations.

6.3 Trust and Open Dialogue

Building trust and establishing a shared understanding of the problem are essential for effective collaborative processes and activities (Ruijer, 2021). This is particularly evident in the context of the EMA, which has demonstrated that when the purpose and benefits of collaboration are clearly communicated, industry stakeholders are more likely to engage positively.

Trust is fundamental in fostering collaboration between public and private sectors. The EMA's approach in explaining the benefits and goals of their initiatives has been instrumental in gaining the industry's cooperation. Companies that understand how public sector support can benefit them are more inclined to participate actively in collaborative efforts. This mutual understanding helps create a cooperative environment, enhancing the effectiveness of collaboration.

Expert 10 emphasizes the significance of trust-building efforts, particularly noting the positive feedback from companies closely working with the EMA on managing medicine

shortages. The development of the ESMP highlights these collaborative efforts, where industry stakeholders play a crucial role. The EMA's strategy of encouraging and supporting these stakeholders, alongside building strong partnerships, ensures that the ESMP benefits all parties involved. This collaborative effort aims to make the management of medicine shortages more effective and efficient across Europe.

Engaging companies unfamiliar with the EMA's role in managing shortages poses challenges. Expert 10 underscores the importance of building personal relationships, changing behaviours, and expanding engagement to improve collaboration. These strategies are key to ensuring effective management of medicine shortages.

Susha & Gil-Garcia (2019) point out that trust is not merely a high-level notion but requires partners to trust each other regarding the specific uses of shared data. Having a powerful shared goal can help develop trust among participants, but it is not always sufficient. Even initiatives with a very good cause can struggle to build the necessary trust. Therefore, trust must be fostered through transparency and clear communication about data usage and the benefits of collaboration.

Building trust and establishing a shared understanding of the problem are critical for effective public-private collaboration. The EMA's approach to encouraging and supporting industry stakeholders, coupled with efforts to build strong partnerships, demonstrates the importance of these elements. By focusing on clear communication, transparency, and mutual benefits, public-private collaborations can become more effective in managing medicine shortages and addressing other public health challenges.

6.4 Trust in Data Handling

The interviews revealed that the fear of data misuse, as described by Ruijer (2021) significantly impacts public-private collaboration. The example of the failed data platform between pharmacies and wholesalers, highlighted by Experts 3 and 4, illustrates how the fear of data misuse can derail collaborative efforts. Expert 10 notes that during the COVID-19 pandemic, the need for EU-level involvement in managing health crises was widely recognised and companies were more open to sharing their data. However, outside such emergencies, companies often remain suspicious and unclear about the necessity of sharing their data.

Susha & Gil-Garcia (2019) also address the fear of data misuse, arguing that data collaboratives should define the exact use of data in advance, prohibiting any other uses. This principle parallels the 'fruit of the poisonous tree' doctrine in U.S. law, which excludes evidence obtained through illegal actions (Pitler, 1968). The doctrine aims to

protect individuals' rights by ensuring that illegally obtained evidence cannot be used against them. By establishing stringent guidelines and protocols, data-driven collaborations can ensure that data is used only for its intended and legally authorised purposes. Legally binding agreements should outline these purposes, with any deviation considered a violation, akin to the 'poisonous tree' doctrine. Furthermore, transparency about data usage and informed consent from data providers can help to ensure trust between the stakeholders.

In data-driven collaborations, it is crucial that the intended use of data is clearly defined and that misuse for any other purpose is strictly prohibited. Expert 10 hopes that new pharmaceutical legislation will grant the EMA additional powers and responsibilities beyond crisis situations. This could clarify the legal basis for data requests and reassure companies that their data is used solely to resolve shortages, not for commercial or public dissemination. By providing a clear legal framework, the legislation could alleviate discomfort among companies, enhancing their understanding of the EMA's role and data usage limits. Such legislative changes could foster trust and enhance effective collaboration in public-private partnerships.

6.5 Mutual Recognition

Mutual recognition is essential for successful collaborative efforts, as highlighted by Ruijer (2021). For the pharmaceutical industry, being seen as a partner rather than an adversary is crucial. Companies seek recognition as collaborators in ensuring the availability of medicines to patients, rather than being perceived merely as profit-driven entities.

In Italy, the leadership of AIFA has fostered trust, with associations expressing confidence in the coordinator. Participants in the TTI (Technical Table on Shortages) perceive the collaboration positively, acknowledging mutual benefits. Similarly, in Finland, Fimea recognizes its reliance on shared information from private stakeholders and aims to be transparent about this dependency.

Parviainen et al. (2021) describe Finland's strategy during the COVID-19 pandemic as "epistemic humility," a concept also referred to as "humble government" by Annala et al. (2020). This approach could be highly beneficial in public-private collaboration to foster mutual recognition. "Epistemic humility" emphasizes the necessity for decision-makers to recognize and accept the limits of their knowledge, which is crucial for effective collaboration during crises like the COVID-19 pandemic.

Acknowledging uncertainty and knowledge limits is fundamental for building mutual trust. In the context of mutual recognition, the public sector should be prepared to adapt based on new information and evolving circumstances. "Epistemic humility" involves understanding that no single entity has all the answers. By openly communicating knowledge gaps and uncertainties, the public sector can build stronger, trust-based relationships. This transparency helps align efforts to manage medicine shortages and other public health challenges, promoting public-private collaboration.

The study by Parviainen et al. (2021) highlights that recognising non-knowledge can lead to more responsive and resilient governance. In mutual recognition, this means that public-private collaborations can become more resilient if both parties are willing to adapt to new information and changing circumstances, ensuring effective collaborative efforts.

6.6 Genuine Stakeholder Engagement

Collaborative governance mandates that nonstate stakeholders hold real responsibility for policy outcomes. According to Ansell & Gash (2008), stakeholders should be directly engaged in the decision-making process. This involvement is critical, as it ensures that stakeholders, have a tangible impact on policy decisions (Ansell & Gash, 2008). While ultimate authority may lie with public agencies, genuine collaboration requires stakeholders to participate actively in all decision-making stages (Ansell & Gash, 2008). Accordingly, genuine stakeholder engagement is crucial in public-private collaborations.

The industry feels more heard compared to previous years, largely due to the COVID-19 pandemic, which has been a catalyst for a shared understanding. Experts unanimously view the pandemic as a turning point in the perception of medicine shortages, facilitating a more inclusive and responsive approach to stakeholder engagement. All private stakeholders aim to integrate the industry's perspective into decision-making processes through collaboration. Being directly affected by medicine shortages and possessing extensive knowledge of the causes, they seek to contribute their insights effectively.

However, the perception of involvement differs at the national and EU levels. At the national level, private stakeholders who actively participate in collaborations feel committed to the process, as they perceive that their perspectives are genuinely heard and taken into account. In contrast, Expert 5 highlights that structured dialogue at the EU level often feels like a formality rather than genuine collaboration, driven more by political will than stakeholder input. This leads to frustration and disillusionment among companies, who feel their contributions are not genuinely considered.

According to De Weerdt et al. (2017), all stakeholders should be involved in discussions before implementing policy measures. Random or poorly considered measures will not address medicine shortages effectively. By allowing stakeholders to explain their positions, collaborations can foster mutual understanding and more effective decision-making. Reliable research on supply disruptions and medicine shortages should guide significant policy actions, with comprehensive stakeholder involvement being essential for effective mitigation strategies (De Weerdt et al., 2017).

6.7 Perceived Impact and Motivation

In Italy, private sector stakeholders view some of their contributions as victories, feeling that ideas generated in the TTI are communicated effectively to the Health Ministry. This sense of accomplishment boosts motivation and participation, highlighting the importance of small wins in collaborative efforts (Ansell & Gash, 2008).

A significant motivation for stakeholders is the proactive approach to addressing medicine shortages, particularly by integrating the industry's perspective. Seeing their influence on policy outcomes reinforces their engagement and commitment. The ability to shape policies and observe tangible outcomes from their contributions is a powerful motivator. This visibility of impact fosters a sense of efficacy and drives continued participation. Their objective is not merely to assert their position but to have their perspectives evaluated by the public sector and decisions made accordingly. Creating a collaborative environment where stakeholders feel their input is valued and impactful is essential. This involves clear communication, transparency, and a shared understanding of goals and outcomes.

Data collaboratives face the challenge of ensuring that private sector data providers understand the benefits of their participation, even if the gains are not immediate or financial (Susha & Gil-Garcia, 2019). Recognising these benefits is crucial for sustained engagement. Experts from the private sector see only a conditional benefit in data sharing. Expert 7 points out that while the industry is not averse to sharing data, they often do not see its usefulness, which can lead to an overabundance of shared data, complicating data management.

Expert 5 highlights that the proposed regulation would standardise data sharing requirements across all EU Member States, eliminating the need for individual deadlines and data sets demanded by NCAs. They support making data reporting binding at the EU level to simplify compliance but caution that standardisation must avoid redundant reporting. Furthermore, Expert 5 emphasises the need to consider the capacities of smaller companies when designing these regulations. While large companies might easily hire

additional staff to handle reporting, smaller companies that are crucial for basic and essential supplies might struggle with these demands.

Expert 2 sees the European solutions as too bureaucratic. According to Expert 2, the many new requirements of the new pharma legislation only mean an overload of data for companies at the European level, without solving the problems of shortages. The industry will have to communicate the shortage six months in advance. The data shared, according to Expert 2, is not useful, as it will create a "big amount of reports that no one will ever see except to recover them to blame companies in case of shortages."

The ability to influence policies and see tangible outcomes from their contributions is a powerful motivator for stakeholders. This visibility of impact fosters a sense of efficacy and drives continued participation. It is important to note that their objective is not merely to assert their position. Instead, they seek to have their perspectives evaluated by the public sector and then have decisions made on the basis of those evaluations. Creating a collaborative environment where stakeholders feel their input is valued and impactful is essential. This involves clear communication, transparency, and a shared understanding of goals and outcomes.

Motivation in public-private collaborations is significantly influenced by perceived impact, proactive engagement, and the recognition of contributions. Ensuring stakeholders see the benefits of their involvement and the value of data sharing is a key factor in maintaining their commitment and participation in these collaborations.

6.8 Root Cause Analysis

One of the main criticisms levelled by experts from the private sector is the failure to address the root causes of medicine shortages. While ad hoc solutions appear to work, the industry highlights a significant lack of long-term structural changes that address underlying problems. There is a pressing need for strategies that go beyond immediate fixes to ensure sustained resolution of medicine shortages. Addressing these root causes requires tackling challenges in pharmaceutical production, geopolitical and economic factors, depressed prices and market dynamics, supplier diversity, and bureaucratic challenges.

De Weerdt et al. (2017) emphasise that random or poorly considered policy measures will not effectively address supply problems. Significant policy actions should be guided by reliable research on supply disruptions and involve comprehensive stakeholder participation. Advisory committees can be effective if their advice significantly

influences decision-making outcomes. However, these committees are often distanced from actual decision-making processes, limiting their impact (Ansell & Gash, 2008).

Currently, existing collaborations appear effective in addressing reactive medicine shortages, providing a quick and straightforward way to discuss emerging problems. However, they seem to fall short in preventive measures, likely due to their limited legal authority to make deep-seated decisions. According to Expert 7, a long-term pharmaceutical strategy is necessary, likely requiring at least a decade to implement effectively. Addressing the root causes of medicine shortages requires a multifaceted approach involving better information exchange, flexible supply chains, updated guidelines, and diversified procurement processes. This holistic approach is necessary to create a resilient and adaptable pharmaceutical market capable of withstanding various geopolitical and economic challenges.

While collaborations alone cannot solve these problems, they can raise awareness among decision-makers. To effectively address medicine shortages, collaborations must evolve from mere information exchanges to mechanisms that influence policy and structural changes. This involves improving external communication, simplifying regulations, and ensuring comprehensive stakeholder involvement in policy discussions. Learning from crises and building resilience through targeted, research-based measures is essential for long-term solutions.

The key lessons from crises, such as the COVID-19 pandemic, include the necessity to prepare for future emergencies and build resilience. This requires thorough root cause analysis and developing solutions tailored to these causes. In summary, while public-private collaboration is effective in addressing immediate medicine shortages, a more comprehensive approach is necessary to tackle the root causes. This includes improving the flexibility of pharmaceutical production, updating guidelines to reflect current geopolitical realities, and restructuring supply chains. Additionally, EU policies should be revised to focus on practical, actionable insights rather than bureaucratic data collection. The key lessons from crises, such as the COVID-19 pandemic include the necessity to prepare for future emergencies and build resilience. This requires thorough root cause analysis and developing solutions tailored to these causes. It also involves simplifying regulations to reduce bureaucratic burdens and improve the flexibility of pharmaceutical production.

In summary, while public-private collaboration is effective in addressing immediate medicine shortages, a more comprehensive approach is necessary to tackle the root causes of these issues. This includes improving the flexibility of pharmaceutical production,

updating guidelines to reflect current geopolitical realities, and restructuring supply chains.

6.9 External Communication

In addition to internal factors of public-private collaboration, external communication is another key factor in the context of medicine shortages. Ruijer (2021) does not address this aspect in her framework. However, this discrepancy may also be attributed to the varying importance of external communication in different types of public-private collaborations. However, it is of paramount importance in the context of medicine shortages, which affect the general population.

Both public and private experts agree that cautious disclosure of information about medicine shortages is crucial to prevent exacerbating the problem. If patients are informed about shortages, it may lead to hoarding behaviours, as observed during the COVID-19 pandemic. However, it is not only patients who engage in hoarding. Since pharmacies are currently limited in their options to address shortages, they often rely on hoarding to manage stock. For significant shortages such as tamoxifen, measures such as faxing prescriptions to wholesalers were implemented in Germany to ensure targeted distribution. However, Expert 6 describes this approach as "extremely time-consuming, bureaucratic, and not remunerated," and therefore as a solution for extreme cases.

External communication in medicine shortages primarily occurs through two channels. Firstly, it involves interactions with the media. As emphasised by Expert 1, tailored communication is crucial for effectively managing medicine shortages. Accordingly, clear and accurate information is vital when speaking to journalists to prevent exacerbating the situation and causing panic. Miscommunication can lead to patients over-purchasing medicines, resulting in further shortages. Journalists, often lacking technical knowledge, may inadvertently spread incorrect messages, worsening the situation. Furthermore, the media sometimes transforms messages to create catchy headlines, complicating communication about shortages. Strategic, audience-specific communication ensures the correct medicines reach the right patients, preventing unnecessary alarm and ensuring appropriate distribution. Expert 1 highlights that proper information dissemination is critical to addressing shortages, as observed over the past four years.

Secondly, external communication involves using early warning systems to disseminate information. The private experts highlight that while early warning systems can be beneficial for preemptive actions, such as enabling another manufacturer to increase production in anticipation of a shortage, they also pose significant risks if not managed

properly. For instance, if an authority detects an impending medicine shortage, they can activate countermeasures. However, if this information leaks to doctors or pharmacists, it can lead to over-prescribing or hoarding, exacerbating the situation rather than alleviating it. Effective management of early warning systems requires not just early detection but also ensuring that the information is used constructively and not spread in ways that cause panic. This is why the Commission's proposal for long reporting deadlines is criticised, as early reporting could result in hoarding and create self-fulfilling prophecies. Furthermore, concerns are raised about making sensitive information public, potentially exposing supply chains to geopolitical risks.

Handling data confidentially by authorities is necessary to mitigate these risks, ensuring that sensitive information does not lead to panic or geopolitical exploitation while still effectively addressing shortages. In Finland, an attempt is made to avoid hoarding by publishing shortage reports two weeks before the start of the shortage. Hence, while early warning systems are valuable, their implementation must be accompanied by clearly defined countermeasures and cautious information dissemination to prevent negative consequences.

While there were some similarities between the findings and the Data Collaborative Governance Framework proposed by Ruijer (2021), it was not the most suitable framework for this thesis. Although the Member States and the EU aim to gather more data on medicine shortages, these collaborations do not primarily focus on data collection. The framework is specifically designed for analysing established data collaboratives, making it more useful in that context. Nevertheless, it still aided in organising the interview results. Consequently, this thesis will not extend the Data Collaborative Governance Framework. However, some theoretical elements could be validated in practice.

The discussion explored the complexities and challenges of public-private collaboration in addressing medicine shortages, emphasising the importance of trust, mutual recognition, and effective communication. Insights from the interviews have provided valuable perspectives on the successes and limitations of current collaborative efforts. Despite the advancements, significant challenges remain, particularly regarding data sharing. The following section will conclude by summarising the key points discussed in this thesis and answering the primary research question and sub-research questions. The conclusion will also outline the research limitations and propose areas for future research.

7 Conclusion

This thesis explores the enhancement of public-private collaboration to facilitate information sharing about medicine shortages within the EU. Through a qualitative approach, the thesis addresses the main research question and sub-questions by analysing strategies and experiences from three EU Member States and two EU initiatives.

RQ: How can public-private collaboration be enhanced to facilitate information sharing about medicine shortages within the European Union?

The issue of medicine shortages presents a significant challenge for the public sector, which must make appropriate decisions to ensure public health safety. Collaboration with the private sector can help address these shortages effectively. The experiences from the COVID-19 pandemic highlight the importance of collaboration to address medicine shortages and raise awareness of the urgency. However, several aspects must be considered for enhancing collaboration and ensuring its effectiveness in the future.

As recognised during the pandemic, both the public and private sectors acknowledge the negative impact of medicine shortages and their shared responsibility to ensure a stable supply to protect public health. Effectively, this increases their willingness to collaborate and exchange information on medicine shortages. The private sector's involvement in decision-making processes is crucial to maintain motivation and avoid frustration. Consequently, the pharmaceutical industry can significantly contribute by sharing its knowledge with the public sector. This knowledge must be recognised by the public sector, as it can facilitate the development of solutions that are precisely tailored to address the underlying causes.

The operation of existing data-driven solutions highlights the significance of private sector involvement. While the pharmaceutical industry and pharmacies view these data-driven solutions as pragmatic, there remains a degree of scepticism, primarily due to the lack of perceived benefits from early warning systems. Data sharing on its own will not resolve medicine shortages. Industry and pharmacy representatives highlight potential threats, such as panic-induced hoarding, which exacerbate the problem. Furthermore, they note that early notification periods are not feasible, as manufacturers themselves often face unexpected shortages due to the lack of transparency within the supply chain. Additionally, penalising non-compliance results in oversharing data, distorts the complete picture of shortages. Industry representatives argue that imposing penalties is ineffective, as shortages themselves already result in significant losses. Public-private collaborations can address these concerns and develop effective solutions. Trust and transparent

information are essential for effective collaborative governance, as they facilitate optimal data utilisation.

Ultimately, public-private collaboration can enhance efforts to mitigate medicine shortages. However, its effectiveness depends on transparent processes, mutual trust, and the willingness to benefit from the existing knowledge of all stakeholders. Nevertheless, the effectiveness of public-private collaboration is limited. While it is beneficial for information sharing and understanding the root causes, it is insufficient to mitigate the emergence of medicine shortages.

Sub-RQ1: How do different EU Member States and EU-level initiatives approach public-private collaboration and information sharing to address medicine shortages?

The thesis reveals several key approaches and insights from public-private collaborations in Italy, Germany, Finland, and the broader EU context.

Italy implements the TTI, coordinated by AIFA, which brings together a broad range of stakeholders to address medicine shortages. This platform facilitates direct communication, regular meetings, and collaborative solutions to shortages. Despite challenges in harmonising diverse stakeholder interests, the TTI has successfully addressed shortages through structured dialogue and proactive engagement.

Germany's strategy involves the Advisory Board for Medicine Shortages, established by law and managed by BfArM. The advisory board includes representatives from various sectors and focuses on building consensus and practical solutions through regular meetings. Germany’s approach underscores the importance of structured collaboration and compliance with legal frameworks to manage shortages effectively.

Fimea in Finland employs a strategy defined by the Finnish Medicines Act, focusing on obligatory medicine storage, special licences, and importation of medicines. Regular situational meetings and newsletters ensure continuous communication and collaboration with stakeholders. Fimea's proactive approach and transparent communication channels aim to stabilise medicine supply and prevent shortages.

At the EU level, the EMA plays a central role in collaborative efforts supported by Regulation (EU) 2022/123. The European Shortages Monitoring Platform (ESMP) consolidates data from various sources, facilitating transparency and collaboration among Member States. The CHESSMEN project further supports these efforts by harmonising resources and practices across Member States.

Given the evidence from the interviews, different EU Member States and EU-level initiatives approach collaboration and information sharing through structured frameworks, trust-building, mutual recognition, and proactive engagement. National strategies in Italy, Germany, and Finland showcase effective models of public-private collaboration. EU-level initiatives like the ESMP and CHESSMEN project standardise responses and enhance collective efforts. Despite advancements, challenges remain, particularly regarding data sharing and regulatory compliance, necessitating continuous improvement and adaptation of collaborative efforts.

Sub-RQ2: What are the key factors influencing effective public-private collaboration and information sharing in mitigating medicine shortages?

Through a detailed analysis of the strategies employed by Italy, Germany, Finland, and EU-level initiatives, several key factors to enhance public-private collaboration are identified.

The experience from the COVID-19 pandemic catalyses shared understanding. Thus, the experience increased awareness and urgency for enhanced public-private collaboration. Clear communication and efforts to build strong partnerships are essential to build trust and maintain open dialogue. Ensuring secure and well-defined data handling assists in maintaining stakeholder's trust and fosters effective data sharing. Mutual recognition among the stakeholders enhances collaboration and facilitates better management of shortages. Particularly, the contributions of the pharmaceutical industry should be acknowledged by the public sector to a greater extent. Furthermore, genuine stakeholder engagement ensures that stakeholder's input is acknowledged and that they are actively involved in decision-making processes. The perceived impact and motivation of stakeholders drive continued participation in collaborative efforts. When stakeholders observe tangible outcomes from their own efforts, they are more committed to public-private collaboration Addressing root causes through flexible supply chains, updated guidelines, and diversified procurement processes is necessary for long-term solutions. In addition, strategic external communication assists in managing public perception to prevent panic-induced shortages and ensures that accurate information reaches the right audiences. By focusing on these key factors, public-private collaborations can become more effective in managing and mitigating medicine shortages.

The thesis addresses the identified research gap by providing an in-depth qualitative analysis of public-private collaboration and current data sharing efforts to address medicine shortages. Through comprehensive interviews involving key stakeholders from the public and private sectors, the thesis highlights the practical challenges and opportunities in fostering effective collaboration. By focusing on the role of regulatory

authorities and their interaction with the pharmaceutical industry, the work provides insights into key factors that enhance public-private collaboration.

In summary, public-private collaboration can facilitate information sharing to identify practical solutions to medicine shortages. Nevertheless, it cannot be considered as the universal solution to mitigate medicine shortages. Long-term solutions require extensive reforms to restore stability to the pharmaceutical market and strengthen supply chains. Additionally, to recognise that the private sector faces uncertainties and does not always have complete data can encourage more productive collaboration and data-sharing solutions. While collaboration cannot fully resolve the complexity of medicine shortages, it can play a critical role in discussing and addressing the root causes.

Although this thesis acknowledges the role of public-private collaboration and information sharing, not all key aspects related to medicine shortages can be examined in depth. Considering the limitations that emerge with the evaluated qualitative data, future research could address further aspects to extend the findings of this thesis.

Future studies should include a broader range of stakeholders from different EU Member States and sectors, such as wholesalers, health insurance companies, and patient advocacy groups. This would provide a more comprehensive understanding of collaboration efforts and help generalise findings across the EU, offering a holistic view of the strategies needed to address medicine shortages effectively. Additionally, combining qualitative data with quantitative data could help ascertain the extent to which the medicine shortages are being addressed effectively. However, the current lack of comparable national shortage data represents a significant challenge.

Furthermore, effective communication with the public and media was emphasised by all stakeholders. Therefore, future research should focus on how open data and strategic communication can improve public understanding, thereby enhancing the management of medicine shortages. This includes how such communication could be integrated within early warning systems.

Additionally, research on the regulatory challenges and solutions for medicine shortages throughout the supply chain is crucial for effectively addressing the issue. Future studies should explore innovative solutions, such as developing agile regulatory frameworks and implementing advanced supply chain technologies. This could enhance efficiency and transparency to develop long-term solutions that ensure a stable supply of medicines.

By addressing these aspects, future research can build upon the findings of this thesis. Effectively, this could provide insights and effective strategies beyond public-private collaboration and information sharing to address medicine shortages in the EU.

References

Acosta, A., Vanegas, E. P., Rovira, J., Godman, B., & Bochenek, T. (2019). Medicine Shortages: Gaps Between Countries and Global Perspectives. *Frontiers in Pharmacology*, *10*, 763. https://doi.org/10.3389/fphar.2019.00763

Adams, W. C. (2015). Conducting Semi-Structured Interviews. In K. E. Newcomer, H. P. Hatry, & J. S. Wholey (Eds.), *Handbook of Practical Program Evaluation* (1st ed., pp. 492–505). Wiley. https://doi.org/10.1002/9781119171386.ch19

Adeoye-Olatunde, O. A., & Olenik, N. L. (2021). Research and scholarly methods: Semi-structured interviews. *Journal of The American College of Clinical Pharmacy*, *4*(10), 1358–1367. https://doi.org/10.1002/jac5.1441

AIFA. (n.d.). *Medicine shortages*. Retrieved 1 June 2024, from https://www.aifa.gov.it/farmaci-carenti

AlAzmi, A., & AlRashidi, F. (2019). Medication Exchange and Sharing Network Program (MESNP) initiative to cope with drug shortages in the Kingdom of Saudi Arabia (KSA). *Risk Management and Healthcare Policy*, *Volume 12*, 115–121. https://doi.org/10.2147/RMHP.S198375

Alsaawi, A. (2014). A Critical Review of Qualitative Interviews. *SSRN Electronic Journal*. https://doi.org/10.2139/ssrn.2819536

Alshenqeeti, H. (2014). Interviewing as a Data Collection Method: A Critical Review. *English Linguistics Research*, *3*(1). https://doi.org/10.5430/elr.v3n1p39

Annala, M., Leppänen, J., Mertsola, S., & Sabel, C. F. (2020). *Humble Government: How to Realize Ambitious Reforms Prudently*.

Ansell, C., & Gash, A. (2008). Collaborative Governance in Theory and Practice. *Journal of Public Administration Research and Theory*, *18*(4), 543–571. https://doi.org/10.1093/jopart/mum032

Assefa, Y., Gilks, C. F., Reid, S., Van De Pas, R., Gete, D. G., & Van Damme, W. (2022). Analysis of the COVID-19 pandemic: Lessons towards a more effective response to public health emergencies. *Globalization and Health*, *18*(1), 10. https://doi.org/10.1186/s12992-022-00805-9

Bade, C., Olsacher, A., Boehme, P., Truebel, H., & Fehring, L. (2023). Reasons for supply side driven drug shortages – A mixed-methods study on first-level, higher-level, and root causes from the perspective of marketing authorization holders. *Research in Social and Administrative Pharmacy*, S1551741123002711. https://doi.org/10.1016/j.sapharm.2023.05.007

Badreldin, H. A., & Atallah, B. (2021). Global drug shortages due to COVID-19: Impact on patient care and mitigation strategies. *Research in Social and Administrative Pharmacy*, *17*(1), 1946–1949. https://doi.org/10.1016/j.sapharm.2020.05.017

Bellinger, G., Castro, D., & Mills, A. (2004). *Data, Information, Knowledge, & Wisdom*. https://www.systems-thinking.org/dikw/dikw.htm

BfArM. (n.d.). *BfArM - Beirat zu Liefer- und Versorgungsengpässen*. Retrieved 7 June 2024, from

https://www.bfarm.de/DE/Arzneimittel/Arzneimittelinformationen/Lieferengpaesse/Beirat/_node.html

Bianchi, C., Nasi, G., & Rivenbark, W. C. (2021). Implementing collaborative governance: Models, experiences, and challenges. *Public Management Review*, *23*(11), 1581–1589. https://doi.org/10.1080/14719037.2021.1878777

Bochenek, T., Abilova, V., Alkan, A., Asanin, B., De Miguel Beriain, I., Besovic, Z., Vella Bonanno, P., Bucsics, A., Davidescu, M., De Weerdt, E., Duborija-Kovacevic, N., Fürst, J., Gaga, M., Gailīte, E., Gulbinovič, J., Gürpınar, E. U., Hankó, B., Hargaden, V., Hotvedt, T. A., … Godman, B. (2018). Systemic Measures and Legislative and Organizational Frameworks Aimed at Preventing or Mitigating Drug Shortages in 28 European and Western Asian Countries. *Frontiers in Pharmacology*, *8*, 942. https://doi.org/10.3389/fphar.2017.00942

Bogaert, P., Bochenek, T., Prokop, A., & Pilc, A. (2015). A Qualitative Approach to a Better Understanding of the Problems Underlying Drug Shortages, as Viewed from Belgian, French and the European Union's Perspectives. *PLOS ONE*, *10*(5). https://doi.org/10.1371/journal.pone.0125691

Bryman, A. (2012). The nature of qualitative research. In A. Bryman, *Social research methods* (Fifth Edition, pp. 379–414). Oxford University Press.

Bryson, J. M., Crosby, B. C., & Stone, M. M. (2015). Designing and Implementing Cross-Sector Collaborations: Needed and Challenging. *Public Administration Review*, *75*(5), 647–663. https://doi.org/10.1111/puar.12432

Castañer, X., & Oliveira, N. (2020). Collaboration, Coordination, and Cooperation Among Organizations: Establishing the Distinctive Meanings of These Terms Through a Systematic Literature Review. *Journal of Management*, *46*(6), 965–1001. https://doi.org/10.1177/0149206320901565

Chen, E., Goold, S., Harrison, S., Ali, I., Makki, I., Kent, S. S., & Shuman, A. G. (2021). Drug shortage management: A qualitative assessment of a collaborative approach. *PLOS ONE*, *16*(4). https://doi.org/10.1371/journal.pone.0243870

CHESSMEN. (2023). *Coordination and Harmonization of the Existing Systems against Shortages of Medicines—European Network*. CHESSMEN. https://www.ja-chessmen.eu/files/upload/leaflet/leaflet-chessmen.pdf

Choo, E. K., & Rajkumar, S. V. (2020). Medication Shortages During the COVID-19 Crisis: What We Must Do. *Mayo Clinic Proceedings*, *95*(6), 1112–1115. https://doi.org/10.1016/j.mayocp.2020.04.001

Clark, S. L., Levasseur-Franklin, K., Pajoumand, M., Barra, M., Armahizer, M., Patel, D. V., Wyatt Chester, K., & Tully, A. P. (2020). Collaborative Management Strategies for Drug Shortages in Neurocritical Care. *Neurocritical Care*, *32*(1), 226–237. https://doi.org/10.1007/s12028-019-00730-7

Corbin, J., & Strauss, A. (2014). *Basics of Qualitative Research: Techniques and Procedures for Developing Grounded Theory*. SAGE Publications.

De Weerdt, E., Simoens, S., Casteels, M., & Huys, I. (2015). Toward a European definition for a drug shortage: A qualitative study. *Frontiers in Pharmacology*, *6*. https://doi.org/10.3389/fphar.2015.00253

De Weerdt, E., Simoens, S., Casteels, M., & Huys, I. (2017). Clinical, Economic and Policy Implications of Drug Shortages in the European Union. *Applied Health*

Economics and Health Policy, *15*(4), 441–445. https://doi.org/10.1007/s40258-016-0264-z

Di Giorgio, D., & Scrofina, G. (2021). *IL TAVOLO TECNICO INDISPONIBILITÀ: Il dialogo nel TTI fra pubblico e privato*. Istituto Poligrafico e Zecca dello Stato S.p.A. - Libreria dello Stato Collana Tracciabilità Sanitaria.

Dill, S., & Ahn, J. (2014). Drug shortages in developed countries—Reasons, therapeutic consequences, and handling. *European Journal of Clinical Pharmacology*, *70*(12), 1405–1412. https://doi.org/10.1007/s00228-014-1747-1

Dorussen, H., Lenz, H., & Blavoukos, S. (2005). Assessing the Reliability and Validity of Expert Interviews. *European Union Politics*, *6*(3), 315–337. https://doi.org/10.1177/1465116505054835

EAHP. (2024). *EAHP 2023 Shortage Survey Report: Shortages of medicines and devices in the hospital sector – prevalence, nature and impact on patient care*. https://www.eahp.eu/sites/default/files/shortages_survey_report_final.pdf

EMA. (n.d.). *European Shortages Monitoring Platform*. Retrieved 26 April 2024, from https://www.ema.europa.eu/en/human-regulatory-overview/post-authorisation/medicine-shortages-availability-issues/european-shortages-monitoring-platform

Emerson, K., Nabatchi, T., & Balogh, S. (2012). An Integrative Framework for Collaborative Governance. *Journal of Public Administration Research and Theory*, *22*(1), 1–29. https://doi.org/10.1093/jopart/mur011

European Commission. (n.d.-a). *Q&A: Addressing medicine shortages in the EU* [Text]. European Commission. Retrieved 14 November 2023, from https://ec.europa.eu/commission/presscorner/detail/en/qanda_23_5191

European Commission. (n.d.-b). *Reform of the EU pharmaceutical legislation*. Retrieved 4 June 2024, from https://health.ec.europa.eu/medicinal-products/pharmaceutical-strategy-europe/reform-eu-pharmaceutical-legislation_en

European Commission. (2022). *Business-to-government data sharing: Questions and answers: Shaping Europe's digital future*. https://digital-strategy.ec.europa.eu/en/faqs/business-government-data-sharing-questions-and-answers

Ferreira, J. (n.d.). *Monitoring and mitigating shortages of medicines and devices*. https://www.ema.europa.eu/en/documents/presentation/presentation-session-1-monitoring-and-mitigating-shortages-medicines-and-devices-j-ferreira-ema_en.pdf

Fimea. (n.d.). *Shortages*. Retrieved 1 June 2024, from https://fimea.fi/en/databases_and_registers/shortages

Fimea. (2023, February 13). *EU Joint Action project CHESSMEN has begun*. Fimea. https://fimea.fi/en/-/eu-joint-action-project-chessmen-has-begun

Gray, A., & Manasse, H. (2012). Shortages of medicines: A complex global challenge. *Bulletin of the World Health Organization*, *90*(3), 158–158. https://doi.org/10.2471/BLT.11.101303

Hale, K., & Brown, M. (2014). Chapter 1: Overview and Context of the Research Process. In M. Brown & K. Hale, *Applied research methods in public and nonprofit organizations* (1st ed., pp. 21–54). Jossey-Bass.

Handoo, S., Khera, D., Nandi, P., Sahu, S., & Arora, V. (2012). A comprehensive study on regulatory requirements for development and filing of generic drugs globally. *International Journal of Pharmaceutical Investigation*, *2*(3), 99. https://doi.org/10.4103/2230-973X.104392

Huss, G., Barak, S., Reali, L., Magendie, C., Carrasco-Sanz, A., Somekh, E., Cohen, R., Levy, C., Namazova-Baranova, L., Vural, M., & Pettoello-Mantovani, M. (2023). Drug Shortages in Pediatrics in Europe: The Position of the European Pediatric Societies. *The Journal of Pediatrics*, *261*, 113472. https://doi.org/10.1016/j.jpeds.2023.113472

Jovanović Lješković, N., Jovanović Galović, A., Stojkov, S., Jojić, N., & Gigov, S. (2021). Medicine Shortages in Serbia: Pharmacists' Standpoint and Potential Solutions for a Non-EU Country. *Pharmaceutics*, *13*(4), 448. https://doi.org/10.3390/pharmaceutics13040448

Kleja, M. (2023, November 28). *Sweden: Failing to report drug shortages could now lead to heavy fines*. Www.Euractiv.Com. https://www.euractiv.com/section/health-consumers/news/sweden-failing-to-report-drug-shortages-could-now-lead-to-heavy-fines/

Klievink, B., Van Der Voort, H., & Veeneman, W. (2018). Creating value through data collaboratives: Balancing innovation and control. *Information Polity*, *23*(4), 379–397. https://doi.org/10.3233/IP-180070

Kuckartz, U. (2016). *Qualitative Inhaltsanalyse. Methoden, Praxis, Computerunterstützung* (3. Auflage). Beltz Verlagsgruppe.

Louloudi, J., Morfonios, N., & Zafeiropoulos, K. (2023, April 19). Why Europe is chronically running out of meds. *VoxEurop*. https://voxeurop.eu/en/health-why-europe-chronically-running-out-meds/

Magnusson, E., & Marecek, J. (2015). Chapter 5: Designing the interview guide. In E. Magnusson & J. Marecek, *Doing Interview-based Qualitative Research: A Learner's Guide* (1st ed., pp. 46–57). Cambridge University Press. https://doi.org/10.1017/CBO9781107449893

Mahoney, J., & Goertz, G. (2006). A Tale of Two Cultures: Contrasting Quantitative and Qualitative Research. *Political Analysis*, *14*(3), 227–249. https://doi.org/10.1093/pan/mpj017

McNamara, M. (2012). Starting to Untangle the Web of Cooperation, Coordination, and Collaboration: A Framework for Public Managers. *International Journal of Public Administration*, *35*(6), 389–401. https://doi.org/10.1080/01900692.2012.655527

Mertens, D. M. (2010). Chapter 3: Literature Review and Focusing the Research. In D. M. Mertens, *Research and evaluation in education and psychology: Integrating diversity with quantitative, qualitative, and mixed methods* (3. ed, pp. 89–121). Sage.

Miljković, N., Godman, B., Kovačević, M., Polidori, P., Tzimis, L., Hoppe-Tichy, T., Saar, M., Antofie, I., Horvath, L., De Rijdt, T., Vida, R. G., Kkolou, E., Preece,

D., Tubić, B., Peppard, J., Martinez, A., Yubero, C. G., Haddad, R., Rajinac, D., … Miljković, B. (2020). Prospective Risk Assessment of Medicine Shortages in Europe and Israel: Findings and Implications. *Frontiers in Pharmacology*, *11*, 357. https://doi.org/10.3389/fphar.2020.00357

Miljković, N., Polidori, P., Vinci, D. L., Poje, D. K., Makridaki, D., Kohl, S., & Süle, A. (2024). Results of EAHP's 2023 shortages survey. *European Journal of Hospital Pharmacy*. https://doi.org/10.1136/ejhpharm-2024-004090

Mulcahy, A. W., Rao, P., Kareddy, V., Agniel, D., Levin, J. S., & Schwam, D. (2021). Assessing Relationships Between Drug Shortages in the United States and Other Countries. *RAND*.

Musazzi, U. M., Di Giorgio, D., & Minghetti, P. (2020). New regulatory strategies to manage medicines shortages in Europe. *International Journal of Pharmaceutics*, *579*, 119171. https://doi.org/10.1016/j.ijpharm.2020.119171

Naderifar, M., Goli, H., & Ghaljaie, F. (2017). Snowball Sampling: A Purposeful Method of Sampling in Qualitative Research. *Strides in Development of Medical Education*, *14*(3). https://doi.org/10.5812/sdme.67670

Oliver, N., Lepri, B., Sterly, H., Lambiotte, R., Deletaille, S., De Nadai, M., Letouzé, E., Salah, A. A., Benjamins, R., Cattuto, C., Colizza, V., De Cordes, N., Fraiberger, S. P., Koebe, T., Lehmann, S., Murillo, J., Pentland, A., Pham, P. N., Pivetta, F., … Vinck, P. (2020). Mobile phone data for informing public health actions across the COVID-19 pandemic life cycle. *Science Advances*, *6*(23), eabc0764. https://doi.org/10.1126/sciadv.abc0764

Parviainen, J., Koski, A., & Torkkola, S. (2021). 'Building a Ship while Sailing It.' Epistemic Humility and the Temporality of Non-knowledge in Political Decision-making on COVID-19. *Social Epistemology*, *35*(3), 232–244. https://doi.org/10.1080/02691728.2021.1882610

PGEU. (2024). *PGEU Medicine Shortages Report 2023*. PGEU. https://www.pgeu.eu/wp-content/uploads/2024/01/PGEU-Medicine-Shortages-Report-2023.pdf

PharmNet.Bund. (n.d.). *Veröffentlichte Lieferengpassmeldungen*. Retrieved 1 June 2024, from https://anwendungen.pharmnet-bund.de/lieferengpassmeldungen/faces/public/meldungen.xhtml

Pitler, R. M. (1968). The Fruit of the Poisonous Tree Revisited and Shepardized. *California Law Review*, *56*(3), 579–651.

Praditya, D., & Janssen, M. (2015). Benefits and challenges in information sharing between the public and private sectors. In *Proceedings of the 15th European Conference on eGovernment 2015* (pp. 246–253).

Provan, K. G., & Kenis, P. (2007). Modes of Network Governance: Structure, Management, and Effectiveness. *Journal of Public Administration Research and Theory*, *18*(2), 229–252. https://doi.org/10.1093/jopart/mum015

Ravela, R., Airaksinen, M., & Lyles, A. (2023). State of the European Union's early notification obligation for drug shortages: Enforcement and compliance in eight European countries (2020–2022). *Journal of Pharmaceutical Policy and Practice*, *16*(1), 135. https://doi.org/10.1186/s40545-023-00646-w

Regulation (EU) 2022/123 of the European Parliament and of the Council of 25 January 2022 on a Reinforced Role for the European Medicines Agency in Crisis Preparedness and Management for Medicinal Products and Medical Devices (Text with EEA Relevance), 020 OJ L (2022). http://data.europa.eu/eli/reg/2022/123/oj/eng

Rezaei, A., & Kamali, A. R. (2022). Analysis of collaboration between AstraZeneca and the higher education sector in the UK. *Industry and Higher Education*, *36*(6), 861–869. https://doi.org/10.1177/09504222221086520

Romano, S., Galante, H., Figueira, D., Mendes, Z., & Rodrigues, A. T. (2021). Time-trend analysis of medicine sales and shortages during COVID-19 outbreak: Data from community pharmacies. *Research in Social and Administrative Pharmacy*, *17*(1), 1876–1881. https://doi.org/10.1016/j.sapharm.2020.05.024

Ruijer, E. (2021). Designing and implementing data collaboratives: A governance perspective. *Government Information Quarterly*, *38*(4). https://doi.org/10.1016/j.giq.2021.101612

Saldaña, J. (2016). *The coding manual for qualitative researchers* (3rd ed.). SAGE.

Shukar, S., Zahoor, F., Hayat, K., Saeed, A., Gillani, A. H., Omer, S., Hu, S., Babar, Z.-U.-D., Fang, Y., & Yang, C. (2021). Drug Shortage: Causes, Impact, and Mitigation Strategies. *Frontiers in Pharmacology*, *12*. https://doi.org/10.3389/fphar.2021.693426

Susha, I., & Gil-Garcia, J. R. (2019). *A Collaborative Governance Approach to Partnerships Addressing Public Problems with Private Data*. Hawaii International Conference on System Sciences. https://doi.org/10.24251/HICSS.2019.350

Susha, I., Janssen, M., & Verhulst, S. (2017). *Data Collaboratives as a New Frontier of Cross-Sector Partnerships in the Age of Open Data: Taxonomy Development*. Hawaii International Conference on System Sciences. https://doi.org/10.24251/HICSS.2017.325

Susha, I., Schiele, J., & Frenken, K. (2022). Business-to-Government Data Sharing for Public Interests in the European Union: Results of a Public Consultation. In M. Janssen, C. Csáki, I. Lindgren, E. Loukis, U. Melin, G. Viale Pereira, M. P. Rodríguez Bolívar, & E. Tambouris (Eds.), *Electronic Government* (Vol. 13391, pp. 515–529). Springer International Publishing. https://doi.org/10.1007/978-3-031-15086-9_33

Thomson, A. M., & Perry, J. L. (2006). Collaboration Processes: Inside the Black Box. *Public Administration Review*, *66*(s1), 20–32. https://doi.org/10.1111/j.1540-6210.2006.00663.x

Van Thiel, S. (2021). Chapter 3: Theoretical Framework. In S. Van Thiel, *Research Methods in Public Administration and Public Management: An Introduction* (2nd ed., pp. 24–42). Routledge. https://doi.org/10.4324/9781003196907

VanderStoep, S. W., & Johnston, D. D. (2009). Chapter 1: Understanding Research. In S. W. VanderStoep & D. D. Johnston, *Research methods for everyday life: Blending qualitative and quantitative approaches* (1st ed, pp. 1–24). Jossey-Bass.

Vassal, G., Kozhaeva, O., Griskjane, S., Arnold, F., Nysom, K., Basset, L., Kameric, L., Kienesberger, A., Kamal, S., Cherny, N., Bricalli, G., Latino, N., & Kearns, P. (2021). Access to essential anticancer medicines for children and adolescents in Europe. *Annals of Oncology*, *32*(4), 560–568. https://doi.org/10.1016/j.annonc.2020.12.015

Verhulst, S., Young, A., & Srinivasan, P. (n.d.). *An Introduction to Data Collaboratives: Creating Public Value by Exchanging Data*. https://datacollaboratives.org/static/files/data-collaboratives-intro.pdf

Vogler, S. (2024). Tackling medicine shortages during and after the COVID-19 pandemic: Compilation of governmental policy measures and developments in 38 countries. *Health Policy*, *143*. https://doi.org/10.1016/j.healthpol.2024.105030

Zovi, A., Musazzi, U. M., D'Angelo, C., Piacenza, M., Vimercati, S., & Cilurzo, F. (2021). Medicines shortages and the perception of healthcare professionals working in hospitals: An Italian case study. *Journal of Interprofessional Education & Practice*, *25*. https://doi.org/10.1016/j.xjep.2021.100472

Appendix

A Excerpt of the List of Medicines with Equivalent Medicines Available from 01.06.2024

NB: i medicinali, per i quali il Titolare AIC non abbia provveduto a comunicare la data effettiva di fine carenza, continueranno ad essere mantenuti nel presente elenco anche oltre la "data di fine presunta" precedentemente comunicata e qui indicata.

Elenco dei farmaci carenti per i quali sono disponibili equivalenti aggiornato al 31/05/2024

Nome medicinale	Codice AIC	Principio attivo	Forma farmaceutica e dosaggio	Titolare AIC	Data inizio	Fine presunta	Equivalente	Motivazioni	Suggerimenti/indicazioni AIFA	Nota AIFA	Classe di rimborsabilità
ABMONO	025358045	ISOCONAZOLO NITRATO	"1% CREMA VAGINALE" 1 TUBO DA 30 G + 6 APPLICATORI MONOUSO	FARMITALIA INDUSTRIA CHIMICO FARMACEUTICA S.R.L.	01.02.2019		SI	Cessata commercializzazione definitiva	Per trattamento alternativo si consiglia di rivolgersi allo specialista o al M.M.G		A TOTALE CARICO DELL'ASSISTITO
ABOCLAV	037350028	ACIDO CLAVULANICO + AMOXICILLINA	"400 MG + 57 MG/5 ML POLVERE PER SOSPENSIONE ORALE" FLACONE DA 70 ML CON CUCCHIAIO DOSATORE	AESCULAPIUS FARMACEUTICI SRL	15.12.2023		SI	Elevata richiesta	Per trattamento alternativo si consiglia di rivolgersi allo specialista o al M.M.G	A TOTALE CARICO DEL SSN.	A TOTALE CARICO DEL SSN.
ABRATERONE DR. REDDY'S	049397021		"500 MG COMPRESSE RIVESTITE CON FILM" 56(1 COMPRESSE IN BLISTER PVC/PVDC/AL	DR. REDDY'S S.R.L.	15.07.2023		SI	Cessata commercializzazione definitiva	Per trattamento alternativo si consiglia di rivolgersi allo specialista o al M.M.G	A CARICO DEL SSN AMBITO OSPED.	A CARICO DEL SSN AMBITO OSPED.
ABRATERONE EG	049475344	ABIRATERONE ACETATO	"500 MG COMPRESSE RIVESTITE CON FILM" 56(1 COMPRESSE IN BLISTER DIVISIBILE PER DOSE UNITARIA AL- PVC/PE/PVDC	EG S.P.A.	26.01.2023		SI	Cessata commercializzazione definitiva	Per trattamento alternativo si consiglia di rivolgersi allo specialista o al M.M.G	A CARICO DEL SSN AMBITO OSPED.	A CARICO DEL SSN AMBITO OSPED.
ABRATERONE MYLAN	049686052	ABIRATERONE ACETATO	500 MG - COMPRESSA RIVESTITA CON FILM - USO ORALE - BLISTER (ALU-PVC/PE/PVDC) - 56 COMPRESSE	MYLAN IRELAND LIMITED	30.06.2024		SI	Cessata commercializzazione definitiva	Per trattamento alternativo si consiglia di rivolgersi allo specialista o al M.M.G	A CARICO DEL SSN AMBITO OSPED.	A CARICO DEL SSN AMBITO OSPED.
ACARBOSIO AUROBINDO	047612027	ACARBOSIO	"50 MG COMPRESSE" 40 COMPRESSE IN BLISTER PVC/PE/PVDC/AL	AUROBINDO PHARMA (ITALIA) S.R.L.	19.03.2024		SI	Elevata richiesta: distribuzione contingentata (carenza relativa solo al canale retail)	Per trattamento alternativo si consiglia di rivolgersi allo specialista o al M.M.G	A TOTALE CARICO DEL SSN.	A TOTALE CARICO DEL SSN.
ACARBOSIO DOC GENERICI	044155012	ACARBOSIO	"50 MG COMPRESSE" 40 COMPRESSE IN BLISTER PVC/PE/PVDC-AL	DOC GENERICI SRL	08.04.2024		SI	Elevata richiesta	Per trattamento alternativo si consiglia di rivolgersi allo specialista o al M.M.G	A TOTALE CARICO DEL SSN.	A TOTALE CARICO DEL SSN.

Declaration of Authorship

I hereby declare that, to the best of my knowledge and belief, this Master Thesis titled "Data-Driven Solutions for Medicine Shortages in the European Union: The Role of Collaborative Governance" is my own work. I confirm that each significant contribution to and quotation in this thesis that originates from the work or works of others is indicated by proper use of citation and references.

Tallinn, 07 June 2024

Lisa Emilia Vogel