

# Exploring the Feasibility of offering a GDP-Compliant Medicine E-Commerce Fulfilment Service

A Case Study at PostNL Fulfilment

Master Thesis

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Project Duration: October, 2025 - March, 2026  
Master: Transport, Infrastructure and Logistics, TU Delft  
Faculty: Faculty of Civil Engineering and Geosciences, Delft

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# Preface

*It has been an unforgettable journey. I started my studies in Delft without fully knowing what to expect, and now here we are. This thesis marks the final step in completing my Master's degree in Transport, Infrastructure and Logistics. Over the past six months, with the support of my supervisors, the colleagues at PostNL, my family and my friends, I had the opportunity to conduct and complete this research at PostNL Fulfilment. Working as a student within a large and professional organisation, surrounded by kind and motivated people, has been a fantastic experience. It allowed me to learn a great deal during the final months of my studies.*

*At PostNL Fulfilment, I would especially like to thank my supervisor Quirin. Over the past six months, you were always there to guide me and to introduce me to your organisation. I truly felt part of the team and greatly appreciated the freedom you gave me to shape this research myself. I experienced our collaboration as very pleasant and would like to thank you and the entire PostNL team for the warm welcome, guidance and enjoyable atmosphere. Hopefully our paths will cross again in the future.*

*I would also like to sincerely thank my supervisors at TU Delft. To be honest, I initially felt a bit intimidated by the idea of completing my thesis independently, but you quickly proved that these concerns were unnecessary. Jan Anne, thank you for our weekly meetings and for helping me bring structure and clarity to this research. After every meeting, I felt reassured and motivated to continue, even during moments when the process felt overwhelming. Joyce, thank you for sharing your legal expertise. It was incredibly helpful to know that I could always turn to you with questions and that you gave me confidence in the legal foundations of this work. Jaap, thank you for agreeing to be my chair. After our earlier research project at Fokker, I very much hoped that you would also be involved in my graduation project, as I have always experienced your guidance as both positive and supportive. If I had to choose again, I would gladly select the same committee.*

*On a personal note, there are many people I would like to thank. During my student years, I met so many wonderful people who made this period one of the most enjoyable times of my life. Thank you all for that. I would especially like to thank both my childhood friends and the very good friends I met during my student years. We have experienced so much together over the past years, not always easy moments, but with each other's support we always managed to get through them. The same was true during the writing of this thesis. Whenever the process became challenging, I knew I could rely on them. My dear friends, especially my roommates, were always there to support me when needed and to celebrate every milestone with me, which made the process of finishing my thesis not only manageable but also something I could enjoy.*

*Finally, I would like to thank my family. As the youngest of three, the path was often paved a little for me, which helped me make well-informed choices throughout my studies. Pien and Rut, thank you for always supporting me. I am very proud of both of you and everything you have accomplished. Dear mom and dad, I want to thank you for always giving me the freedom to make my own choices, both in my studies and in my personal development, and for making those choices possible in the first place. Knowing that I always had your support gave me the confidence to follow my own path, which resulted in an incredibly enjoyable and unforgettable time.*

R.A.C. Hoogeveen  
Delft, March 2026

# Abstract

*This thesis examines how the Dutch legislative and institutional framework determines the opportunities and limitations for non-pharmaceutical fulfilment providers in the B2C fulfilment of medicines. It explores the legal, organisational and market conditions that would allow a non-pharmaceutical company to offer an e-commerce fulfilment service that complies with Good Distribution Practice (GDP), with using PostNL Fulfilment as a case study. An exploratory mixed-methods research design is employed, combining literature and desk research on the Dutch pharmaceutical supply chain and legislative context, a stakeholder analysis, semi-structured interviews with pharmacists and other stakeholders, and the development of eight fulfilment scenarios. These scenarios are analysed using a framework of legal requirements and market-oriented design criteria. An actor-level implication analysis then assesses the institutional and administrative consequences.*

*The results show that pharmaceutical logistics in the Netherlands are regulated by a pharmacy-focused licensing system based on roles and locations, in which pharmacists remain responsible for dispensing medicines and ensuring patient safety. Non-pharmaceutical participation is therefore only possible through carefully regulated hybrid arrangements that ensure compliance with GDP, verifiable separation of responsibilities and robust contractual oversight. While none of the examined scenarios are explicitly on legal basis, the feasibility decreases as the executing party's role becomes more similar to that of a full logistics back office, comparable to the operational structure typically observed in conventional non-pharmaceutical fulfilment services. This is due to interpretative grey areas at the interface between dispensing and logistics, as well as the centralisation of multiple pharmacies and the associated distribution of roles and medication flows. Market feasibility is greatest in predictable segments with large volumes (e.g. repeat prescriptions), although it remains structurally constrained by the highly regulated nature of the pharmaceutical supply chain, which is characterised by a limited number of dominant actors who largely shape market access and operational conditions. In general, scalable implementation requires step-by-step expansion and clarification of regulations/legislation and governance designs that can be monitored and audited.*

**Key words**— pharmaceutical fulfilment, medicine e-commerce, Good Distribution Practice (GDP), Dutch medicines legislation, third-party logistics (3PL)

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# Nomenclature

## Abbreviations

<b>Abbreviation</b>	<b>Definition</b>
3PL	Third-Party Logistics Provider
AIS	Apotheek Informatie Systeem
AP	Autoriteit Persoonsgegevens
AV	Algemene Verkoop
B2B	Business-to-Business
B2C	Business-to-Consumer
CBG	College ter Beoordeling van Geneesmiddelen
CIBG	Centraal Informatiepunt Beroepen Gezondheidszorg
DC	Design criteria
DPIA	Data Protection Impact Assessment
DTP	Direct-to-Patient
EC	European Commission
EEA	European Economic Area
EMA	European Medicines Agency
EU	European Union
FMD	Falsified Medicines Directive
GDP	Good Distribution Practice
GDPR	General Data Protection Regulation
Gnw	Geneesmiddelenwet
HREC	Human Research Ethics Committee
IGJ	Inspectie Gezondheidszorg en Jeugd
JV	Joint Venture
KNMP	Koninklijke Nederlandse Maatschappij ter bevordering der Pharmacie
KPI	Key Performance Indicator
MSc	Master of Science
NMVO	Nederlandse Medicijnen Verificatie Organisatie
NPCF	Nederlandse Patiënten Consumenten Federatie
O2O	Online-to-Offline
PI	Power–Interest
QMS	Quality Management System
R	Requirement
RP	Responsible Person
RWAs	Reduced Wholesale Arrangements
SQ	Sub-question
TIL	Transport, Infrastructure and Logistics
U.A.	Uitgesloten van Aansprakelijkheid
UA	Uitsluitend Apotheek
UAD	Uitsluitend Apotheek en Drogist
UR	Uitsluitend op Recept
VWS	Ministerie van Volksgezondheid, Welzijn en Sport
WDA	Wholesale Distribution Authorization
Zvw	Zorgverzekeringswet

# Summary

## Introduction and research context

The Dutch pharmaceutical supply chain is characterised by strict regulatory authority supervision, clearly defined institutional roles and high patient safety standards. Medicines are dispensed exclusively by licensed pharmacists (Art. 61, Gnw), and the entire supply chain is subject to European and national legislation and regulations, including the Medicines Act and Good Distribution Practice (GDP) guidelines.

However, the digitisation of pharmaceutical services and the growth of e-commerce logistics are prompting questions as to whether parts of the pharmaceutical fulfilment process could be reorganised [1]. In particular, large non-pharmaceutical fulfilment centra have advanced storage, order picking and last-mile capabilities that could increase efficiency within the pharmacy sector. Fulfilment refers to the outsourced logistical back-office process through which customer orders are operationally executed on behalf of a selling party. In practical terms, fulfilment encompasses the end-to-end management of physical product flows. However, the involvement of non-pharmaceutical fulfilment providers in pharmaceutical supply chains raises complex legal and organisational questions. In particular, the distinction between logistics handling and regulated delivery activities is not always clearly defined within existing legislative frameworks.

Against this background, this study addresses the central research question:

*'How does the Dutch legislative and institutional framework influence the possibilities and limitations for non-pharmaceutical fulfilment providers in B2C medicine fulfilment?'*

This research question is formulated, because there is a clear gap in the literature. There are sources that demonstrate interest in e-pharmacy logistics [38] [56] [60], but none of the literature reviewed analysed the desired model in detail. Researching this niche model is difficult because it sits at the intersection of health legislation, supply chain practice and emerging e-commerce. In particular, insufficient insight exists into whether, and under what legal and regulatory conditions, a non-pharmaceutical fulfilment company could undertake the logistical execution of B2C prescription medicine fulfilment on behalf of multiple pharmacies without compromising legal responsibility, quality standards and patient safety.

Four sub-questions have been formulated to answer this main research question:

1. How is extramural pharmaceutical care and medicine logistics organised in the Netherlands, and how does this compare to international approaches to B2C medicine delivery?
2. What do current Dutch medicines legislation and GDP guidelines prescribe regarding medicine logistics?
3. To what extent is there a viable market for external fulfilment services in the pharmacy sector, and how willing are pharmacists to outsource the fulfilment of medicines?
4. Which fulfilment scenarios can be developed for non-pharmaceutical fulfilment providers, and how feasible are they in legal, logistical, and organisational terms?
5. What are the systemic and actor-specific implications of potential participation of non-pharmaceutical fulfilment providers in B2C medicine logistics?

Instead of conducting a purely technical or financial feasibility study, the research takes an exploratory approach. The aim of the research is to systematically identify the structural possibilities and limitations by developing and evaluating a series of organisational and legal scenarios. Based on these scenarios, the study analyses the legal boundaries, institutional frictions, and implications for different actors that would arise if non-pharmaceutical fulfilment suppliers were to take on the logistical back-office role for one or more pharmacies.

## Research design and methodology

In order to address this research gap, a qualitative, multi-methods design was adopted:

- **Literature review and desk research** The study was conducted to analyse the structure of the pharmaceutical supply chain, the legal framework governing medicine logistics and international developments in e-pharmacy distribution models. This theoretical research formed the basis of the study's context and concepts;
- **Stakeholder analysis** was conducted to determine the roles and responsibilities of the key players in the pharmaceutical supply chain, such as pharmacies, wholesalers, regulators and logistics providers;
- **Semi-structured interviews** were conducted with pharmacists, legal experts and logistics professionals. These interviews provided insights into the interpretation of legislation, operational constraints and pharmacists' willingness to outsource logistical activities.

The empirical research then translated the legal and institutional findings into a structured analytical framework. This framework consists of:

- **Legal and regulatory requirements (R1–R4)**, derived from medicines legislation and GDP guidelines;
- **Market design criteria (DC1–DC7)**, which were derived from market structure analysis and stakeholder interviews.

These elements were combined to create a feasibility framework for assessing potential fulfilment configurations. Based on this analytical foundation, eight organisational fulfilment scenarios were developed and evaluated. A case study of PostNL Fulfilment was then conducted to test the applicability of the analytical framework in a real-world logistics context. Finally, an impact analysis was conducted to assess the implications of introducing new hybrid structures for stakeholders.

## Pharmaceutical supply chain and its legislation

The Dutch pharmaceutical supply chain operates within a strictly regulated, pharmacy-centered model. Medicines typically go from the manufacturer to the wholesaler and then to the pharmacy before finally reaching the patient [16]. However, pharmacies are not merely distribution points; they have exclusive legal authority to dispense prescription-only (UR) and pharmacy-only (UA) medicines, and are responsible for providing patient information, conducting medicine safety surveillance, ensuring product traceability, implementing recall procedures and ensuring compliant storage (Art. 61.1, Gnw). Although digitisation and central processing have improved efficiency, the final dispensing of medicines remains the legal responsibility of the pharmacist, meaning the system is resistant to complete logistical outsourcing.

Consequently, the pharmaceutical logistics sector is subject to a legislative system that clearly distinguishes between distribution and dispensing activities, as set out in the Dutch Medicines Act and the European GDP guidelines. This role-based licensing system significantly restricts the ability of non-pharmaceutical actors to participate in the delivery of medicines. The legislative analysis identified four mandatory legal requirements for the feasibility of the scenario:

- The dispensing of medicines is specific to a person and a location (Art. 61.5, Gnw): *UR/UA medicines are dispensed exclusively by a licensed pharmacist (R1)*;
- Organisations that store or distribute medicines must hold the relevant pharmacy license or a WDA (Art. 18.1, Gnw): *All the necessary permits are in place (R2)*;
- According to the IGJ, unlabeled medicines may only be stored at legally recognised locations under GDP supervision: *Unlabeled medication is stored in legally recognised locations only (R3)*;
- GDP requirements apply throughout the entire supply chain, imposing strict obligations regarding temperature control, validated transport, documentation, traceability, quality systems and staff training: *Full compliance with GDP rules is guaranteed for all storage and transport activities (R4)*.

Table 1 shows that, although some legislative domains have strict legal requirements, others are subject to interpretative uncertainty. In particular, there is ambiguity surrounding the operational boundary between logistical handling and dispensing-related activities, and the legislative treatment of centralised fulfilment centres serving multiple pharmacies.

**Table 1:** Legislative certainty map based on legal and regulatory analysis

<b>Legislative domain</b>	<b>Hard must-comply (legal certainty)</b>	<b>Grey areas (interpretative uncertainty)</b>
Dispensing authority	'Ter hand stellen' is exclusively reserved for a licensed pharmacy; legal responsibility remains with the pharmacist.	The operational boundary between logistics handling and dispensing-related activities is not explicitly defined in legislation.
Licensing structure	Licences are legally bound to a specific legal entity and recognised physical location (pharmacy or wholesale).	The extent to which hybrid structures (e.g. joint ventures, cooperatives or embedded pharmacy models) satisfy the location-based licensing logic remains interpretative.
Storage duration	Storage of medicines for more than 72 hours requires a wholesale or pharmacy license.	The interpretation of structural transit storage within fulfilment-style hub operations may vary depending on supervisory practice.
Unlabeled medicines	Unlabeled medicines may only be stored within licensed pharmacy (B2C) or wholesale (B2B) environments.	The permissibility of centralised back-office processing for multiple pharmacies without triggering wholesale classification is not explicitly regulated.
Multi-pharmacy centralisation	Legal responsibility for dispensing remains with the individual pharmacy.	Whether central fulfilment models resemble in fact wholesale or a central pharmacy structure remains sensitive to regulatory interpretation.
GDP compliance	Temperature control, traceability and quality management systems are mandatory for all storage and transport activities involving medicines.	The scope and depth of GDP expectations for non-pharmaceutical actors operating within hybrid fulfilment models are not exhaustively specified.
Data governance (GDPR)	Delivery data linking a patient to a specific medicine qualifies as health data under GDPR.	The allocation of controller and processor roles in integrated fulfilment models can be complex and interpretation-dependent.

### Market structure and pharmacists perspectives

The Dutch pharmacy market offers selective and conditional opportunities for external fulfilment providers, rather than broad access potential. It is a highly concentrated and vertically integrated sector, in which dominant pharmacy chains and wholesalers benefit from economies of scale and well-established logistics infrastructures [73]. Consequently, large-scale or generic entry is unlikely. However, smaller and independent pharmacies often face operational inefficiencies, creating limited but tangible demand for targeted logistics support. Pharmacies are suffering from staff shortages, increasing the workload for pharmacists [58]. Furthermore, the growth of online and hybrid pharmacies, particularly in the repeat prescription segment, is characterised by predictable and high volumes, represents the most realistic entry point for specialised fulfilment services in the short to medium term.

Interviews showed that pharmacists' willingness to outsource depends on the activity in question. While the core responsibilities of pharmacists are not open to debate, they are more open to outsourcing logistics-intensive tasks such as storage and last-mile delivery, provided the 3PL acts as a supportive extension of the pharmacy.

The findings of this analyses were translated into a set of commercial design criteria for scenario development:

- *All categories of medicine can be included in the work (DC1);*
- *The scenario is based on a clearly defined and commercially viable pharmacy segment and does not depend on broad market-wide acceptance (DC2);*
- *Focus on predictable, high-volume flows (DC3);*

- *Clear legal and operational separation between pharmacy and fulfilment entity is ensured (DC4);*
- *The scenario delivers clear operational efficiency benefits. (DC5);*
- *The service must deliver medicines quickly and reliably (DC6);*
- *Patients must be able to communicate with and access the service throughout the process (DC7).*

While scenarios that do not align with these structural market conditions may be legally permissible, they are unlikely to be commercially viable in practice.

#### Scenario development, case study and evaluation

Based on the theoretical and empirical research, the study developed and evaluated eight fulfilment scenarios for non-pharmaceutical logistics providers, ranging from minimal involvement to fully integrated organisational models:

- **S1: Distribution only:** The company solely transports medicines between those involved in the supply chain and patients, with the pharmacist remaining fully responsible for dispensing;
- **S2: OTC medicines only:** The company only fulfils orders for over-the-counter (OTC) medicines, thus avoiding the strict legislative requirements associated with prescription medicines;
- **S3: Pharmacy distribution point:** The pharmacy carries out patient-specific processing, after which medicines are transferred to the fulfilment company for distribution to patients;
- **S4: Wholesaler (B2B):** The company obtains a WDA wholesale license. It distributes medicines to pharmacies and other authorised parties, but does not supply them directly to patients;
- **S5: Central filling (B2B):** The company prepares patient-specific medicine orders on behalf of pharmacies. The pharmacy then performs the final pharmaceutical checks and dispensing in accordance with their license;
- **S6: In-house pharmacy:** A licensed pharmacy operates within the fulfilment centre, retaining pharmaceutical responsibility, while the fulfilment company is responsible for logistical operations;
- **S7: Joint venture:** A fulfilment company and a pharmacy set up a jointly owned entity that combines pharmaceutical and logistical activities;
- **S8: Cooperative model:** Pharmacists work together with a fulfilment provider through a cooperative structure that organises shared fulfilment services.

These scenarios are assessed using a feasibility framework consisting of legally binding requirements (R1–R4) and market-oriented design criteria (DC1–DC7). R1–R4 reflect mandatory compliance with the Medicines Act, licensing obligations, and GDP standards. DC1–DC7 evaluate structural viability in terms of segmentation, scalability, operational efficiency, and governance separation. The scenarios are assessed against these requirements and criteria using check marks for full compliance, crosses for non-compliance, and question marks for ambiguities.

**Table 2:** Compliance with the feasibility framework

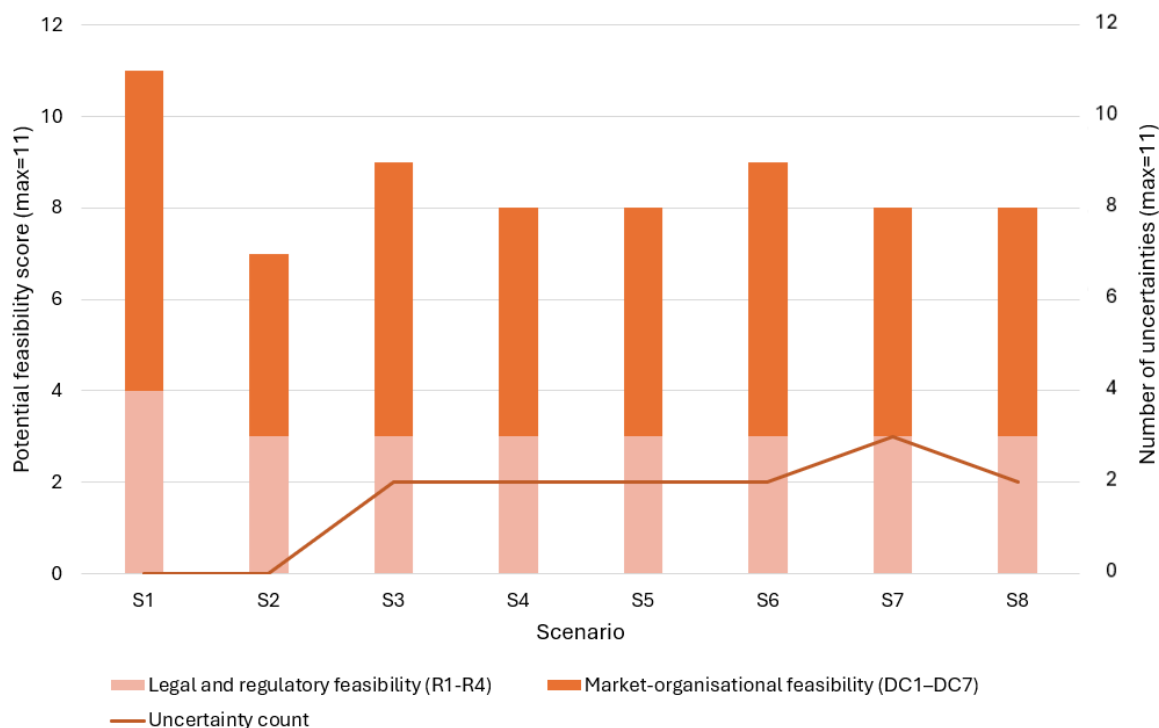
Design specification	S1	S2	S3	S4	S5	S6	S7	S8
R1	✓	✓	✓	✓	✓	✓	✓	✓
R2	✓	✓	?	?	?	?	?	?
R3	✓	✓	✓	✓	✓	✓	✓	✓
R4	✓	n/a	✓	✓	✓	✓	✓	✓
DC1	✓	×	✓	✓	✓	✓	✓	✓
DC2	✓	✓	✓	×	×	✓	?	×
DC3	✓	×	✓	✓	✓	✓	✓	✓
DC4	✓	✓	?	?	?	?	?	?
DC5	✓	✓	✓	✓	✓	✓	✓	✓
DC6	✓	✓	✓	✓	✓	✓	✓	✓
DC7	✓	✓	✓	✓	✓	✓	✓	✓

Following this assessment, it is evident that none of the scenarios are explicitly ruled out based on the legal requirements. The greatest uncertainty arises under R2 (permits) and DC4 (clear legal and operational separation):

- **Dispensing versus logistics:** There is no clear legal boundary between logistical support and regulated dispensing, which creates a grey area for 3PL activities;
- **Multi-pharmacy processing:** There are no explicit rules for a single fulfilment centre serving multiple pharmacies in a B2C context, and the division of responsibilities and oversight is unclear.

These reflect legislative uncertainty rather than formal incompatibility. However, legal feasibility does not automatically imply market robustness. Scenarios S2, S4, S5 and S8 perform poorly in terms of various design criteria, which limits their structural attractiveness and scalability.

The comparative results of this analysis are summarised in Figure 1, which visualises the structural feasibility and legislative uncertainty associated with each scenario.



**Figure 1:** Comparative structural feasibility and uncertainty across scenarios

It is important to note that this visualisation is based solely on compliance with legal, regulatory and organisational specifications. It does not consider other strategic factors, such as the extent of logistics outsourcing, operational integration, or organisational complexity. While S1 appears to be the most favourable scenario in this analysis, this does not necessarily mean it will provide the most desirable outcome for fulfilment providers or pharmacies. In addition, the practical relevance depends on the value created for pharmacies. Although some scenarios (e.g. S1–S2) only offer a modest reduction in internal workload, they can still generate value at the supply chain level. Conversely, scenarios such as S6–S8 offer greater potential for reducing labour and space constraints, but are associated with higher legal and organisational uncertainty. This highlights the trade off between value creation and feasibility: the most beneficial configurations require the most careful governance design. Determining the most suitable configuration requires an organisation-specific assessment that considers strategic positioning, operational capabilities, and partnership preferences, as illustrated by the personalised analysis conducted in the case study.

Overall, the analysis shows that, while participation by non-pharmaceutical fulfilment providers is not prohibited by law, it is structurally limited. Feasibility depends on carefully designed hybrid arrangements, strict management separation, and legislative clarification. Under the current framework, step-by-step integration appears to be a more realistic prospect than fully integrated, end-to-end models.

### Case study: PostNL Fulfilment

A case study was conducted at PostNL Fulfilment as part of the research to investigate the practical applicability of the analytical framework developed. This study is not intended to evaluate PostNL as a company; rather, it serves as a test case to evaluate the feasibility of applying the analytical framework in a real organisational context.

PostNL Fulfilment is a major logistics service provider specialising in non-pharmaceuticals, with extensive experience in e-commerce fulfilment activities. Although the company is GDP-certified for transporting medicines, it does not hold a pharmacy or wholesale license, nor does it intend to apply for one. This clearly limits its potential role within the pharmaceutical supply chain.

Applying the scenario framework to the PostNL case study demonstrates how abstract legal and market-related feasibility conditions can be translated into organisation-specific assessments. When the scenarios were evaluated against PostNL's strategic and operational constraints, the internal pharmacy model (S6) was found to be the configuration that best matched the company's capabilities while retaining pharmaceutical responsibility within the pharmacy. This demonstrates how the framework can assist organisations in identifying feasible participation models within a highly regulated system.

### Systemic implications and recommendations

The findings show that the participation of non-pharmaceutical suppliers has implications for the pharmaceutical system at multiple levels, necessitating coordinated regulatory, organisational and strategic measures. Table 3 provides an overview of the implications for the various actors.

**Table 3:** Comparison of implications per actor

Domain	Regulators and government	Pharmacies	Fulfilment Company	Science and policy
Key legal question	Operationalisation of dispensing vs. logistics; licensing route	Delegation without loss of legal responsibility	Avoiding unintended qualification as wholesaler or pharmacy	Defining assessment frameworks and pilot structures
Biggest uncertainties	Multi-pharmacy B2C models, data handling	Dispensing and last check, FMD responsibilities, GDPR contracts	Storage duration and licensing, segregation of flows, exception handling	Limited empirical evidence and lack of uniform assessment frameworks
Governance focus	Inspection methodology, auditability, enforceability	Contracts, audits, patient communication and quality assurance	GDP-QMS, contract compliance, separation of flows and roles	Measurement frameworks, model clauses and comparative research
Commercial impact	Legislative uncertainty inhibits investment and innovation	Only feasible with efficiency gains without compromising care	Selective market dependent on predictable volumes and scale	Policy impact through pilots and dissemination of best practices

These implications also give rise to a number of recommendations for practice and future research:

- **Future research** should clarify key legal and administrative ambiguities surrounding hybrid pharmaceutical delivery models, particularly the distinction between dispensing and logistics, and the governance of multi-pharmacy delivery structures;
- Clearer guidelines on licensing requirements, separation mechanisms and oversight criteria could help **regulators and policymakers** reduce uncertainty about compliance while maintaining safety standards;
- **Pharmacies** should ensure that they have strong contractual agreements, quality management systems and clear governance arrangements in place for outsourcing logistics, as they remain legally responsible for dispensing;
- For **fulfilment providers**, market entry should align with existing pharmacy-centric structures and legislative and regulatory constraints. Specifically for PostNL Fulfilment, a phased entry strategy

is recommended. The internal pharmacy model (S6) best fits PostNL's operational boundaries and provides a suitable configuration for the first practical tests of the framework.

### Discussion and limitations

This study emphasises that the feasibility of pharmaceutical deliveries cannot be assessed based solely on formal compliance with legislation. The interaction between legislation, its interpretation by regulators and professional standards plays a decisive role in determining what is considered acceptable in practice. In particular, the lack of clarity surrounding the operational definition of delivery and shared delivery environments suggests institutional inadequacy with regard to hybrid models. This suggests that innovation in pharmaceutical logistics in the first place requires not deregulation, but rather clearer specifications of governance interfaces and accountability mechanisms.

As the research is exploratory and scenario-based, the findings depend on interpretative assumptions regarding legal boundaries and operational design. Restricted access to regulatory authorities meant that supervisory perspectives could not be directly validated, and the empirical basis consists of a relatively small sample of stakeholders. Furthermore, focusing on a single case limits the generalisability of the results, as other fulfilment providers may operate under different strategic or organisational circumstances. Therefore, the results should be interpreted as context-sensitive and analytically indicative rather than universally conclusive.

### Conclusion

The conclusion addressed the main research question. As the study has a layered structure comprising structural, legal and market-oriented analyses, the conclusion is also multifaceted:

- **Pharmacy-centered foundation:** The Dutch system is structurally pharmacy-oriented: licensing, authority and legal responsibility are role- and location-based and anchored to recognised pharmaceutical entities;
- **Possibilities: conditional and pharmacy-led:** Participation is not explicitly prohibited, but is only feasible in carefully designed, pharmacy-led configurations with strict role separation, GDP compliance and demonstrable control mechanisms;
- **Institutional limitations: licensing logic and interpretative uncertainty:** Limitations arise when fulfilment activities approach dispensing responsibilities or trigger additional licensing requirements. Interpretative ambiguities (e.g. R2 & DC4) increase compliance and investment risk;
- **Market limitations:** Due to chain integration, existing logistics infrastructures and pharmacists' retained responsibility, realistic opportunities are limited to selective, predictable high-volume segments rather than scalable end-to-end outsourcing models;
- **Not a binary outcome;** Feasibility cannot be reduced to "possible" or "impossible"; it is conditional, governance-dependent, and limited to specific segments.

# 1

## Introduction

### 1.1. Research context

The market for home delivery of medicines is undergoing significant changes as a result of demographic and technological developments. Firstly, in 2022, approximately 70% of the population in the Netherlands used prescription medicines annually [14]. This figure is estimated to be in excess of 12 million people. Furthermore, the ageing population is resulting in an increased demand for care: individuals live longer and utilise more medications, particularly for chronic conditions [1] [48]. In addition, there has been an increase in number of elderly individuals living independently in their own homes. By the year 2040, it is estimated that approximately 2.5 million people aged 75 and over will reside in their own homes, compared to 1.4 million in 2020 [72]. These trends have led to an increased demand for efficient home delivery of medicines, with the aim of ensuring that less mobile or chronically ill patients can also receive their medication safely on time.

Concurrently, the digitisation of healthcare and pharmacy is creating new opportunities in the domain of pharmaceutical logistics. It is becoming increasingly evident that a growing number of pharmaceutical establishments are undertaking initiatives to digitise their operational procedures, with electronic prescriptions and automated distribution systems being the primary example of this trend [1]. Patients are becoming more familiar with online services and are expecting similar levels of convenience and rapid delivery that are characteristic of other e-commerce services [17]. In addition, there is an observable increase in the number of online pharmacies and pharmaceutical delivery platforms that provide medicines directly to the consumer. The acceleration of e-health and telepharmacy developments has been further influenced by the experience gained during the COVID-19 pandemic, when contactless delivery of healthcare products was deemed necessary.

Furthermore, logistics services are also undergoing rapid developments. In response to the specific requirements of the healthcare sector, specialised logistics service providers are establishing distribution networks that adhere to Good Distribution Practice (GDP) standards. These networks are typically equipped with temperature-controlled storage facilities, trained personnel, and real-time monitoring systems to ensure the quality, safety, and traceability of medicines throughout the distribution process. Consequently, current fulfilment companies have expanded their operational scope to encompass direct distribution to healthcare institutions and patient. Fulfilment refers to the outsourced logistical back-office process through which customer orders are operationally executed on behalf of a selling party. In practical terms, fulfilment encompasses the end-to-end management of physical product flows, including: inventory management, order processing and picking & packing, distribution and last-mile delivery, returns handling, and often also administrative and IT integration, such as order tracking and data exchange (see Figure 1.2). Thanks to track-and-trace technology, temperature protection, and certified delivery personnel, reliable delivery within 24 hours is now achievable across large parts of the Netherlands and other European countries. This professionalisation of the pharmaceutical supply chain thus forms the structural basis on which innovative fulfilment models, such as direct-to-patient deliveries, can be further developed.

## 1.2. Problem definition and gap

Despite the above developments, the current legal framework in the Netherlands (see Chapter 4) offers non-pharmacy entities limited opportunities to dispense prescription medicines to patients. According to the Medicines Act and related legislation, prescription medicines must be dispensed to patients under the responsibility and supervision of a licensed pharmacist. In practice, this has resulted in a standard distribution structure whereby medicines are supplied from manufacturers to pharmaceutical wholesalers, then to pharmacies, and finally to patients. Dispensing to patients usually takes place via physical collection or home delivery organised and carried out by the pharmacy itself. In both cases, the pharmacy remains the central and legally responsible party for storage, processing and delivery to the patient.

This report examines emerging fulfilment models in which non-pharmaceutical third-party logistics (3PLs) are responsible for some or all of the logistics processes traditionally carried out by pharmacies. Ideally, medicines would be delivered directly to a non-pharmaceutical fulfilment centre, which would then manage inventory storage, order picking, packaging, distribution and delivery to patients on behalf of multiple pharmacies, thus taking over the whole fulfilment process (see Figure 1.2).

Such a configuration raises significant legal, regulatory and patient safety issues, given the strict requirements that apply to the provision and supervision of medicines. As this implementation structure is not currently in practice and despite the use of broad and inclusive search terms (see Table 2.2), an extensive review of the academic literature yielded no case studies examining a business-to-consumer (B2C) model for medicine fulfilment by 3PLs. Instead, the few related studies focus on broader e-pharmacy chains or 3PL in healthcare:

- **3PL in healthcare supply chain:** Bian et al. [38] model a game between manufacturer, 3PL, and retailer, showing how 3PLs emerge as 'orchestrators' that provide transportation and integrated procurement services. Similarly, Li et al. [88] observe that 3PLs offer a 'relatively perfect distribution system' and have become 'indispensable' for the distribution of medicines within Chinese healthcare networks.
- **Online pharmacies and last-mile delivery:** Pabba et al. [56] reviewed existing research on online pharmacy chains and found that these models are a combination of online orders and physical pharmacy activities. Their evaluation highlight recurring themes, including trust and legitimacy, digital technology usage, and regulatory oversight importance. Meanwhile, Pooters et al. [60] focus on last-mile delivery for a Dutch hospital pharmacy, demonstrating how improved home delivery planning can boost efficiency by around 34%. Recent research into crowdsourced delivery models has also examined how prescription collection and medicine delivery can be organised using a combination of pharmacy couriers and external drivers. All these studies consistently demonstrate that home delivery of medicines is operationally complex due to factors such as strict delivery time windows, prescription processing, and coordination between patients, pharmacies, and delivery drivers. In all cases, however, the pharmacy or hospital remain in charge of the previous logistical steps.
- **Omni-channel and hybrid proposals:** Several recent articles propose indirect models. For example, Yang [87] proposes the 'online ordering, offline home delivery' strategy, in which e-pharmacies use local drugstores for order pick-up / delivery. However, this model still relies on licensed pharmacies as hubs rather than on an independent 3PL.

These sources demonstrate interest in e-pharmacy logistics, but none of the literature reviewed analysed the desired model in detail. Researching this niche model is difficult because it sits at the intersection of health legislation, supply chain practice and emerging e-commerce. This lack of academic insight is the main research gap that this study addresses. In particular, insufficient insight exists into whether, and under what legal and regulatory conditions, a non-pharmaceutical fulfilment company could undertake the logistical execution of B2C prescription medicine fulfilment on behalf of multiple pharmacies without compromising legal responsibility, quality standards and patient safety. Situating the analysis at the intersection shown in Figure 1.1 aims to provide new insights into a fulfilment structure that remains under-exposed in academic literature.



Figure 1.1: Research gap

### 1.3. Research objective and scope

In response to the identified gap in the academic and practical understanding of the third-party, B2C delivery of medicines, this study examines how the Dutch legislative and institutional framework shapes the opportunities and structural limitations for non-pharmaceutical fulfilment service providers who wish to handle the logistics of delivering prescription medicines on behalf of multiple pharmacies. Through a combination of legal analysis and market and scenario research, the study will translate an under-exposed theoretical delivery structure into a series of practical, legally substantiated scenarios.

The scope of this study is limited to warehouse operations within the fulfilment centre, as illustrated in the blue box in the figure below.

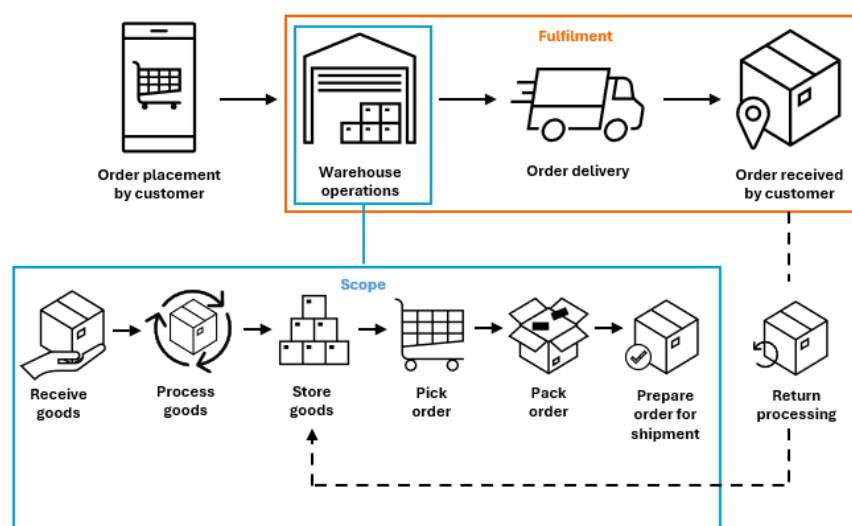


Figure 1.2: Research scope

Return processing is considered to be outside the scope. In conventional e-commerce fulfilment warehouses, returns typically represent 0.5-1% of the total order volume. In the context of medicines, however, return rates are expected to be even lower, since patients actively request medication that is medically necessary. Consequently, reverse logistics is not anticipated to play a significant operational role in B2C pharmaceutical fulfilment. The issue of transportation is also not considered, given the

existence of a substantial amount of GDP-certified transportation. The scope of this study is limited to domestic fulfilment within the Netherlands, with no provisions for cross-border activities. Consequently, the analysis is confined to the Dutch legal and regulatory framework. The study is limited to coldstore and ambient shipments of medicines that can be stored within a temperature range of 2-8 °C and 15-25 °C respectively. The storage or transport of active pharmaceutical ingredients (APIs), veterinary medicines, and products requiring special storage/security (including substance covered by the Dutch Opium Act) are excluded from the scope of this study. The focus is on the online sale of UA, UAD, UR and OTC products by pharmacies (see Section 3.2). This study facilitates a targeted evaluation of the feasibility of fulfilment by third parties within the context of Dutch medicines legislation.

## 1.4. Terminology

This study adopts specific terminology to ensure conceptual clarity. The key terms used throughout the analysis are defined below.

### 1.4.1. Distribution versus fulfilment

Throughout this report, a clear distinction is made between the terms '*Distribution*' and '*Fulfilment*'. Both in scientific and academic sources about logistics and supply chain, '*Distribution*' is typically defined as the downstream process of physically transporting and delivering goods from a central location to end users. The focus of distribution is primarily on transportation, routing and last-mile delivery.

*'Fulfilment'*, on the other hand, refers to the end-to-end-logistics process that begins with order receipt and ends with successful delivery to the customer. As shown in Figure 1.2 this also includes inventory management, warehousing, order processing, picking, packing, distribution, delivery, and returns.

In much of the existing literature and academic sources, the term '*Distribution*' appears to be used as a broad umbrella term that implicitly also includes fulfilment activities. However, this report maintains the above-mentioned clear distinction. This distinction is applied consistently throughout the study, as it is essential for analysing legal responsibilities, licensing requirements and feasible organisational scenarios.

### 1.4.2. 3PL versus fulfilment centre

In this study, the terms '*third-party logistics provider*' (3PL) and '*fulfilment centre*' are used in related but distinct ways. In logistics literature, a '*3PL*' is an external logistics service provider that performs activities on behalf of customers. The scope of these activities can vary considerably; a '*3PL*' may provide transportation or distribution services only, warehousing functions only, or a broader combination of outsourced logistics activities. Therefore, the term refers to an organisational actor whose level of involvement depends on contractual and operational agreements.

As mentioned before, a '*fulfilment centre*', by contrast, refers to a specific operational facility in which the end-to-end order fulfilment process is executed. Fulfilment thus describes the integrated execution of the entire order-handling process, rather than a single logistics function.

This study empirically focuses on '*fulfilment centres*' as operational environments in which pharmaceutical logistics could be organised. However, many of the regulatory and governance considerations discussed apply more broadly to '*3PLs*' as organisational entities. For this reason, both terms are used where appropriate.

## 1.5. Research questions

Based on the problem statement and the identified research gap, the following main question has been formulated:

*'How does the Dutch legislative and institutional framework influence the possibilities and limitations for non-pharmaceutical fulfilment providers in B2C medicine fulfilment?'*

This question takes an analytical and exploratory approach to the subject. Rather than assessing the immediate feasibility of predefined business models, the study examines how the existing legislative structure and institutional context influence the scope for non-pharmaceutical suppliers to participate in

the pharmaceutical supply chain (see Section 1.6 for the research positioning and analytical structure of this study).

The use of the term 'influence' suggests that participation is not solely determined by legislation, but by the interaction between legal requirements, supervisory authorities, professional roles and market dynamics. The research therefore focuses on identifying structural requirements and criteria, interpretative ambiguities and organisational implications that influence potential involvement. By combining multiple analyses, the study aims to clarify where limitations arise and where there may be room for innovation, without assuming implementation as an inevitable outcome.

In order to answer this main question, five sub-questions have been formulated (Table 1.1), each of which highlights a specific aspect of the question.

**Table 1.1:** Sub-questions and their purpose

<b>Question</b>	<b>Purpose</b>
1. How is extramural pharmaceutical care and medicine logistics organised in the Netherlands, and how does this compare to international approaches to B2C medicine delivery?	To demonstrate the current scope of possibilities in other legal frameworks.
2. What do current Dutch medicines legislation and GDP guidelines prescribe regarding medicine logistics?	To understand the legal obstacles that exist and the extent to which the legislation and regulations leave room for interpretation and to derive the legal and regulatory constraints for the scenario building.
3. To what extent is there a viable market for external fulfilment services in the pharmacy sector, and how willing are pharmacists to outsource the fulfilment of medicines?	To determine whether the scenarios that are ultimately devised also have market potential and to derive the market constraints for the scenario building.
4. Which fulfilment scenarios can be developed for non-pharmaceutical fulfilment providers, and how feasible are they in legal, logistical, and organisational terms?	To gain insight into the most promising route and the conditions that must be met.
5. What are the systemic and actor-specific implications of potential participation of non-pharmaceutical fulfilment providers in B2C medicine logistics?	To analyse how different actors would be affected by different participation models.

The sub-questions provide a step-by-step response to the primary question. This configuration guarantees that the primary question is addressed not solely in a theoretical sense, but also in a practical manner, with substantiation derived from legislative frameworks, extant literature, and empirical insights.

## 1.6. Research positioning and analytical structure

This study adopted an explicitly exploratory approach to investigating the potential involvement of non-pharmaceutical stakeholders in the Dutch pharmaceutical supply chain. Rather than assessing predefined business models, the study first sought to gain insight into the structural and institutional context in which such models could theoretically emerge.

The analytical basis of the thesis consisted of three interrelated components. Firstly, the current pharmaceutical supply chain was analysed in Chapter 3 to gain a clear understanding of how extramural pharmaceutical care and medicine logistics are organised in the Netherlands. This chapter primarily aimed to clarify the existing system architecture, identify structural characteristics and substantiate

the research gap outlined in Section 1.2. It also identified potential areas where logistical innovation could theoretically occur. Importantly, however, this chapter did not identify any limitations in terms of feasibility, but rather formed the contextual basis for the subsequent analyses.

Building on this systemic insight, Chapter 4 examined the legal and regulatory framework, and Chapter 5 analysed the market structure and implementation dynamics. The legal requirement and market design criteria for the scenario building in Chapter 6 were derived from these two chapters. These design specifications are explicitly stated in the respective conclusions, which together define the boundaries within which each implementation model must operate.

In Chapter 6, these legal and market restrictions were systematically consolidated into an integrated feasibility framework. This framework formed the basis for eight implementation scenarios, comprising adjustments to existing structural configurations and new collaboration models between pharmacies and non-pharmaceutical fulfilment providers. Notably, given the strict legislative framework and the already highly structured and concentrated market, the scenario analysis examines not only how B2C fulfilment can be organised, but also which forms of participation are realistically accessible to non-pharmaceutical actors wishing to enter the medical logistics sector.

The scenarios were exploratory in nature. Rather than providing a definitive assessment of which model should be implemented, the aim was to systematically investigate what would be possible within the existing legislative, institutional and market structure of the Dutch pharmaceutical system. Chapter 2 elaborated on this methodological approach and explained how the logic of the exploratory scenarios was embedded in the overall research design.

## 1.7. Relevance of study

In this section the relevance of the study is explained.

### 1.7.1. Scientific and societal relevance

This study makes a contribution to the existing literature on the subject of supply chain compliance and innovation within regulated sectors, with a particular focus on the pharmaceutical industry. It explores the potential development of fulfilment models within the legal frameworks of pharmaceutical distribution, combining insight from legal, logistical, and organisational perspectives. In addressing this research gap, the study offers a comprehensive overview of the subject, which is a notable strength given that many previous studies have focused on a single perspective. The methodological approach, which combines legal research, interviews and scenario design, is also an example of integrative and multidisciplinary research within the fields of supply chain management and healthcare logistics.

Furthermore, in the context of implementable scenarios, the research contributes to accessibility and efficiency in the delivery of pharmaceutical care. The outsourcing of logistics can also result in the reduction of pressure on pharmacists, thereby enabling them to direct their attention towards core tasks such as the provision of medication guidance. In addition, the centralisation of logistics offers opportunities to cost reduction and sustainability. This research is of particular relevance to policy discussions on future-proof pharmacy, as it can inform potential legislative changes with the aim of facilitating safe and innovative medicine distribution.

### 1.7.2. Master program relevance

This thesis is closely aligned with the MSc TIL program, particularly with the Networks Track. The Transport Networks specialisation involves the resolution of a real-world logistics design problem. This problem involves multiple actors and is constrained by legislation and spatial limitations. The design of a GDP-compliant, direct-to-patient model for the delivery of medicines for PostNL integrates the core competencies of TIL: transport systems and services, infrastructure network design, and supply chain control. The organisation also employs transport policy and governance to translate EU/NL rules into actionable activities. The work requires quantitative reasoning about network performance, in addition to qualitative stakeholder analyses. This is in line with TIL's emphasis on informed decision-making in complex situations. The research demonstrates TIL's core principle of integrating technical design with institutional and management considerations to deliver feasible, efficient, and socially responsible mobility and logistics solutions, as evidenced by the production of a minimum viable, verifiable operational

concept with indicative economic data.

## 1.8. Report structure

This thesis is structured in such a way that it systematically provides insight into the feasibility of using third-party logistics providers (3PLs) to deliver medicines within the Dutch pharmacy sector.

Chapter 1 introduces the research context, problem statement, research objective and research questions. Chapter 2 describes the research design and methodological choices. Chapter 3 presents a literature review with a focus on pharmaceutical distribution, outsourcing and logistics within regulated healthcare contexts.

Furthermore, Chapter 4 outlines the institutional and legislative framework for pharmaceutical distribution in the Netherlands. This chapter has been placed separately in order to provide a coherent and complete overview of the relevant legislation and regulatory principles prior to the development of the scenarios. Rather than introducing the legal restrictions for each scenario, this chapter establishes the basic rules and assumptions that determine what is permitted in principle within the current system. Chapter 5 looks at how the Dutch pharmaceutical market is organised in practice. It identifies the key players and market dynamics, as well as potential opportunities for external logistics service providers.

Finally, Chapter 6 translates the insights from previous chapters into practical considerations and substantiates the development of implementation scenarios. While the legislative framework introduced in Chapter 4 provides a clear basis for this analysis, it is not treated as a static or exhaustive set of constraints. As the implementation models examined in this study do not yet exist in practice, the framework is actively interpreted and nuanced in light of empirical observations, and critically discussed where necessary. This approach acknowledges that, while the rules are relatively clear in theory, their application to innovative and hybrid implementation models often involves ambiguity and interpretative flexibility. In some cases, it also involves considering temporary or conditional legislative adjustments.

# 2

## Research design

In order to answer the research questions, this study employs a mixed-methods research design. This approach was chosen in order to capture the complex and highly regulated nature of the pharmaceutical sector, in which legal structures, market dynamics and stakeholder perspectives are closely intertwined.

This chapter outlines the design of the study and explains how each methodological component contributes to the overall objective. Section 2.1 outlines the research approach and the underlying logic of the study. Section 2.2 provides a detailed description of the research methods employed, such as document analysis and semi-structured interviews, and clarifies their relationship to the sub-questions. Section 2.3 describes how the findings were validated, including how the scenario assumptions and interpretations were checked with stakeholders and against documented frameworks. Section 2.4 discusses the limitations of the research design and reflects on methodological considerations. Finally, Section 2.5 explains how data is managed, including procedures for anonymisation, storage and the ethical handling of interview material. Together, these sections provide an overview of the research design that informs the subsequent theoretical, market and empirical chapters.

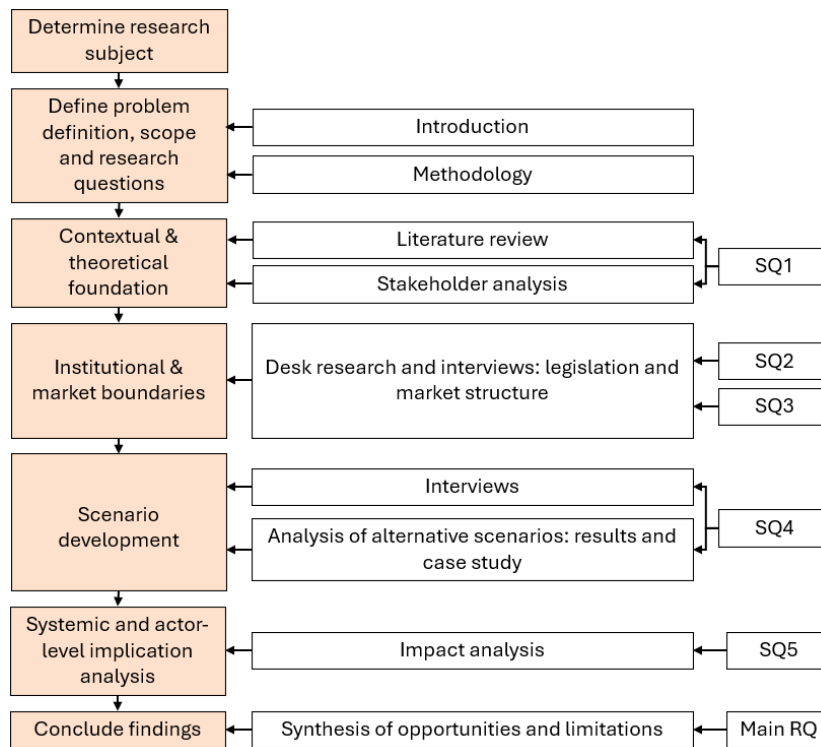
### 2.1. Research approach

The study employs a qualitative research approach to examine the legal, logistical, and operational feasibility of non-pharmaceutical fulfilment suppliers participating in the fulfilment of B2C medicines. The multidimensional nature of the main research question, which is a combination of legislative frameworks, market acceptance, and logistics process design, is accommodated by a qualitative design, which facilitates an in-depth exploration of both normative conditions (what is legally permissible) and practical implementation (what is organisationally feasible). As Flick [22] argues, qualitative methodologies are especially appropriate for dealing with issues inherent in institutional, social, and policy frameworks, since they empower researchers to document the experiences, reasoning, and expectations of stakeholders. Table 2.1 provides a comprehensive overview of the methods used for each sub-question.

**Table 2.1:** Overview of sub-questions with corresponding methods and deliverables

<b>Sub-question</b>	<b>Method</b>	<b>Deliverable</b>	<b>Chapter</b>
1.	Literature review, desk research, stakeholder analysis	Comparative overview of extramural pharmaceutical care and delivery models (NL and international); list of stakeholders and their roles with a power-interest grid	Chapter 3
2.	Desk research	Overview of legal conditions	Chapter 4
3.	Desk research, semi-structured interviews	Analysis of pharmacy sector structure and willingness to outsource fulfilment	Chapter 5
4.	Desk research, semi-structured interviews, scenario development, case study	Set of feasible fulfilment scenarios with exploration of legal, logistical, and organisational viability, including case study for PostNL Fulfilment	Chapter 6
5.	Impact analysis	Structured analysis of systemic and actor-specific implications of non-pharmaceutical fulfilment participation	Chapter 7

The research combines a theoretical analysis of legislation and compliance standards with empirical insights. The employment of this methodological mix ensures that the findings in both academic literature and professional practice, thereby ensuring a robust and comprehensive research foundation. In Figure 2.1 the research flow of this study is given. The left-hand column designates the stage of the research process, while the middle column gives the associated method and the right-hand column identifies the specific sub-question that is addressed.



**Figure 2.1:** Research flow; relation between methods and answering the research questions

## 2.2. Research methods

This section explains the methodology used to answer the research questions.

### 2.2.1. Literature review / desk research

A structured research establishes the legislative, operational and market-related basis for GDP-verifiable service provision, from the warehouse to the patient. This involves compiling rules, the guidelines and previous practices to ensure that subsequent design choices are well-founded and verifiable. This method is relevant to sub-questions 1, 2, 3, and 4. It has been conducted with the aim of developing a more profound understanding of the subject.

The selection of literature reviews was conducted in accordance with the following criteria: publications were required to be peer-reviewed articles published in or after 2018, and to cover key concepts such as the pharmaceutical supply chain en B2C models. A snowball method was employed to identify relevant literature, both backward and forward. Forward snowballing entailed the review of the references cited in key articles in order to identify additional sources. Conversely, backward snowballing involved the review of subsequent articles in which these articles were cited. The majority of literature was retrieved from academic search engines such as Scopus and Google Scholar, thus ensuring comprehensive coverage of peer-reviewed publications that met the defined criteria. The conceptual and methodological framework for the literature review is delineated in Table 2.2.

**Table 2.2:** Conceptual and methodological framework for literature review

<b>Concept Groups</b>	<b>Keywords</b>	<b>Truncation</b>
Pharmaceutical Supply Chain	Good Distribution Practice (GDP); Wholesale Distribution Authorisation (WDA); Falsified Medicines Directive (FMD); NMVS; GMP; licen?e/authorisation; compliance	( good AND distribut* AND practic* ) OR GDP OR ( wholesale AND distribut* AND authorisation ) OR WDA OR ( falsif* AND medicin* AND directiv* ) OR FMD OR NMVS OR ( good AND manufact* AND practic* ) OR GMP OR licen?e OR authorisation OR complian*
Challenges and Risks	Regulatory & role responsibility; accountability/liability; cold chain, GDPR; traceability, cybersecurity	( regulator* AND responsib* ) OR ( role* AND responsib* ) OR accountab* OR liabilit* OR ( cold AND chain ) OR ( temperat* AND excursion* ) OR GDPR OR ( data AND protect* ) OR traceab* OR seriali?ation OR cybersecur*
B2C Models	B2C; mail-order; e-pharmacy, online pharmacy; hybrid model; Direct-to-Pharmacy (DTP); urban–rural	B2C OR ( business-to-consum* ) OR ( mail AND order* ) OR mail-order* OR e-pharm* OR ( online AND pharmac* ) OR ( internet AND pharmac* ) OR ( hybrid AND model* ) OR ( direct-to-pharmac* ) OR DTP OR urban OR rural OR urban–rural
Market Demand and Adoption Drivers	Patient acceptance, willingness to use; e-prescription; remote care; rural/urban access; demand-driven supply; demand forecast	( patient AND accept* ) OR ( willing* AND to AND use ) OR adopt* OR e-prescri* OR eRx OR ( electronic AND prescri* ) OR ( remote AND care ) OR telemedic* OR telehealth* OR ( rural OR urban ) AND access* OR ( demand-driv* AND suppl* ) OR ( demand AND forecast* )
Categorisation	UR (prescription-only), NR/OTC; UA, UAD, AV; ambient; coldstore; packaging	UR OR ( prescription-only ) OR prescri* OR NR OR OTC OR ( over-the-counter ) OR UA OR UAD OR AV OR ambient OR ( cold AND stor* ) OR cold-chain OR packaging

This study addresses an area of research for which there is little formal academic literature available, since the large-scale involvement of non-pharmaceutical suppliers in the distribution of B2C medicines has not yet been widely implemented in practice. Consequently, as already discussed in Section 1.2, the existing scientific literature does not offer a comprehensive overview of the legal, organisational, and operational complexities of such models.

To adequately reflect the current state of knowledge and practice, this research combines peer-reviewed academic literature with desk research on legislation, guidelines and policy documents, as well as selected publications from industry and regulatory bodies. Academic sources are used to frame broader developments in the fields of e-pharmacies, pharmaceutical logistics and centralised dispensing models (Chapter 3), while legal and policy documents provide insight into the binding constraints under which pharmaceutical fulfilment models must operate (Chapter 4).

The review on academic publications was conducted primarily using Scopus and Google Scholar. Targeted searches were also performed to locate legislation, guidelines and policy documents, including national and European pharmaceutical legislation, regulatory guidelines and parliamentary documents.

Due to the diverse nature of the sources employed, the reference list in References is categorised into three distinct groups:

- Scientific and academic literature;
- Professional and industry sources;
- Legislation, guidelines and policy documents.

This reflects the interdisciplinary nature of the research and the central role of legislative frameworks in shaping feasible B2C medicine distribution scenarios.

### 2.2.2. Stakeholder analysis

A stakeholder analysis was conducted to systematically identify the actors involved in or affected by the possible outsourcing of pharmaceutical fulfilment processes to non-pharmaceutical logistics service providers. The objective of this analysis is to map the interests, roles, influence, and potential resistance or support of stakeholders in order to inform the design of legally compliant and operationally feasible fulfilment scenarios.

The analysis was structured using the power-interest grid as a methodological framework. This instrument categorises stakeholders according to their capacity to influence the fulfilment model and their degree of involvement or interest in the subject [89]. The stakeholders can be divided into four groups:

1. **Key players:** must be closely engaged;
2. **Keep satisfied:** their satisfaction must be managed;
3. **Keep informed:** they should be updated regularly;
4. **Minimal effort:** they require only basic monitoring.

The four groups are then placed on a Power-Interest grid, as illustrated in the figure below.

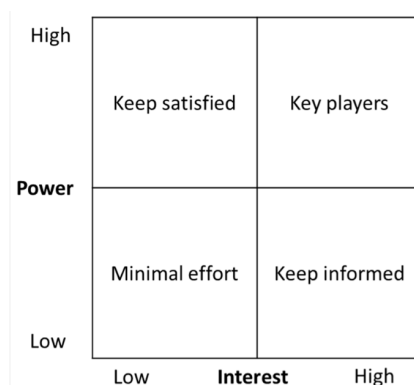


Figure 2.2: Power-Interest grid [89]

This stakeholder analysis helped to identify both strategic opportunities and institutional bottlenecks. It supports scenario design by clarifying whose cooperation is essential, and how operational responsibilities can be delegated without leading to conflicts with legislation.

### 2.2.3. Semi-structured interviews

This study used semi-structured interviews to answer sub-question 3 and 4, as these provide detailed, experience-based insights from stakeholders involved in the organisation and logistics of pharmaceutical deliveries. To ensure a well-founded perspective on the research problem, a total of 5 interviews with different stakeholder groups have taken place. The selection of interviewees was based directly on the stakeholder analysis presented in subsection 2.2.2. Those stakeholders who were identified as being highly interested in and/or influential within the power-interest grid were selected for interview.

Three interviews have been conducted with community pharmacists, who play a central role in dispensing medicines and can provide valuable specialist knowledge for this case. Although only three pharmacists were interviewed, this number was deemed sufficient to represent the pharmacy perspective, as their responses quickly converged. All three interviewees indicated that all pharmacists will give

the same answer, because they *"are in the same boat and bound by laws and regulations"*. Given the uniform legislation context in which they operate, this consensus suggests that additional interviews with pharmacists would likely yield similar information. The three pharmacists were selected from a range of practice settings, including an online pharmacy initiative, a group of general community pharmacies and a national chain, to identify any nuanced differences. However, their views on key issues proved to be largely consistent.

Initially focusing on pharmacists enables the research to gather expert insights into operational realities and limitations, which are invaluable for developing scenarios in later chapters. The initial research design included interviews with regulatory bodies and healthcare decision-makers because their views are essential for assessing the institutional feasibility of the proposed scenarios. However, due to the sensitive nature of the subject, these individuals were unwilling to participate. Consequently, the study relied on interviews with a drug dispensing company and a legal expert to gain informed insights into legislative boundaries and operational constraints. This adapted approach enabled legal and practical considerations to be taken into account, albeit without direct validation by government agencies.

All interviews followed a semi-structured format, combining a predetermined set of leading questions with sufficient flexibility to allow respondents to elaborate on topics they considered most relevant. As a result of this open interview structure, the interviews differed in sequence and emphasis, despite being guided by the same core themes. The pharmacists interviewed indicated that they preferred the interviews not to be recorded due to the sensitive nature of the information discussed. Therefore, the interview reports in Appendix D are based on detailed notes taken during the interviews. These notes were then developed into structured summaries that are written as consistently as possible for all interviews, allowing for systematic comparison. Relevant quotes used in the analysis chapters were taken from these written reports.

#### 2.2.4. Scenario development

This study uses scenario development to answer sub-question 4, which examines which implementation models could enable non-pharmaceutical logistics service providers to legally and operationally participate in the fulfilment of medicines to consumers (B2C). Scenario development is widely recognised as an effective tool for exploring possible future scenarios in environments characterised by institutional constraints and rapidly evolving practices. According to Schoemaker [69], scenarios facilitate decision-making by systematically structuring uncertainties, enabling researchers to compare alternative trajectories without requiring accurate prediction. Similarly, Börjeson et al. [7] argue that scenarios help researchers to develop internally consistent and plausible futures that reflect key uncertainties, making them particularly valuable in environments where legislation and policy play a significant role. In logistics and supply chain research, scenarios are often employed to evaluate operational feasibility under various constraints, including legal restrictions, organisational roles, and compliance requirements.

In order to establish a clear conceptual foundation, this study draws on the scenario typology of Börjeson et al. [7]. This typology distinguishes three overarching categories of scenario study: predictive, explorative and normative (Figure 2.3). Each category is linked to a different guiding question about the future: *What will happen?*, *What can happen?*, and *How can a specific target be reached?* Each category contains two scenario types, resulting in a six-type framework. This typology does not prescribe that all six types must be developed, but it does offer a conceptual lens through which the nature and purpose of scenarios constructed within a study can be classified.

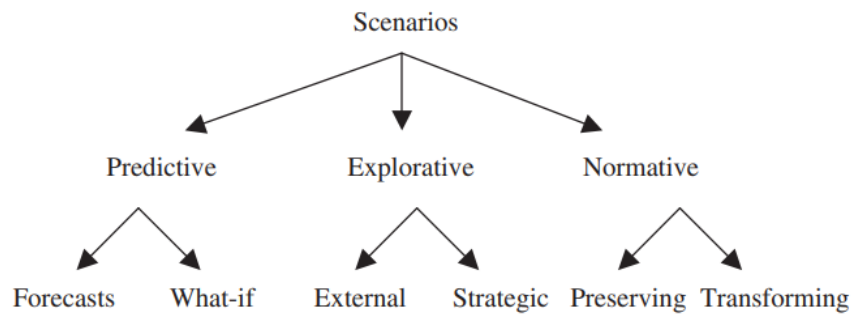


Figure 2.3: Scenario typology [7]

The 'explorative' scenario category is the most suitable for this research. These scenarios are designed to investigate potential futures in contexts characterised by uncertainty, ambiguity and multiple interacting actors; circumstances that are central to the legal and organisational challenges of outsourcing pharmaceutical fulfilment. Within this category, there is a distinction between external exploratory scenarios, which are shaped by developments beyond the control of the actors involved, such as institutional or legal changes, and strategic exploratory scenarios, which are driven by the choices and interactions of the actors involved.

In general, scenario development forms a bridge between conceptual analysis and practical exploration. This allows this study to formulate several plausible implementation models that reflect real uncertainties in the areas of legislation and organisation, thereby supporting a structured exploration of the conditions under which logistics service providers can realistically contribute to B2C medicine distribution in the Netherlands.

### 2.2.5. Case study

In answer to sub-question 4, this study examines the consequences of the most feasible fulfilment strategy identified in Chapter 6, as determined by a case study conducted at PostNL Fulfilment. This is the fulfilment branch of PostNL that offers e-commerce companies end-to-end logistics solutions. It serves as a concrete case study within this research. PostNL Fulfilment is responsible for the management of inventory, order picking, and shipping of products for various online stores (see Figure 1.2), thereby relieving the online seller of these tasks. The service is characterised by its high level of automation. The process of collecting and packaging warehouse orders is conducted with precision, utilizing automated robotic systems and pick-to-light mechanisms to ensure the absence of errors. Inventory systems are linked to web shops, thereby providing entrepreneurs with real-time insight into their stock and shipments. PostNL Fulfilment has thus constructed a robust infrastructure for fast and reliable fulfilment, including returns processing and customer service integration.

Furthermore, PostNL Fulfilment has developed a specialised expertise in the processing of temperature-controlled goods. For instance, a facility designated as a Food Fulfilment Centre is equipped with refrigeration and freezer infrastructure for the storage of temperature-sensitive products [59]. In addition, a Beauty & Care fulfilment service is available, where products are stored under optimal conditions. In the latter, stocks are managed according to their expiration date and stored in a sterile and safe manner, compliant with requirements [59]. This experience is relevant because it establishes the foundation for the handling of medicines, which are frequently temperature-sensitive and have a limited shelf life. PostNL is already operating the Health & Secure delivery service, which is transporting in accordance with GDP. However, it should be noted that this does not involve any other fulfilment activities, such as inventory management, storage and packaging. The PostNL case is of particular interest in this regard. The company possesses the necessary logistical capabilities and experience with quality systems to potentially support medicine fulfilment.

PostNL Fulfilment therefore serves as a suitable empirical test case for the feasibility framework developed in this study. Rather than analysing the organisation itself as the primary research object, the case study provides a practical testing ground to evaluate the applicability of the methodological approach, particularly the scenario development and feasibility framework (consisting of the legal re-

quirements and market design criteria (see Section 1.6)), in a real logistics context. By testing the theoretically derived scenarios against PostNL Fulfilment's operational characteristics, capabilities and limitations, the study examines whether the proposed framework offers a practical method for evaluating fulfilment configurations. In this way, the case study demonstrates the practical applicability of the method and illustrates how similar logistics service providers could use the framework to evaluate potential involvement in pharmaceutical fulfilment.

### 2.2.6. Impact Analysis

To answer sub-question 5, a qualitative analysis of the impact on various actors was conducted. This approach is based on stakeholder theory [23], and system thinking approaches [46], and is used to evaluate the influence of institutional and structural changes on actors within a socio-technical system.

According to stakeholder theory, organisations and systems are conceptualised as constellations of actors with different interests, positions of power and dependencies [23]. When it comes to legislative transitions or market restructuring processes, it is essential to analyse the consequences for different stakeholders in order to gain insight into the systemic implications, feasibility and implementation dynamics [47].

This study approached the involvement of non-pharmaceutical parties in B2C pharmaceutical fulfilment as a structural system intervention, analysing the implications for different dimensions (legislative, operational, market and policy) for each stakeholder. The result is a structured overview of the implications and shifts at the system level for each actor, forming the basis for exploring institutional feasibility and policy relevance.

## 2.3. Methods for validation

To ensure the robustness and credibility of this qualitative research, various validation techniques were applied. First, member checking was used to reinforce the accuracy of the empirical findings. Summaries of the interpretations of the interviews were shared with the participants so that they could check whether their views had been correctly represented. This is in line with Birt et al. [5], who argue that member checking increases credibility by reducing researcher bias.

Secondly, the principles of content validation as described by Burnard [10], were applied in the analysis. Throughout the process, interview notes, and preliminary interpretations were repeatedly reviewed to ensure consistency and analytical transparency.

Finally, triangulation was applied by systematically comparing insights from interviews, desk research, and legal documentation. By aligning stakeholder perspectives with legislative sources and operational practices, the research increases validity and reduces the risk of single-source bias. This approach is supported by Haq et al. [28] and Trullols et al. [77], who emphasise triangulation as an important technique for strengthening the reliability of qualitative research.

## 2.4. Limitations for methods

Despite the fact that the mixed research design provides a comprehensive basis for investigating the legal, logistical, and organisational feasibility of B2C medicine dispensing, it is important to note that each method used in this study has inherent limitations. The most relevant methodological limitations are outlined below.

### 2.4.1. Literature review / desk research

This form of research forms the basis for analysing legislation, market structures and international B2C models. However, it is inherently limited by the availability, scope, and quality of existing sources. Legislative information is scattered across multiple EU and Dutch publications, and interpretations may differ depending on the stakeholder. Furthermore, the literature on B2C medication dispensing by non-pharmaceutical parties is extremely limited, increasing dependence on related areas such as health-care logistics and e-commerce dispensing. This carries the risk of overgeneralisation when applying external insights to the Dutch context. To overcome these limitations, triangulation with interview perspectives and legal documents was applied, but complete elimination of bias is not possible [77].

### 2.4.2. Stakeholder analysis

Stakeholder analysis supports the identification of actors and power relations, but also entails various methodological limitations. Stakeholder mapping can be influenced by the researcher's interpretation of the influence and interests of actors, which can lead to incorrect classifications. Furthermore, the complexity of the pharmaceutical sector means that power relations can shift rapidly in response to policy changes or organisational restructuring. Holznagel et al. [70] emphasise that asymmetries in the information available to actors can distort the analysis. Although these limitations were partially mitigated by comparing interview input with regulatory and legislative documents, the mapping remains a simplified representation of a dynamic field.

### 2.4.3. Semi-structured interviews

Semi-structured interviews offer rich and context-specific insights, but they also have a number of well-documented disadvantages. Interview data can be influenced by social desirability, whereby participants tailor their answers to what they think is expected of them [15]. Interviewer bias can also influence the way questions are phrased or interpreted [6]. Furthermore, interviews are time-consuming to conduct, transcribe, and analyse [40]. Although careful wording and a structured protocol were used to minimise these limitations, the subjectivity inherent in interviews cannot be completely eliminated.

The process of qualitative coding of interview findings is inherently subjective and open to interpretation, which can introduce potential bias from the researcher. The process of coding interview narratives can result in the fragmentation of the data, potentially leading to the loss of contextual information [11]. As this study was conducted by a single researcher, it was not possible to establish inter-coder reliability. This resulted in an increased influence of individual interpretation. In an attempt to mitigate this risk, the full transcripts were reviewed during the analysis and reflection practices were applied, but it should be noted that coding remains an inherently interpretative exercise.

### 2.4.4. Scenario development

The development of implementation scenarios is based on assumptions about legal interpretations, operational conditions in fulfilment centres, and the willingness of pharmacists to outsource. The development of scenarios is therefore subject to uncertainty, particularly in areas where the legal framework contains grey areas or where interviewees have expressed divergent expectations. It is acknowledged that, due to the exploratory nature of the scenarios, their feasibility is dependent on contextual factors, such as legislative changes, which are beyond the scope of this study.

### 2.4.5. Case study

A single case study design offers depth but limits generalisability [27]. The findings derived from PostNL's operational environment may not be applicable to other logistics service providers, which may differ in terms of infrastructure, capacity, or quality systems. Although triangulation was used to contextualise the findings, the case study inherently represents one possible organisational context for the delivery of medicines.

### 2.4.6. Impact analysis

Qualitative analysis of the impact on different actors is inherently interpretative, as assessments of stakeholder influence depend on the chosen analytical framework [23]. The results are also influenced by system boundaries, meaning that including or excluding actors affects the identified implications [46]. Furthermore, this method leads to structural consequences rather than the empirical validation of behavioral responses. Although this limits predictive accuracy, this approach is well suited to the exploratory nature of the study, which focuses on understanding the structural and institutional consequences rather than predicting behavioural outcomes. It enables the systematic identification of shifts in responsibilities, power relations and governance structures resulting from the introduction of new actors into a regulated pharmaceutical system.

## 2.5. Data management plan and ethical consideration

Since this research requires human participation, it is important to develop a data management plan and it is essential to engage in a thorough discussion of ethical considerations to ensure the integrity

of the research process.

### 2.5.1. Data management plan

This research is in accordance with the ethical guidelines established by the Delft University of Technology, which stipulate the principles for conducting research involving human subjects in a responsible manner and in compliance with the established ethical and legal standards [79]. As this thesis comprises interviews with stakeholders in the pharmaceutical and logistics sectors, a structured data management plan (DMP) has been formulated to ensure the secure processing, storage, and use of the collected data throughout the project. This DMP can be found in Appendix B.

### 2.5.2. Ethical considerations

Ethical considerations play a crucial role in research involving human participants. In line with social research ethics outlined by Bryman [9], four key principles guide this study:

- Avoidance of harm to participants;
- Ensuring informed consent;
- Protection of privacy and confidentiality;
- Avoidance of deception.

To uphold these principles, several measures were implemented:

- Informed consent: Prior to each interview, participants were asked to sign a consent form confirming that they understood the study, that participation was voluntary, that the interview would be recorded, and that they could withdraw at any time without consequences. This process ensured transparency and autonomy for participants during data collection. The informed consent form can be found in Appendix C.
- Privacy and confidentiality: The interviewees are anonymised throughout the thesis, unless they have given their explicit consent to disclose their position or organisation. Furthermore, the interview data is stored securely and is not shared outside the research team.
- Safe interview environment: The interviews were conducted in person or online, depending on the participant's preference. Both formats provided a safe and comfortable environment, allowing interviewees to speak freely about legal uncertainties, implementation processes, and organisational practices.
- No deception: Participants were never misled about the objectives or results of the research.

# 3

## Pharmaceutical supply chain analysis

This chapter provides a review of the extant academic literature and reports to map the structure of the current medicine supply chain, identify key logistical challenges, and examine international developments in B2C delivery models. It is evident that these insights collectively constitute the analytical foundation upon which the feasibility and desirability of outsourcing fulfilment activities to non-pharmaceutical entities can be evaluated.

This chapter is concerned with sub-question 1:

- **SQ1:** How is extramural pharmaceutical care and medicine logistics organised in the Netherlands, and how does this compare to international approaches to B2C medicine delivery?

This chapter is outlined as follows: Section 3.1 describes the current supply chain structure, followed by an overview of medicine categories in Section 3.2. Section 3.3 discusses key logistical challenges, while Section 3.4 examines market demand and drivers for outsourcing. Section 3.5 briefly explores international B2C fulfilment models, and Section 3.6 concludes with a stakeholder analysis to support subsequent scenario development. These insights form the conceptual foundation for the subsequent market analysis and the scenario development, in which the feasibility of different fulfilment models is further evaluated.

### 3.1. Dutch pharmaceutical supply chain

The pharmaceutical supply chain is defined as the regulated end-to-end system that facilitates the delivery of medicines from the point of production to the patient, thereby ensuring quality, traceability, and regulatory control at every stage of the process. In the Netherlands, extramural pharmaceutical care is organised through a network of pharmacies which purchase medicines from wholesalers and deliver them to patients. This section describes the process by which a typical prescription is delivered to a patient under the current system.

When a patient visits a general practitioner or specialist, an electronic prescription is usually issued and sent directly to the pharmacy via the national digital infrastructure. Once the pharmacy has received the prescription, it checks its accuracy and suitability before dispensing the medication. In many cases, the required medication is available directly from the pharmacy's stock. If not, the pharmacy places an order with one of the Dutch pharmaceutical wholesalers (see subsection 5.1.2). These wholesalers cannot deliver to the patients directly due to legislation. The figure below shows how patients can obtain medication from a pharmacy via the full pharmaceutical supply chain [16].

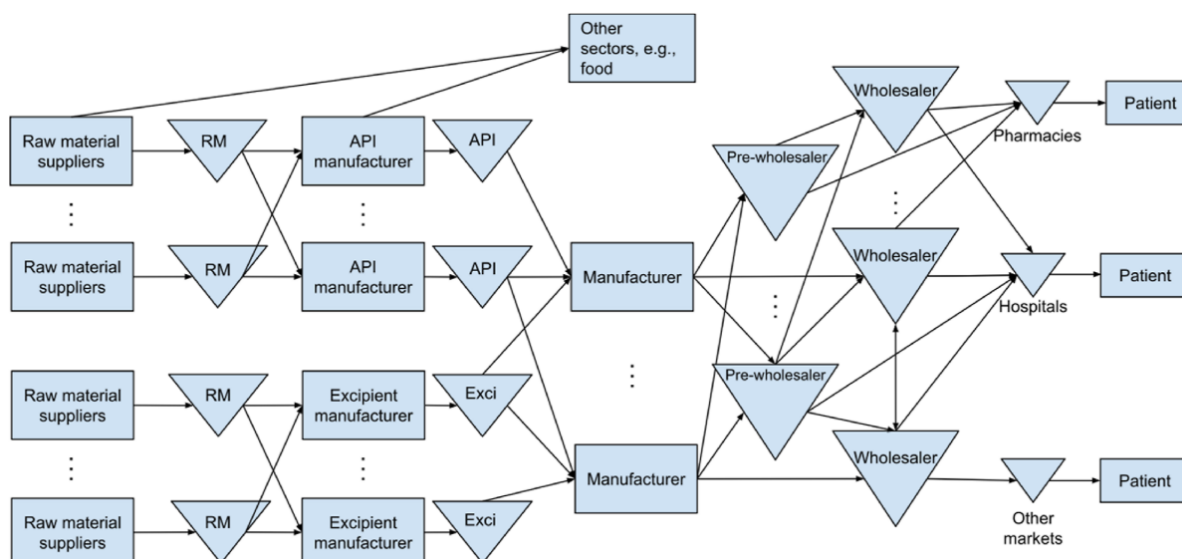


Figure 3.1: Pharmaceutical supply chain [16]

The dispensing phase is traditionally performed at the pharmacy counter. The vast majority of Dutch patients still collect their medications in person, reinforcing the pharmacy's role as a physical point of care [37]. Home delivery services do exist, but are limited in scope. They are primarily offered to specific patient populations such as elderly, palliative care patients, or those with mobility limitations. These deliveries are usually handled by the pharmacy's own delivery staff, bicycle couriers, or small contracted postal services which are solely responsible for the last-mile delivery [16].

Although this traditional process is becoming more automated and digitalised, it is essentially manual and local. In recent years, various innovations have improved efficiency. For example, some pharmacies now routinely use rapid dispensing robots to retrieve medications from storage [8]. Such automated systems significantly speed up the picking process and reduce errors, enabling pharmacy staff to focus on providing advice.

In addition, central filling services have emerged, which are centralised facilities (often run by wholesalers or large pharmacy chains) that process repeat prescriptions in batches. A pharmacy can send batches of routine repeat prescriptions to a central hub, where robots and people package and label the orders per patients, which are then send to the pharmacy. Studies and reports indicate that such central filling operations can reduce workload and errors at pharmacies by automating repetitive tasks [85].

In short, the Dutch supply chain is pharmacy-centric. Wholesalers deliver medicines to the pharmacies, doctors prescribe medicines via e-prescriptions, and pharmacies check and dispense medicines to patients. Patients usually pick up the medicines. New technologies are gradually streamlining and improving the safety of the chain. However, the final stage remains fragmented, with each pharmacy currently managing its own limited delivery service. There is no national third-party courier network for, for example, standard prescriptions, so home deliveries are ad hoc and targeted. While this established model provides a strong foundation for care, it may struggle to scale up as patient demand for home delivery continues to grow.

## 3.2. Medicine categories

Medicines are classified into the following two categories according to their availability [55]:

- **UR — Prescription-only medicines** (Uitsluitend op Recept): these medicines may only be supplied against a doctor's prescription, typically via pharmacies.
- **UA — Pharmacy-only** (Uitsluitend Apotheek): Medicines issued only in a pharmacy;
- **NR — Non-prescription / self-care medicines** (niet-receptplichtig, zelfzorggeneesmiddelen),

also called Over-The-Counter medicines (OTC).

Since the Medicines Act on 1 July 2007, two categories of OTC medicines have been defined:

- **UAD — Pharmacy or drugstore** (Uitsluitend Apotheek en Drogist): Those issued in pharmacies or non-pharmacy outlets are known as 'drogist';
- **AV — General sales** (Algemene Verkoop): Available in general retail.

Within these different categories, it is important to distinguish between, for example, storage (ambient, 15-25°C - coldstore, 2-8 °C) and processing requirements, risks and dependencies, and licensing requirements and compliance. The legislation per medicine category are outlined in Section 4.2.

### 3.3. Challenges in current logistics

The existing pharmacy-led system faces significant operational challenges that give rise to exploring alternative delivery models. The most important challenges are:

- **GDP compliance:** GDP compliance is a system-wide requirement. A study of practical data from GDP inspections reveals the most common causes of failure. These are: incomplete supplier/customer qualification, gaps in temperature recording/monitoring, deliveries to unauthorised recipients, missing contracts, and inadequate recall systems. Each of these risks poses patient safety and legal risks if any component (including outsourced transport) fails to meet requirements [2].
- **Role responsibilities:** It is imperative to acknowledge the significance of establishing clear channel/role boundaries. Authorities underscore that vertical agreements and margin rules in the context of pharmaceutical distribution, such as the delineation between wholesale and retail, and service-related fees, serve as critical determinants of the activities that are permitted to be performed by whom and under what circumstances. This has the potential to result in the emergence of grey areas if logistics providers become involved in regulated activities [12].
- **Data protection:** Integrating serialisation data and package tracking systems exposes B2C fulfilment models to various interrelated risks. Data protection risks arise when multiple parties (such as pharmacies, carriers and IT providers) process special categories of health data without clearly defined task divisions or adequate safeguards. Uncertainty regarding responsibility or sub-processor chains increases the likelihood of accountability gaps and potential GDPR violations [19]. Also, cybersecurity remains a critical challenge. Studies show that the healthcare sector is a constant target for ransomware and data theft, with many incidents originating from compromised suppliers [18].
- **Traceability:** Risks related to traceability include technical and procedural vulnerabilities at scanning and data exchange points. Under the FMD, erroneous scans or premature decommissioning may disrupt product flows, which could compromise patient safety. Furthermore, if not properly secured, interfaces that exchange encrypted files or unique identifier lists between manufacturers, wholesalers and pharmacies to manage high transaction volumes add new potential breach vulnerabilities [24].
- **Drug shortages:** Drug shortages are a global problem and are only set to become more widespread. Shortages can lead to medication-related problems, such as errors, rationing, delayed delivery and, in some cases, refusal of treatment. Shortages affect not only patients, but also healthcare providers, who are confronted with a lack information about shortages. This puts pressure on primary and hospital care and leads to higher costs [78].

These challenges highlight areas for improvement and emphasise the importance of exploring models in which specialised logistics companies could fulfil orders within legal constraints. This could improve consistency and capacity without compromising individual pharmacies.

### 3.4. Market demand and adoption drivers for B2C models

Current demand for B2C delivery of medicines is driven by structural pressures in the pharmaceutical supply chain, demographic changes and technological advances in prescribing and patient care. Some

observable trends already indicate a gradual shift towards more decentralised, patient-centric delivery models.

The first factor is the increasing volatility of demand for medicines, which puts pressure on traditional pharmacy-centric distribution models. National healthcare systems are experiencing frequent fluctuations in prescription volumes and an increasing number of drug shortages due to factors on both the demand and supply sides, such as pricing policies and productions. Consequently, pharmacies are seeking distribution channels that enable more flexible inventory management and prompt delivery, thereby indirectly stimulating interest in B2C delivery options [50].

Secondly, current forecasting capabilities in pharmaceutical logistics remain limited, which restricts pharmacies' ability to predict and prepare for peaks in demand. Most pharmacies and wholesalers still rely on simple forecasting mechanisms, such as moving averages or qualitative assessments, despite evidence that these methods systematically underestimate or overestimate demand. The benchmark study by Merkuyeva et al. shows that such methods often lead to large forecasting errors, sometimes exceeding 40%, resulting in overstocking, stock outs, or unnecessary rush orders [45].

Thirdly, demographic trends and changes in healthcare provision are driving up the demand for home-delivered medicines. Due to an ageing population, an increase in chronic diseases and an expansion in home care models, an increasing proportion of patients require a regular, predictable supply of medicines [41]. The growing popularity of electronic prescriptions and digital patient monitoring is further reinforcing this shift [61].

Furthermore, data will be the main driver of adoption; a richer and safer use of prescription and outcome data will enable demand-driven supply chains (the right packaging at the right time), thereby increasing service consistency and patient trust. At the same time, demographic and non-pricing factors (e.g. ageing populations) will determine demand intensity by segment and region, favouring hybrid configurations that combine central hubs in densely populated urban areas with local delivery in sparsely populated regions [41].

Finally, as forecasting tools such as AI-assisted symbolic models mature and outperform simple moving average, suppliers can better align their capacity with peaks in demand. They can also reduce waste from temperature fluctuations by making smarter routing and packaging choices, while maintaining the level of service that drives patient satisfaction. This closes the loop between operational capacity and market demand [80].

## 3.5. International B2C Models

In the pharmaceutical sector, business-to-customer (B2C) distribution encompasses a range of routes through which medicines are delivered directly to patients, outside the traditional chain of "manufacturer - (pre-wholesaler) - full-line wholesaler - pharmacy - patient". Despite the fundamental multichannel nature of European markets, with total wholesalers constituting the anchor point, manufacturers and pharmacists have been experimenting with alternative models that integrate the patient interface, digital ordering, and last-mile logistics into new configurations.

### 3.5.1. Mail-order pharmacies

The term 'mail-order pharmacies' is defined as 'digital-first' pharmacies, as they centralise the dispensing of medicines and deliver them exclusively to the customer's home. A longitudinal analysis of NHS prescription data reveals that the UK market leader, Pharmacy2U, is a consistent outlier in terms of volume, with online pharmacies' dispensing activities growing exponentially since 2019 [33]. It is important to note that the provision of additional clinical services for patients has not kept pace with this growth. Aside from scale, the qualitative evidence from community pharmacy teams highlights the value proposition of mail-order dispensing, particularly in terms of convenience and accessibility for immobile, older and rural residents. In broader context, pharmacists consider home delivery to be a valid form of "remote pharmaceutical care", although this may have implications for the comprehensive care availability in pharmacies. It is considered to be the most appropriate course of action for patients who are clinically stable and adhere to the prescribed therapeutic regimen [33].

### 3.5.2. E-pharmacy platforms (self-built vs. 3PL)

It is evident that B2C models exhibit significant variation in their approach to last-mile logistics management. A comparative analysis of two prominent Chinese online pharmacies provides a useful illustration of this phenomenon. Consumer reviews of one pharmacy, which is hosted on a marketplace with self-built logistics, emphasise logistics and customer service. In contrast, another pharmacy, which operates its own chain using 3PL, is predominantly rated on price. The study concludes that tighter logistics control provides a strategic advantage and recommends a hybrid Online-to-Offline (O2O) approach, working with local pharmacies to improve distribution efficiency. The same evidence underscores a general design choice for B2C pharmaceutical dispensing: delivery via an in-house network (speed, reliability, brand service) versus a 3PL (variable performance, lower fixed costs) [42].

### 3.5.3. Hybrid models using pre-wholesalers/3PL and DTP links

Pre-wholesalers, who frequently function as 3PL providers, offer ambient/refrigerated storage, order preparation, and distribution services on behalf of manufacturers to wholesalers, hospitals, or pharmacies, without acquiring ownership of the goods. Reduced Wholesale Arrangements (RWAs) are also described, whereby manufacturers limit distribution to a small group of selected wholesalers. Both instruments are used alongside Direct-to-Pharmacy (DTP) contracts to tighten control at the downstream interface. In a business-to-consumer context, these definitions clarify the integration of GDP-compliant fulfilment services provided by parcel service providers into the supply chain operations of manufacturers or large distributors. This integration involves the transfer of transport and execution of services (and the associated GDP obligations) without transferring ownership of the product or assuming liability for sale [82].

Moreover, analytical research into the model choices of new entrant suggests that a DTP pharmacy configuration, integrating telemedicine, online care, and home delivery, can outperform both traditional pharmacies and "normal" e-pharmacies in terms of profits and patient experience. This emphasises the commercial advantage of models that link healthcare services to reliability in the final stage of the delivery process [86].

### 3.5.4. Urban - rural configuration

Geographical location has been shown to influence the performance of models and the costs of services. In Northern Ireland, there is a marked variation in the density of pharmacies across different local districts. In this study, respondents explicitly linked home delivery to the overcoming of distance and mobility barriers. In densely populated urban areas, the advantages of centralised mail order companies are clear, with short distances to parcel centres and predictable delivery windows. In less densely populated or hard-to-reach areas, however, O2O/community fulfilment models leverage local proximity to maintain continuity of care while delivering doorstep convenience. This usefully diversifies a carrier's route mix and usage profile [33].

## 3.6. Stakeholders

Within this framework and the scope of the study, regulators and other stakeholders play a crucial role. This stakeholder analysis focuses on actors who have a formal role, decision-making authority or restrictive influence over the organisation of the fulfilment of medicines in B2C environments. The various stakeholders listed below are divided into regulatory and supervisory authorities, industry organisations and interest groups, operational actors and end users.

### 3.6.1. Regulatory and supervisory authorities

- **The European Commission (EC):** drafts EU directives and regulations (such as 2001/83/EC, 2011/62/EU and 2016/161), and draws up GDP guidelines. The EC thus determines the framework for the distribution of medicines in the internal market. The EC is relevant because it initiates legislation and proposes amendments.
- **The Medicines Evaluation Board (College ter Beoordeling van Geneesmiddelen (CBG)):** This is the Dutch medicines authority responsible for assessing, registering and monitoring medicines. It assesses whether medicines can be placed on the market, monitors their quality and safety, and implements European directives, such as the Falsified Medicines Directive, in national as-

assessment processes.

- **The Healthcare and Youth Inspectorate (Inspectie Gezondheidszorg en Jeugd (IGJ)):** It supervises compliance with pharmaceutical legislation and GDP. It inspects manufacturers, wholesalers, pharmacies and logistics service providers. It focuses on enforcing licensing requirements and quality systems to ensure a safe distribution chain. The IGJ also provides important guidance, such as the FAQ on the 72-hour rule [30], and is therefore a key player in operational enforcement.
- **Farmatec:** Farmatec is the official body responsible for issuing licenses within the pharmaceutical supply chain, including the WDA [21]. It assesses license applications from manufacturers, wholesalers and other parties that wish to process, store or distribute medicines. This makes Farmatec a crucial stakeholder, as it determines which logistics and pharmaceutical companies are legally permitted to join the supply chain.
- **The Dutch Medicines Verification Organisations (NMVO)** is responsible for the management of the national register (NMVS) for the purpose of FMD verification. Manufacturers, pharmacies and wholesalers operating within the Netherlands are obligated to connect to the NMVS. Each medicine package is assigned a unique code. It is the responsibility of manufacturers, licensees and wholesalers to ensure that each unique code is entered into the NMVS. It is the responsibility of the pharmacist to ensure that the code on the package is compared with the NMVS for each medicine dispensing. It is important to note that verification scans can also be conducted in other locations within the chain. Consequently, the NMVS meticulously records each movement of a drug packaging. The entity responsible for registering such a "movement" is also known. The document's objective is to provide a comprehensible overview of the pertinent legislation and regulations concerning the safety of the NMVS and the safeguarding of personal and corporate data [51] [52].
- **Autoriteit Persoonsgegevens (AP)** is the supervisory authority for the General Data Protection Regulation (GDPR) (Algemene Verordening Gegevensbescherming (AVG)). It is imperative to acknowledge that health data is categorised as a distinct type of personal data, for which specific and rigorous legislative frameworks are in place [3].

### 3.6.2. Industry organisations and interest groups

- **Koninklijke Nederlandse Maatschappij ter bevordering der Pharmacie (KNMP):** This is a representative body for community pharmacists. The KNMP represents the interests of the pharmacy sector and advocates the integration of physical and online pharmacies. It is critical of initiatives outside the 'pharmacy network' due to concerns about quality and cooperation [36].
- **Patiëntenfederatie Nederland (NPCF):** This is an interest group that represents patients and consumers. The NPCF promotes the interests of end users, such as accessibility and the safety of care. Alongside with health insurers, the NPCF campaigns for digital innovation that enhances patient safety [57].
- **Health insurers:** Although not explicitly mentioned, insurers in the Dutch system are interested in efficient distribution and low costs [20]. They can support models that reduce overall costs, such as centralised processing and delivery, which can be cost-effective on a large scale. However, they will also require proven safety and compliance. Their interest lies in ensuring that any new processing service is compatible with insurable care and does not entail additional risks or liability.

### 3.6.3. Operational actors

- **Pharmacist:** Pharmacists dispense medicines to patients. As final dispensers, the pharmacists are subject to their own professional standards and are responsible for the safe transport and storage of medicines. As stakeholders, they depend on reliable distribution and regulations governing internet sales and delivery differentiation.
- **Responsible Person (RP):** This person is legally required in every company with a WDA [65]. This person is responsible for ensuring compliance with GDP regulations and quality systems within the company. The RP monitors procedures, maintains contact with the inspectorate and ensures that the company operates legally. They are operationally crucial and influence compliance.
- **3PLs:** These are companies that provide storage, transport, or other logistical services for the pharmaceutical sector. These companies form the scope of the study and are operationally responsible for ensuring that deliveries are in good condition, traceable, and timely. Their interests

are economic (expanding services) and qualitative (liability for errors). As subcontractors, they must comply with GDP regulations and recognise the opportunities (e.g. outsourcing markets) and limitations (e.g. licensing requirement) that these regulations present.

- **Wholesalers:** Licensed pharmaceutical wholesalers (WDA holders) purchase, store and distribute medicines within the supply chain. They operate under GDP requirements and are responsible for maintaining product quality and traceability. As established intermediaries between manufacturers and pharmacies, they hold a strong market position and may be directly affected if 3PLs expand into licensed or centralised distribution activities.
- **ICT- and e-health suppliers:** Companies that provide e-prescription systems and track-and-trace solutions. They support the digital supply chain, for example by facilitating links between pharmacy and logistics systems. They are interested in ensuring that systems comply with regulations.

#### 3.6.4. End users

- **Patients:** They are the end users of medicines. Although they are not directly involved in the supply chain, their interests are at stake (e.g. the right to safe and accessible medication and privacy in home delivery).

Table 3.1 provides an overview of each key stakeholder's interests and degree of influence, and indicates who should be involved in designing and implementing improvements.

Table 3.1: Stakeholder analysis

Stakeholder	Interest	Power
<b>Regulatory and supervisory authorities</b>		
<b>EC</b>	<b>Medium:</b> Relevant because EU legislation forms the basis, but will not change in the short term within this study.	<b>High:</b> Can change regulations and determines the limits of what member states are allowed to permit.
<b>CBG</b>	<b>Low:</b> The CBG does not directly influence fulfilment because it has no distribution or licensing tasks.	<b>Low-Medium:</b> Influence on product classification, but no control over distribution processes.
<b>IGJ</b>	<b>High:</b> Directly determines what is and is not permitted within distribution and fulfilment.	<b>High:</b> Can revoke permits, enforce regulations, and block logistical scenarios.
<b>Farmatec</b>	<b>High:</b> 3PLs need Farmatec if they want to carry out storage or distribution >72 hours.	<b>High:</b> Without a Farmatec license, 3PLs are legally prohibited from performing certain fulfilment tasks.
<b>NMVO</b>	<b>Medium:</b> Relevant mainly for UR verification; 3PLs are not allowed to scan or decommission.	<b>Medium:</b> Cannot prohibit actions directly, but the system imposes strict technical limits.
<b>AP</b>	<b>High:</b> B2C fulfilment involves health data; privacy rules strongly affect operational feasibility.	<b>High:</b> Can prohibit processes or impose fines; determines limits of data sharing.
<b>Industry organisations and interest groups</b>		
<b>KNMP</b>	<b>High:</b> Strong interest in maintaining professional responsibility, patient safety, and control over dispensing processes.	<b>Medium-High:</b> No direct legislative power, but significant influence through professional standards, lobbying, and sector-wide guidance that shapes acceptable practice.
<b>NPCF</b>	<b>High:</b> Strong interest in accessibility, privacy, reliability, and safety of medicines distribution.	<b>Low-Medium:</b> No formal regulatory authority; indirect influence through public opinion and collaboration with insurers and policymakers.
<b>Insurers</b>	<b>Medium:</b> They have a financial interest in efficient and cost-reducing fulfilment models, but only if these maintain patient safety and remain compliant.	<b>Medium:</b> They cannot change regulation, but they do influence which distribution models can scale in practice.
<b>Operational actors</b>		
<b>Pharmacist</b>	<b>High:</b> Decide whether and which logistics tasks may be delegated to 3PLs	<b>Medium:</b> No legislative power, but decisive for delegation and collaboration
<b>RP</b>	<b>Medium:</b> Directly involved in operational feasibility of out-sourcing to 3PLs.	<b>Medium:</b> Internal authority to approve or block fulfilment processes.
<b>3PL</b>	<b>High:</b> Primary target group of this study and directly restricted by legal constraints.	<b>Low-Medium:</b> Cannot change legislation; depend on pharmacists and license holders; responsible for obtaining licenses if needed.
<b>Wholesalers</b>	<b>High:</b> Strong commercial interest, as hybrid fulfilment models may affect their distribution role and competitive position.	<b>Low-Medium:</b> Limited direct decision-making power over the introduction of new hybrid models; influence is mainly indirect through market position and existing contractual relationships.
<b>ICT suppliers</b>	<b>Medium:</b> Interest in scalable, interoperable fulfilment models that require digital integration and data exchange.	<b>Low:</b> No decision-making power; influence is technical and facilitative.
<b>End users</b>		
<b>Patients</b>	<b>Medium:</b> Strong interest in safe and timely delivery.	<b>Low:</b> Limited direct power, indirect influence via patient organisation and public opinion.

In order to gain a clear insight into the influence and involvement of stakeholders, a power-interest diagram has been developed (Figure 3.2).

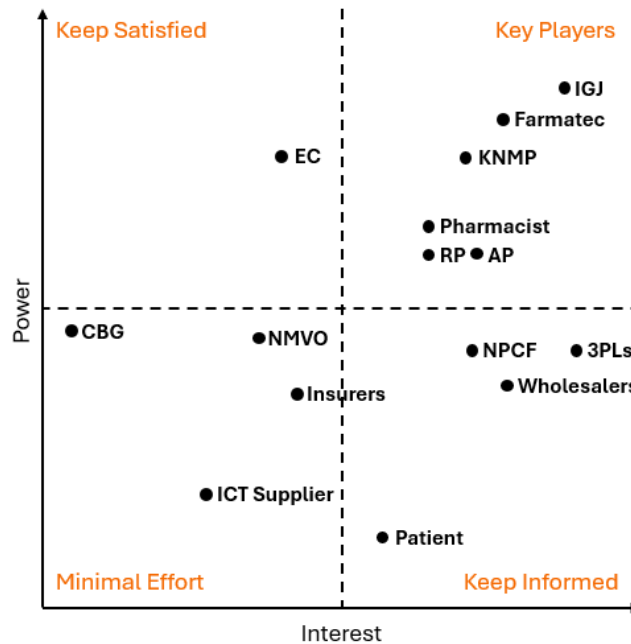


Figure 3.2: Stakeholder Power-Interest grid

### 3.6.5. Collaborations and tensions

Within the Dutch pharmaceutical distribution system, clear mutual dependencies exist between stakeholders, as well as structural tensions affecting the feasibility of new B2C fulfilment models. One important collaboration is that between pharmacies and fulfilment companies (3PLs). When logistics activities are outsourced, the pharmacy remains legally responsible for the medicine and must ensure that the fulfilment company performs its operational tasks in accordance with GDP. In accordance with GDP, this collaboration must be set out in a contract, including explicit agreements on storage conditions, transport, quality assurance and supervision.

However, pharmacies are in fact small and medium-sized enterprises that operate in a highly regulated market and have limited financial resources. Consequently, they tend to prioritise activities closely related to revenue generation, operational control and risk management. Patient safety is the primary concern, and errors in outsourced logistics directly affect both the patient and the pharmacy's legal liability. For this reason, pharmacies are generally reluctant to outsource fulfilment activities unless it offers clear economic or strategic advantages over the current working method. Therefore, outsourcing is only considered if it demonstrably leads to improvements in efficiency, scalability or cost-effectiveness without compromising quality or safety controls.

Furthermore, the responsibility of the pharmacy (or wholesaler) extends beyond simply concluding a contract. The IGJ states that the license holder must actively supervise compliance with GDP by the 3PL engaged, including through audits and quality agreements. While this dependency relationship necessitates cooperation, it also places considerable organisational and administrative pressure on pharmacies, which may limit their willingness to outsource.

In addition to operational cooperation, clear tensions exist at policy and market levels. A notable example of this is the dispute between professional pharmacist organisations and health insurers. The KNMP, for example, opposes initiatives by health insurers such as VGZ that promote the concept of fully independent online pharmacies. The KNMP has raised concerns about the loss of integrated pharmaceutical care, the fragmentation of responsibilities and the potential risks to patient safety and continuity of care [29]. On the other hand, health insurers see e-pharmacies and scalable B2C models

as a means of improving the efficiency and accessibility of pharmaceutical care. The Ministry of Health, Welfare, and Sport partly supports this vision and has publicly stated that it sees added value in independent online pharmacies, particularly in light of increasing capacity pressures and staff shortages in healthcare [29]. This tension manifests as lobbying, public debate and uncertainty for implementation partners such as fulfilment companies, who depend on policy flexibility and support from their professional groups.

Tensions may also arise between the government and the parties responsible for implementation. For example, strict enforcement by the IGJ may conflict with pharmacies' and logistics service providers' desire for greater operational flexibility in areas such as central storage and automated order processing. Additionally, friction may arise between pharmaceutical wholesalers and logistics service providers when wholesalers insist on maintaining their traditional role in the chain by insisting on transit through their own distribution networks at the expense of independent 3PL solutions.

At the same time, some forms of cooperation are inevitable. This is particularly true of the implementation of the Falsified Medicines Directive (FMD). To ensure the correct verification and traceability of medicines, multiple parties—including manufacturers, wholesalers, pharmacies and logistics companies—must work together to ensure that each package is scanned and registered correctly. Errors or negligence in one area can have direct consequences for the entire chain, highlighting the need for collaboration across the entire supply chain.

### 3.7. Conclusion

This chapter answers SQ1. The analysis shows that the Dutch pharmaceutical supply chain operates within a pharmacy-centric, highly regulated model, in which pharmacists have exclusive authority over the dispensing of medicines. Although recent innovations, such as electronic prescriptions, automation and central processing, have improved efficiency, the final stage of delivery remains fragmented and difficult to scale up. Meanwhile, demographic pressures and the rising demand for home care are creating an increasing need for reliable B2C delivery models.

Examples from other countries show that large-scale direct delivery to patients is feasible when clinical responsibility remains with pharmacists and logistical tasks are delegated under strict quality and data protection conditions. In the Netherlands, however, legal restrictions limit the role of non-pharmaceutical actors, despite operational challenges and market trends driving demand for alternative delivery configurations (see Chapter 4).

Finally, the stakeholder analysis reveals that regulatory authorities, professional organisations and pharmacies work together to determine how these rules are interpreted and applied in practice. Supervisory bodies such as the IGJ and Farmatec play a decisive role in determining what is considered permissible, while professional organisations influence the boundaries of what is considered acceptable outsourcing. This reinforces the conclusion that feasibility is not only a legal issue, but also a matter of governance and stakeholders.

Overall, the analysis suggests that there is conceptual scope for pharmacy-led B2C models supported by specialised logistics service providers, provided that professional oversight and GDP compliance are ensured. These findings form the basis for the subsequent legislative and market analysis and scenario development.

# 4

## Legislative framework analysis

The fulfilment of medicines in the Netherlands is governed by a complex, multi-layered legislative framework comprising European directives, national legislation, professional guidelines and operational standards. Together, these rules determine which parties are authorised to carry out specific activities within the pharmaceutical supply chain, the conditions under which they can do so, and their associated responsibilities. Due to the scope and complexity of this framework, the aim of this chapter is not to provide an extensive legal overview. Instead, it focuses on the legislative and regulatory elements most relevant to the research objective.

Figure 4.1 illustrates the analytical structure employed in this chapter. The legislative framework is examined in increasing detail. At the most general level, European regulations establish the fundamental principles for the fulfilment of medicines and quality assurance. These principles are then implemented and specified in Dutch national legislation. Within this national framework, regulatory obligations are differentiated according to the role of stakeholders such as pharmacists and logistics service providers. These obligations are then refined according to medicine categories, in line with the UR, UA, UAD and AV classification system. At the operational level, there are additional requirements regarding labeling, traceability and handling sensitive health data.

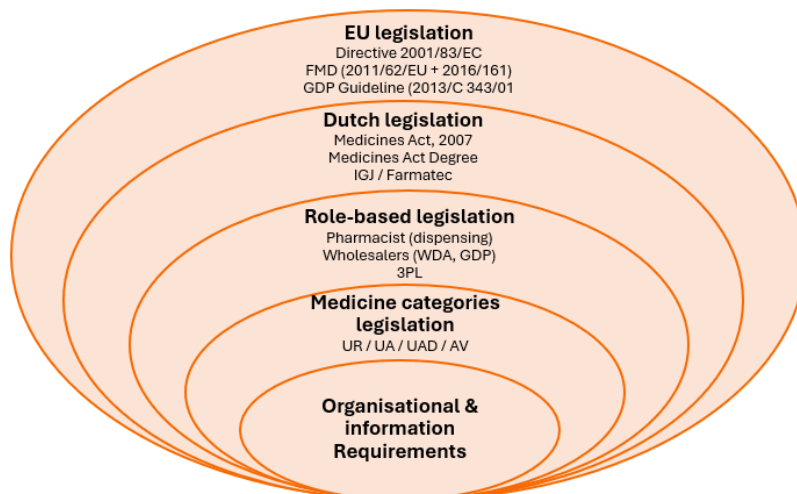


Figure 4.1: Legislative framework structure

This layered approach clarifies how legislative responsibilities and restrictions accumulate throughout the supply chain, highlighting potential ambiguities or tensions when operational activities are delegated outside the traditional pharmacy environment.

This chapter precedes the scenario analysis in order to prevent legal rules from being introduced in a fragmented or ad hoc manner for each scenario. Instead, it provides a clear, comprehensive overview of the current legislative context. It explicitly acknowledges, however, that this framework was developed for traditional, pharmacy-focused fulfilment models and does not anticipate innovative or hybrid implementation configurations. In the subsequent scenario chapter, therefore, the rules and principles outlined in this chapter are used as an analytical lens rather than as fixed conclusions.

This chapter addresses sub-question 2:

- **SQ2:** What do current Dutch medicines legislation and GDP guidelines prescribe regarding medicine logistics?

Section 4.1 outlines the key European and Dutch legislation concerning the distribution and supply of medicines. It establishes the overarching legal framework within which pharmacies and external logistics service providers must operate. This framework forms the basis for all subsequent analyses. Section 4.2 distinguishes between the legal requirements for each category of medicinal product. This distinction is essential for exploring the suitability of outsourcing fulfilment activities and identifying segments with different levels of legislative complexity. Section 4.3 examines how legal responsibilities and obligations differ between various stakeholders, including pharmacies, wholesalers, and logistics service providers. It clarifies the distribution of responsibility and liability within the pharmaceutical sector, which is crucial for evaluating possible collaboration models. Section 4.4 discusses data protection requirements and the use of pharmacy information systems. It emphasises how data management restricts the delegation of fulfilment activities and influences the integration of external logistics service providers into pharmaceutical processes. Section 4.5 analyses temporary relaxations that occurred during the pandemic. It provides insight into how the legislative framework can adapt in exceptional circumstances.

## 4.1. (Inter)national legislative framework

This section discusses the EU directive drawn up by the EU legislator and their implementation in the Netherlands. It will provide a general overview. Section 4.3 then follows, offering a more detailed overview of the laws and regulations for various stakeholders.

### 4.1.1. Europe

The legislator framework for the fulfilment of medicines in the EU is formed by European directives and regulations. Directive 2001/83/EC (the community law on medicinal product for human use) establishes the fundamental principles for the production, authorisation and distribution of human medicines. Among other things, this directive stipulates that medicines may only be marketed with a valid marketing authorisation, and establishes the basis for the licensing system for production and distribution. In the Netherlands, this directive has largely been implemented in the Medicines Act in 2007 (see subsection 4.1.2).

In 2011, Directive 2001/83/EC was amended by Directive 2011/62/EU, also known as the Falsified Medicines Directive (FMD). The purpose of this amendment was to combat the import and distribution of falsified medicines within the legal supply chain. The FMD introduced an obligation for manufacturers of prescription medicines to apply safety features to their packaging. From 9 February 2019, all prescription medicines in the EU must have a unique identification code (2D barcode) and an anti-tampering seal. The details of these requirements are set out in implementing regulation 2016/161, which specifies exactly how these safety features must be applied to the packaging and which exceptions apply.

In addition to these EU directives, there are EU measures that set out the practical quality requirements for distribution. EU Directive 2013/C 343/01 (Good Distribution Practice, or GDP) contains guidelines on good distribution practices for medicinal products and how to comply with the GDP Quality Management System (QMS). The European Medicines Agency (EMA) notes that Directive 2001/83/EC (and related regulations) establishes the fundamental legal requirements for distribution, whereas the 2013 GDP guidelines set out the practical standards for storage, transportation, and traceability. In other words, distributors must comply with GDP regulations to ensure the quality and safety of products during storage and transport.

### 4.1.2. The Netherlands

The above EU directives have been implemented into Dutch national legislation. The Medicines Act (Geneesmiddelenwet (Gnw), 2007) sets out the Dutch regulations governing the production, import, wholesale and delivery of medicines. This Act implements numerous provisions from EU directives, particularly 2001/83/EC and subsequent amendments. Article 61 of the Gnw stipulates that only pharmacists and dispensing general practitioners may dispense medicines to patients (see Section 4.2). According to the Gnw, a legislative amendment shows that wholesalers may only supply to other wholesalers and those authorised to dispense the medicines in question. This means that wholesalers in the Netherlands may not supply medicines directly to consumers, but only to pharmacies or certified doctors. This will be discussed in more detail in subsection 4.3.1 and subsection 4.3.2.

The Medicines Act Regulations (Regeling Geneesmiddelenwet) and the Medicines Act Decree (Besluit Geneesmiddelenwet) set out the detailed implementation rules. For example, the Act provides for licensing systems for wholesalers (Wholesale and Distribution Authorisation (WDA)) and preparers (preparation license). Companies that prepare, package or label medicines (or have them packaged and labeled) as part of 'preparation' require a preparation license. Those who only store, pick and transport are classified as 'wholesalers', for which a wholesale license is required (Art. 18, Gnw). On that basis, logistics service providers with wholesale activities must comply with EU GDP guidelines.

A separate licensing regime applies to pharmacies. Public pharmacies (and general practitioners who dispense medicines) require a pharmacy license. Subject to certain conditions, including geographical distances, a general practitioner may apply for a license to operate a pharmacy. This licensing requirement is set out in Article 61 of the Gnw. Online pharmacies and web shops must also register with the relevant register (Online Providers of Medicines at the Centraal Informatiepunt Beroepen Gezondheidszorg (CIBG)) and display the mandatory EU logo if they wish to sell medicines online.

The IGJ is responsible for supervising this medicines legislation, monitoring compliance with GDP and other legal obligations. Licenses such as the WDA are granted by Farmatec, which is part of the Ministry of Health, Welfare and Sport (see Section 3.6 for more information on the role of these authorities).

## 4.2. Legislation by medicine category

As mentioned in Section 3.2, there are several important medicine categories for this research area: UR, UA, UAD and AV. This classification is unique in Europe, combining maximum accessibility with guaranteed safety. It not only prevents abuse, but also ensures that the necessary pharmaceutical care and information is provided when medicines are dispensed. As mentioned earlier in this chapter, there are specific rules regarding the dispensing of certain categories of medication. This section will therefore provide a brief overview of the rules that apply to each category.

### 4.2.1. UR- and UA-medication

UR medicines require a valid prescription involving a pharmacist for checking and dispensing. Article 61, paragraph 1, of the Gnw states:

*"Without prejudice to the provisions elsewhere in this Act, it is prohibited for anyone to offer for sale, sell, or dispense UR medicines or UA medicines, with the exception of:*

- a. pharmacists practicing their profession in a pharmacy;*
- b. general practitioners who hold license as referred to in the tenth or eleventh paragraph;*
- c. persons and bodies designated for this purpose by ministerial regulation in the circumstances referred to in the regulation. "*

This means that, for the B2C delivery of this category of medication, there must always be a licensed pharmacist involved in processing the prescription and dispensing the medicine. Online sales of these medicines to consumers are legal in the Netherlands, provided they are carried out by a registered pharmacy that complies with all healthcare obligations.

### 4.2.2. UAD-medication

These self-care products may be sold online and delivered to your home, but only by authorised retailers. Article 62 of the Gnw imposes the same requirements on the sale of UAD medications as those

mentioned in subsection 4.2.1, but adds the following:

- *"d. druggists who practice their profession in a drugstore or other point of sale of UAD medicines."*

A drugstore with a UAD license may therefore supply UAD products in-store and via an online shop, provided that the 'responsible care' requirements are met, for example, by providing advice from a qualified drugstore staff member. While this involves fewer logistical requirements than UR medication (as no prescription check is required), measures against misuse must still be implemented (age verification, package insert information, etcetera).

### 4.2.3. AV-medication

AV medicines can be sold freely and shipped directly to consumers. Namely, Article 62 of the Gnw imposes the same requirements on the sale of AV medicines as those mentioned in subsection 4.2.1 and subsection 4.2.2, but adds:

*"with the exception of those who carry out sales activities in the course of their business and are registered for this purpose in the commercial register."*

This category may therefore also be sold via general e-commerce platforms, as long as the seller provides clear instructions for use.

## 4.3. Role-based legislative obligations

To gain a more in-depth understanding of the rules applicable to stakeholders within the scope of this research, this section provides an overview of the relevant laws and regulations on role basis.

### 4.3.1. The Dutch pharmacist

In the Netherlands, pharmacists occupy a legally protected and central position in the dispensing of UR and UA medicines. As previously mentioned, Article 61 of the Gnw states that only pharmacists working in a public pharmacy, or in specific cases, dispensing general practitioners, are authorised to dispense these categories of medicines to patients (see subsection 4.2.1).

In order to practice legally, a pharmacist must be registered as an Article 3 healthcare professional under the individual Healthcare Profession Act (Wet BIG) and listed in the BIG register. This registration confirms the the pharmacist meets the professional, educational and legal requirements necessary to practice the profession.

In addition to the pharmacist's personal registration, each public pharmacy must be supervised by one registered pharmacist. This pharmacist is registered with the IGJ as being responsible for one pharmacy location, meaning that a pharmacist can only be responsible for one pharmacy address at any give time, this phenomenon is also known as '1 vent, 1 tent' (Art. 61.5, Gnw). Furthermore, according to Article 61.1 of the Gnw, pharmacists are only permitted to dispense UR and UA medication at the location where the pharmacist is registered. This establishes the direct legal link between the pharmacy license, the physical location and the pharmacist who bears ultimate responsibility.

A key legal and professional principle that is relevant to this research is that the pharmacist is ultimately responsible for the dispensing process, regardless of operational delegation. According to the KNMP guidelines '*Ter hand stellen*', the pharmacist is responsible for ensuring the correctness and safety of dispensing, pharmaceutical and clinical checks, appropriate packaging and storage conditions, and the overall organisation and safeguarding of the dispensing process. Although tasks in the logistics process, such as preparing, packaging or delivering medication, may be delegated under the responsibility of the pharmacists, their legal obligation to supervise and ensure correct delivery remains in full force.

It is also important to note that stocks of unlabeled, non-specific UR medicines (i.e. medication not intended for an individual patient) may not be stored outside the pharmacy without the appropriate license. As only a pharmacist in the pharmacy can dispense UR medication (Art. 61.1 Gnw), keeping prescription-only medicines outside the pharmacy would mean they have not yet been formally dispense to a patient. Any party keeping such stock outside the pharmacy is legally considered a

wholesaler with 'wholesale stock' and therefore requires a wholesale license, which is B2B only (Art. 18.1, Gnw, in conjunction with Art. 61.1, Gnw).

Importantly, neither the Medicines Act nor the guidelines stipulate that a pharmacist must be physically present for each step of the fulfilment process. Tasks may be delegated. However, delegation does not diminish professional responsibility. For B2C pharmaceutical fulfilment models, these legal conditions imply that while operational logistics can be outsourced, the dispensing authorisation and final professional responsibility remain tied to a BIG-registered pharmacist who is registered for a single pharmacy address. Any scenario in which a logistics provider participates in B2C fulfilment must therefore ensure that the pharmacist's legal responsibilities (particularly regarding oversight, clinical checks and safeguarding quality) are maintained.

#### 4.3.2. Wholesalers

As previously mentioned, in the Netherlands, a WDA is required to operate a wholesale business in medicinal products (Art. 18.1, Gnw). One of the requirements for a WDA is that the organisation has a Quality Management System (QMS) that incorporates the requirements of the GDP guideline. It contains requirements in the areas of quality management, personnel, premises and equipment, documentation, activities, complaints, returns, potentially falsified medicines, medicine recalls, outsourced activities, self-inspection, transport and specific provision for brokers. A WDA permits the company to purchase medicines within the European Economic Area (EEA) and supply them to authorised parties. Different rules apply outside the EEA, but as this study is limited to domestic transport, this will not be discussed in further detail. The law defines 'wholesale' as any activity relating to the purchase, storage, delivery or export of medicinal products manufactured by third parties. Wholesalers may only supply other wholesalers or individuals authorised to dispense medicines to patients, such as pharmacists, hospitals or doctors with a pharmacy license. They are not legally permitted to serve consumers directly. This means that wholesalers have a purely B2B function in the chain.

In practice, a distinction is made between a regular 'wholesale' and a 'contract wholesaler'. A regular wholesaler purchases medicines in its own name and sells them on to customers (pharmacies, institutions, etc.). A contract wholesaler, on the other hand, distributes and stocks goods on behalf of another party, such as a manufacturer or another wholesaler, without owning or purchasing the stock itself. According to the Beleidsregel Aanhoudend Geneesmiddelenvoorraad 2024, a contract wholesaler is defined as 'holding stock for the trade license holder/wholesaler A of medicines that have not been purchased by them'.

From a legal perspective, however, both types of wholesaler must comply with the same licensing requirements and GDP standards. For instance, according to Article 18 of the Gnw, a WDA license is required, whether the wholesaler is acting on their own behalf or on behalf of third parties. Under EU rules (Art. 80, Directive 2001/83/EC), wholesalers must adhere to the principles of Good Distribution Practice. Specifically, this means that every wholesaler must have an adequate quality assurance system in place, as well as a qualified Responsible Person (RP) to ensure compliance with GDP guidelines (paragraph 2.2, GDP guideline 2013/C 343/01). This RP obligation is also embedded in Dutch law through Article 36 in the Gnw, which stipulates that distribution must take place under expert supervision. The RP ensures that temperature control, batch administration, recall procedures and other quality aspects comply with applicable GDP requirements.

Finally, wholesalers may stock unlabeled medicines and distribute them in their original manufacturer packaging. However, they must ensure that what they deliver complies with all packaging and labeling requirements for the next stage of the supply chain. For example, they must ensure that a pharmacy can still apply a label for the patient upon receipt. Any actions involving repackaging or final labeling for end users fall outside the scope of a wholesale license and require a pharmacy license instead.

#### 4.3.3. Logistics / fulfilment service provider

3PLs that transport or temporarily store medicines for clients are not legally classified as a separate category under the Medicines Act. Instead, they fall under either a pharmacy license, a wholesale license, or they operate purely as transporters with no storage function. A 3PL without its own pharmacy or wholesale license may only transport medicines and store them for a very short period of time as part of the transportation process. The IGJ has set a limit of 72 hours in its policy explanation:

- **Transport en storage (<72 hours):** If a 3PL only transports or stores medicinal products for a short period at a hub or cross-dock, no separate license is required. In this case, however the services are subject to GDP regulations and contractual agreements with the license holder (including quality systems, audits, etcetera) [30];
- **Longer storage and distribution (>72 hours):** If a 3PL stores medicines for longer, or carries out additional distribution activities, this is considered wholesale. In that case, a WDA is required [30]. A license is also required for transport involving structural transit storage for more than 72 hours.

Furthermore, a 3PL may not attach patient labels to prescription medicines or deliver them directly to end users without a pharmacy license. Such actions fall under the category of 'dispensing', which is legally reserved for pharmacists (Art. 61, Gnw). Additionally, repacking, or labeling is classified as 'preparation' under the Medicines Act (Art. 1.1 (ee), Gnw). The Act states:

*"prepare: the complete or partial manufacture of medicinal products or active substances, or their packaging or labeling;"*

Furthermore, the Medicines Act (Art. 1.1 (gg), Gnw) gives the following meaning to the term 'labeling':

*"labeling: the application of information to the outer packaging or primary packaging;"*

Therefore, if a logistics service provider wished to label or (re)package medicines for patient on behalf of a pharmacy, they must either hold a pharmacy or manufacturer's license, or this activity must be carried out under the direct responsibility of a pharmacist.

#### 4.3.4. Health insurers

Health Insurers do not formally play a direct role in the fulfilment of medicines to consumers. Although they finance the provision of medication to policyholders, they do not dispense medication themselves. In practice, they limit themselves to concluding contracts with pharmacies and distribution partners to ensure that their insured persons have access to pharmaceutical care in accordance with the Health Insurance Act (Zorgverzekeringswet (Zvw), 2006). Legally, however, this does not change the supply chain, but a health insurer can arrange for certain medications to be delivered to the patient's home via a specialised pharmacy or a delivery service. Their influence is mainly indirect and contractual in nature (e.g. preference policies and logistical agreements). In the context of this study, the role of health insurers is therefore limited to that of interested parties. They benefit from cost-efficient and reliable models, but they have no legal powers or responsibilities within the pharmaceutical logistics chain.

#### 4.3.5. Role-based legislation overview

To clarify the legal boundaries between pharmaceutical fulfilment activities, Table 4.1 provides an overview of the activities permitted by law for each type of actor per category of medicine.

3PLs are not included as a separate category in this table. As discussed earlier in this chapter, there is currently no regulatory model that legally authorises 3PLs to deliver medicines directly to patients. Depending on the scope of their activities, 3PLs either operate under the responsibility of a pharmacy or as a recognised wholesaler, or are limited to transport activities only (<72 hours storage). For the sake of legal clarity, the table therefore focuses on actors that are explicitly recognised in pharmaceutical legislation. Health insurance are therefore also excluded from this overview as they have no formal legal authority within the pharmaceutical logistics chain and do not carry out any regulated fulfilment or dispensing activities.

**Table 4.1:** Legal permissions per actor and medicine category

Activity / Actor	Pharmacy	Drugstore	Wholesaler	Contract wholesaler	Carrier (transport only)
<b>UR medicines</b>					
Sell / dispense to patients	✓	×	×	×	×
Pharmaceutical release	✓	×	×	×	×
Patient-specific labeling	✓	×	×	×**	×
Hold unlabeled stock	✓	×	✓	✓	×
Storage > 72 hours	✓	×	✓	✓	×
<b>UA medicines</b>					
Sell / dispense to patients	✓	×	×	×	×
Patient-specific labeling	✓	×	×	×	×
Hold unlabeled stock	✓	×	✓	✓	×
<b>UAD medicines</b>					
Sell / dispense to patients	✓	✓	×	×	×
<b>AV medicines</b>					
Sell / dispense to patients	✓	✓	✓	✓	×
<b>Regulatory status</b>					
WDA required	×	×	✓	✓	×
RP required	✓*	×	✓	✓	×
GDP Guidelines	✓	✓	✓	✓	✓

To avoid confusion, some specifications in the table are marked with (an) asterisk(s):

- **\* Pharmacy & RP required:** In this case, the RP is the registered pharmacist with a pharmacist license. No separately designated RP is required.
- **\*\* Contract wholesaler & Patient-specific labeling:** Patient-specific labeling can only be carried out under the responsibility of a licensed pharmacist and within the remit of a pharmacy license. In some cases, such as central filling, labels are printed at an external location but are still approved by the pharmacist, or they are required to have their own pharmacy license. In such cases, responsibility still falls to the pharmacist.

## 4.4. Data protection and information governance

Within the EU, any information relating to a person's physical or mental health, or the provision of health-care, is considered 'health data' under the General Data Protection Regulation (GDPR). Such data is special category of personal data, requiring specific safeguards, stricter legal bases and demonstrable accountability from both controllers and processors. Therefore, shipping or delivery data that links a patient's identity to a particular medicine falls under this regulation, even when processed by third parties such as logistics or IT service providers. Controllers must take the appropriate technical and organisational measures to ensure and demonstrate compliance with Articles 24 and 32 of the GDPR. The European Court of Justice has interpreted the concept of 'controller' broadly, meaning that logistics service providers and carriers may be considered joint controllers if they determine the essential means or purposes of processing. This shared responsibility makes precise contractual agreements and liability clauses between marketing authorisation holder, pharmacies and mail processing companies all the more necessary.

## 4.5. COVID-19 relaxations

During the pandemic, there has only been limited structural relaxation in the pharmaceutical sector in the Netherlands. Instead, temporary measures and adjustments to supervision and enforcement were mainly used to ensure continuity of care. Some of these temporary measures are relevant to this study as they demonstrate the circumstances in which the regulator can permit exceptions to the traditional, pharmacy-centered model. The temporary measures were as follows:

- **Temporary storage outside the pharmacy:** One clear, practical measure was to temporarily

permit the storage of medicines outside pharmacies, particularly in clinical settings, in order to enable the treatment of patients with the virus. An April 2020 overview document explicitly states that the IGJ “temporarily permits storage outside pharmacies under certain conditions” to enable healthcare to continue [31]. This measure shows that storage outside the pharmacy is not unthinkable, but the space created was clearly crisis-driven and conditional. For B2C fulfilment by a 3PL, this means that there is room for temporary deviation, but this does not automatically provide structural legitimacy for a scalable model.

- **Exchange of stocks between pharmacies:** The same overview of the latest news on the Coronavirus also mentions that, under certain conditions, pharmacists were temporarily allowed to exchange stocks in order to prevent shortages, and that the IGJ would not enforce this normally prohibited behaviour until a certain date. This illustrates that enforcement can be adjusted in exceptional circumstances to ensure availability. However, this tolerance for the current pandemic does not constitute structural permission for multi-pharmacy B2C fulfilment involving central hubs or shared storage.
- **Remote consultations and digitisation of patient contact:** The sector explicitly referred to an ‘accelerated guide to remote consultation’, indicating a practical acceleration and acceptance of working methods involving remote consultation. This has direct implications for B2C models, as remote consultation and communication may be necessary to ensure ‘care components’ when logistics are centralised. However, this primarily affects care and communication processes rather than the delegation of physical implementation activities to non-pharmaceutical parties.

## 4.6. Conclusion

This chapter examined the Dutch and European legislative framework governing medicine logistics and fulfilment, with the aim of answering sub-question 2: *What do current Dutch medicines legislation and GDP guidelines prescribe regarding medicine logistics?* The analysis shows that pharmaceutical fulfilment in the Netherlands is part of a complex, multi-layered, role-based legislative system. Legal responsibilities are closely linked to professional roles, licenses and physical locations.

Dutch pharmaceutical legislation and GDP guidelines clearly define who is permitted to carry out specific activities within the pharmaceutical supply chain. Key principles include the exclusive right of pharmacists to dispense prescription medicines, strict licensing requirements for wholesaling and storage, and extensive GDP obligations for all parties involved in handling, storing or transporting medicines. Consequently, non-pharmaceutical logistics service providers looking to enter the pharmaceutical fulfilment market must meet significant legal, organisational, and compliance requirements. A 3PL provider can only operate in this market if it strictly limits itself to short-term transport activities or obtains the appropriate wholesale license and operates according to GDP-compliant quality systems. Even then, legal responsibility for dispensing medicines and ensuring patient safety remains with the pharmacy.

The analysis also shows that the legislative framework was not designed with the concept of independent B2C handling by non-pharmaceutical actors. Instead, it is based on clearly defined roles between pharmacist, wholesaler and transporter, each with their own legal obligations. This role-based structure significantly limits the extent to which fulfilment activities can be outsourced without incurring additional licensing requirements. Consequently, a fulfilment company wishing to participate meaningfully in B2C medicine fulfilment must establish extensive contractual agreements, implement robust quality assurance mechanisms and establish robust oversight structures, creating high barriers to entry compared to other e-commerce sectors. In other words, while the legislative framework defines strict legal boundaries, not all elements carry the same degree of interpretative certainty; a distinction that becomes particularly relevant when assessing innovative fulfilment configurations. Table 4.2 provides a structured overview to help distinguish between non-negotiable legal obligations and interpretative grey areas.

**Table 4.2:** Legislative certainty map based on legal and regulatory analysis

<b>Legislative domain</b>	<b>Hard must-comply (legal certainty)</b>	<b>Grey areas (interpretative uncertainty)</b>
Dispensing authority	'Ter hand stellen' is exclusively reserved for a licensed pharmacy; legal responsibility remains with the pharmacist.	The operational boundary between logistics handling and dispensing-related activities is not explicitly defined in legislation.
Licensing structure	Licenses are legally bound to a specific legal entity and recognised physical location (pharmacy or wholesale).	The extent to which hybrid structures (e.g. joint ventures, cooperatives or embedded pharmacy models) satisfy the location-based licensing logic remains interpretative.
Storage duration	Storage of medicines for more than 72 hours requires a wholesale or pharmacy license.	The interpretation of structural transit storage within fulfilment-style hub operations may vary depending on supervisory practice.
Unlabeled medicines	Unlabeled medicines may only be stored within licensed pharmacy (B2C) or wholesale (B2B) environments.	The permissibility of centralised back-office processing for multiple pharmacies without triggering wholesale classification is not explicitly regulated.
Multi-pharmacy centralisation	Legal responsibility for dispensing remains with the individual pharmacy.	Whether central fulfilment models resemble in fact wholesale or a central pharmacy structure remains sensitive to regulatory interpretation.
GDP compliance	Temperature control, traceability and quality management systems are mandatory for all storage and transport activities involving medicines.	The scope and depth of GDP expectations for non-pharmaceutical actors operating within hybrid fulfilment models are not exhaustively specified.
Data governance (GDPR)	Delivery data linking a patient to a specific medicine qualifies as health data under GDPR.	The allocation of controller and processor roles in integrated fulfilment models can be complex and interpretation-dependent.

Overall, this chapter concludes that Dutch pharmaceutical legislation and GDP guidelines form a highly restrictive yet coherent framework that prioritises patient safety, accountability and traceability. While there are some ambiguities that permit non-pharmaceutical service providers to participate in B2C pharmaceutical logistics, it seems to be only possible under strict conditions and within clearly defined limits.

To translate these legislative findings into practical design framework as mentioned in Section 1.6 for the scenario development for Chapter 6, the key legal conditions have been consolidated into a set of mandatory requirements. These requirements serve as a strict checklist for feasibility: any scenario that does not meet them is not legally feasible. The following table provides an overview of the mandatory legislative and regulatory conditions that each scenario must demonstrably meet.

**Table 4.3:** Requirement framework based on legal and legislative analysis

<b>#</b>	<b>Requirement</b>
R1	UR/UA medicines are dispensed exclusively by a licensed pharmacist.
R2	All the necessary permits are in place.
R3	Unlabeled medication is stored in legally recognised locations only.
R4	Full compliance with GDP rules is guaranteed for all storage and transport activities.

# 5

## Market potential analysis

This chapter conducts an examination of the structure and dynamics of the Dutch pharmaceutical market. The aim of this examination is twofold: firstly, to assess the practical feasibility of outsourcing medicine dispensing to non-pharmaceutical logistics service providers; and secondly, to assess the potential demand for such an action. Utilizing the conceptual insights from the preceding chapter, this study explores the organisational structure of the sector and the factors that influence pharmacists' decision to outsource (part of) their dispensing activities. The analysis is based on a mixed method, combining theoretical research (desk research) to map pharmacy types, market size, and sector developments with insights from semi-structured interviews. These interviews were documented using detailed notes taken during the conversations rather than audio recordings or formal coding, partly due to the sensitive nature of the information. The relevant quotes used in the analysis were taken from these notes and presented in anonymised form (see Section 5.2). These interviews reveal how pharmacists view outsourcing, what concerns they have, and what operational or regulatory circumstances influence their decision-making.

This chapter addresses sub-question 3:

- **SQ3:** To what extent is there a viable market for external fulfilment services in the pharmacy sector, and how willing are pharmacists to outsource the fulfilment of medicines?

Section 5.1 analyses the structure and dynamics of the Dutch pharmaceutical market. It provides insight into the extent to which the market offers economic opportunities for external fulfilment services. It outlines the market context within which a collaboration with a third-party logistics provider (3PL) must be explored. Section 5.2 examines pharmacists' views on fulfilment collaboration, as revealed through interviews. It considers how pharmacists experience current logistics practices, where they identify potential efficiencies, and the conditions under which they would engage external logistics service providers.

### 5.1. Theoretical research on pharmaceutical market

This section gives the main types of pharmacies relevant to B2C fulfilment, which major players are there in the field and the current market structure.

#### 5.1.1. Types of pharmacy

The pharmacy sector in the Netherlands has different types of pharmacies [44], each with its own role and regulations. The main categories are:

- **Public pharmacies:** These are regular neighborhood and city pharmacies that are accessible to all members of the community [20]. The organisation is responsible for the direct dispensing of medicines to patients, encompassing both prescription and over-the-counter medications. The majority of pharmacies in the Netherlands can be categorised as such, offering B2C services (see subsection 5.1.3);

- **Outpatient pharmacies:** These facilities are situated in or in the environs of hospitals and primarily serve outpatient patients, defined as individuals who have been discharged from hospital care or require specialist medication. Although outpatient pharmacies dispense prescription medication directly to patients, this is usually carried out on site (in the hospital) [26];
- **Hospital pharmacies:** These institutions are responsible for the provision of medication to admitted patients within the hospital. It does not facilitate direct deliveries to external patients, but to hospital facilities. Consequently, they are not particularly relevant to B2C logistics;
- **On-call pharmacies:** These pharmacies provide services outside of standard operating hours, including evenings, nights and weekends. They are often set up regionally (sometimes located at a hospital) to provide emergency medication when regular pharmacies are closed. Patients pick up their medication in person in emergencies; there is usually no home delivery;
- **Online pharmacies:** These are pharmacies where orders are placed digitally and medicines are delivered to your home by mail or courier. Internet pharmacies usually have a physical pharmacy license at a specific location, but operate nationwide through delivery. They focus on B2C delivery via logistics partners;
- **Pharmacist-general practitioners:** In sparsely populated areas where there is no public pharmacy nearby, general practitioners are allowed to perform pharmacy functions. They dispense medicines directly to their own patients (often during the consultation). Although this group supplies medicines directly to patients, they generally do so without external logistics; the patient receives the medication directly at the general practitioner's practice. Pharmacist-general practitioners are found in regions where a regular pharmacy is not economically viable. This is a form of subsidised provision for basic pharmacy services in remote areas to ensure (the general practitioner acts as a pharmacist to ensure continuity).

Of the types of pharmacy previously mentioned, public pharmacies (which also can conduct online activities) and online pharmacies are of particular relevance to a fulfilment service provider that wishes to assume responsibility for B2C fulfilment. It is evident that hospital pharmacies do not engage in external delivery services; rather, service pharmacies and outpatient pharmacies primarily provide acute medication on site. This suggests a lower probability of outsourcing fulfilment, given that their patients present directly at the counter in urgent situations. Pharmacist-general practitioners operate on a small scale and at a local level, and are neither required nor permitted to provide external delivery.

### 5.1.2. Major players: pharmaceutical wholesalers and pharmacy chains

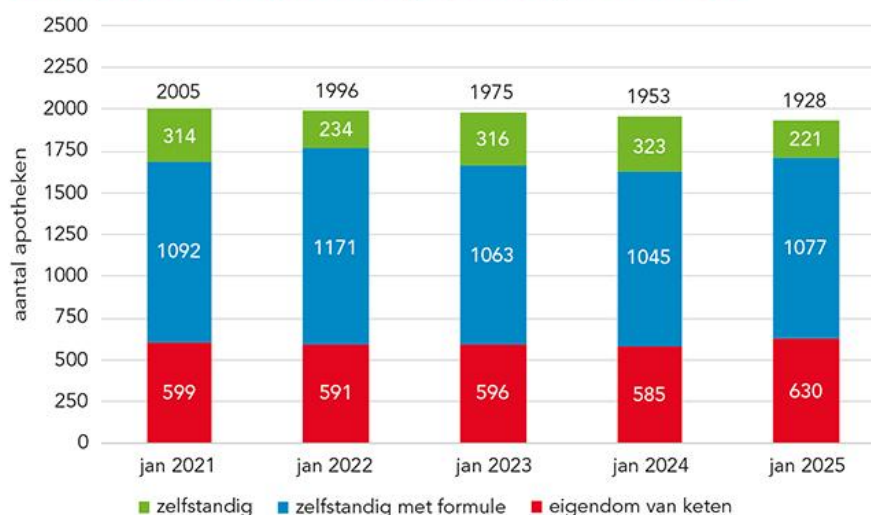
An important feature of the Dutch pharmacy market is that it is dominated by a few large players, particularly on the wholesale and chain side. On the wholesale side, there are currently four large pharmaceutical wholesalers offering a full range of medicines. These four, Alliance Healthcare, Brocacef, Mosadex, and Pluripharm, together supply all pharmacies in the Netherlands, as well as pharmacists, hospitals, and other healthcare. These wholesalers are not permitted to supply patients directly; all medicines must be dispensed through a pharmacy. They are also referred to as full-range wholesalers. In principle, every public pharmacy purchases its medicines through (one of) these large distribution companies. In addition to these big four, there are approximately 150 smaller licensed wholesalers, but they have a limited range or only serve their own group of pharmacies (e.g., specialised importers or hospital suppliers) [73].

### 5.1.3. Number of pharmacies and market structure

As this study only considers public and online pharmacies, the figures for these two types of pharmacy are shown.

#### Public pharmacies

In the Netherlands, the number of public pharmacies fluctuates between 1,900 and 2,000 locations. The trend over the last five years shows a slight decrease in the total number of pharmacies (Figure 5.1). This decline is partly due to mergers, economies of scale, and profitability constraints for independent pharmacies [75].



**Figure 5.1:** Number of public pharmacies by chain ownership and formula affiliation (Jan 2021-Jan 2025) [75]

At the same time, there is a clear shift in the market structure: the majority of pharmacies have joined chains or formulas (84% of all public pharmacies), while the number of fully independent pharmacies has declined significantly [75]. An important reason for this is that individual pharmacists are hardly able to negotiate independently with health insurers about reimbursements and contracts [68]. Economies of scale and collective purchasing have become crucial, which has reinforced the drive towards chain formation.

#### Online pharmacies

Online pharmacies are a growing segment of the Dutch pharmaceutical market, becoming increasingly relevant in discussions about external fulfilment services. These internet pharmacies allow patient to order prescriptions and OTC medicines online and have them delivered by mail or courier, eliminating the need for a physical pharmacy visit. Use of online pharmacy services has increased in recent years, particularly for repeat prescriptions and chronic medication. During the pandemic, acceptance of remote healthcare and home delivery of medicines increased dramatically, further legitimizing online pharmacies in the eye of patients and policymakers.

In practice, online pharmacies focus almost exclusively on repeat prescriptions because they are predictable and logistically efficient and they cannot supply acute or emergency medication. It is estimated that repeat prescriptions may account for 80% of the total dispensing volume [76].

Despite this growth, the total market share of online pharmacies in the Netherlands remains relatively small. While the Dutch digital pharmacy market is expected to have reached approximately USD 1.5 billion in 2025, this is still small compared to the total market for prescription drugs, which is valued at around USD 40 billion [34]. Consequently, traditional pharmacies continue to process the vast majority of prescriptions.

However, market forecasts indicate continued growth potential, driven by an ageing population and digitisation, but also by prevalence of chronic diseases and the growing acceptance of online prescriptions [34]. As online pharmacies operate on small margins and depend on large volumes, the continuous optimisation of logistics is essential. In this context collaborating with specialised 3PLs can offer advantages in terms of storage, packaging and last-mile delivery.

#### 5.1.4. Theoretical drivers for outsourcing fulfilment

An important factor influencing the feasibility of external fulfilment services is understanding why pharmacies would consider outsourcing their fulfilment activities. Although the interviews conducted as part of this study in Section 5.2 mainly concerned traditional pharmacies, which generally operate as local dispensing points, several structural developments in the sector suggest that outsourcing logistics may become increasingly relevant, particularly for online pharmacy models.

Firstly, many public pharmacies in the Netherlands are under increasing operational pressure, primarily due to staff shortages and rising workloads. According to industry reports, in 2025 approximately three-quarters of Dutch community pharmacies is facing staff shortages [53] [58]. This will significantly impact daily operations, increasing the workload for pharmacists and pharmacy assistants. Additionally, pharmacies dedicate considerable time to operational tasks such as managing medicine shortages, administrative work, and inventory management [74].

Secondly, the growth of online pharmacy models, as discussed in Figure 5.1.3, introduces a different operational logic to that of traditional pharmacies. Online pharmacies are increasingly adopting large-scale dispensing and home delivery models. In this context, fulfilment activities such as storage, order picking and packaging resemble typical e-commerce logistics processes. Therefore, outsourcing these activities to specialised fulfilment providers can improve scalability, reliability and operational efficiency. While this model is less relevant for small neighborhood pharmacies, it can be particularly attractive for online pharmacies or those that dispense on a large scale.

Finally, various studies emphasise that pharmacists want to focus primarily on their core tasks of providing pharmaceutical care and supporting patients. While logistical and administrative activities are necessary, they do not directly contribute to clinical care. Therefore, sector analyses increasingly point to digital services, automated dispensing and logistics partnerships as possible solutions for maintaining service quality despite increasing workloads and staffing constraints [74] [54].

Overall, these developments suggest that interest in outsourcing fulfilment is likely to be driven primarily by organisational and logistical factors rather than pharmaceutical ones. While traditional pharmacies currently depend on internal activities, the continued growth of online pharmacies and digital delivery models could provide a stronger incentive to outsource fulfilment activities to specialised logistics service providers.

## 5.2. Pharmacists perspectives

This section examines how legislation and regulations work in practice, as well as how pharmacists within the scope of this research view potential collaboration with a non-pharmaceutical logistics service provider. This was achieved through interviews with three pharmacists: pharmacist 1 (P1), pharmacist 2 (P2), and pharmacist 3 (P3) (see Appendix D). These interviews reveal a cautious yet informative perspective on collaborating with external fulfilment and logistics service providers in the pharmaceutical market. They emphasised that any external dispensing service must operate within the strict legal framework applicable to pharmacies, whereby a licensed pharmacist remains responsible for dispensing medicines. As P3 put it:

*"Behind the seemingly straightforward act of preparing and handing out a prescription lies a great deal of laws and regulations to protect the patient."*

### 5.2.1. Current role of logistics providers

All three pharmacists confirmed that non-pharmaceutical logistics service providers are currently only used for transport and delivery, and not for other fulfilment steps. For example, P1 uses a parcel service to deliver medicines to patients, including international shipments, but the carrier's role is strictly limited to last-mile delivery. The pharmacy retains control over processing prescriptions, labeling and verification before handing over the sealed package to the courier. An interesting point made by P1 is the responsibility for home delivery with their external delivery service:

*"Once it leaves the pharmacy, the delivery service is responsible, and the patient is responsible for where the delivery takes place"*

Another point the respondent emphasised, is that they do not foresee logistics companies playing a more extensive role in the broader fulfilment process:

*"Their role remains limited to transport and handover, not to pharmaceutical or content-related processing. If they do perform these tasks, you are effectively turning the 3PL into a semi-wholesaler or pharmacists, roles which they are not equipped to fulfill."*

In other words, as any pharmacist will confirm, these tasks form an integral part of the role and cannot

therefore be outsourced to a 3PL company under the current system.

### 5.2.2. Internal efficiency and external outsourcing

All three pharmacists indicated that they actively strive for efficiency and centralisation within pharmacy sector, but always under the supervision of a pharmacist. For instance, P1 has implemented a centralised speed fill facility to process repetitive chronic prescriptions for all its affiliated pharmacies. Every day, hundreds of packages are prepared in a central distribution centre and sent back to the local pharmacies in sealed, patient-specific bags. However, this smart fill process is crucially carried out by the pharmacy's own qualified staff and the packages are sent back to the pharmacy before being dispensed to the patient. This highlights that pharmacies are willing to automate or centralise fulfilment activities, but they keep such innovations within their own organisation or within the legal boundaries of the pharmacy. Certain steps, P1 addresses, such as labeling medications in the pharmacy information system (Apotheek Informatie Systeem (AIS)), cannot legally be performed by an external party without a pharmacy license.

Another interesting point is that P2 uses its own speed fill machine within the pharmacy. According to the respondent, no certified employees are required to operate this machine because no direct 'pharmaceutical actions' are performed. However, the uncertified employee does provide the medication with the correct label, which is part of the process of dispensing, for which the pharmacist is responsible (subsection 4.3.1). However, according to P2, it is a foolproof system and even uncertified employees can operate the machine. Nevertheless, the pharmacist claims that this speed fill machine cannot be operated without a pharmacist nearby:

*"As errors such as jamming or incorrectly applied labels must always be corrected by a licensed pharmacist. The medication is also checked again when it is dispensed."*

In addition to these internal efficiency measures, P3 also considered the inefficiencies of the current medicine delivery practices. According to the respondent, many pharmacies still rely on "a few delivery vans driving around in the afternoon" to deliver medicines to patients, a practice which they described as highly inefficient. This highlights the fact that, while pharmacies are optimizing their internal delivery processes, the last mile of the supply chain is often still organised in an ad hoc matter.

### 5.2.3. Outsourcing to a 3PL

When discussing the idea of an external logistics company playing a greater role in order fulfilment, pharmacists were generally sceptical and protective of their domain. The idea of a 3PL functioning as an independent 'mail-order pharmacy' outside of the traditional pharmacy system met with fierce resistance. P2 states:

*"When pharmacists hear the term 'mail-order pharmacy', they immediately reject the idea."*

All respondents shared this sentiment: direct B2C medication processing by a non-pharmacy entity is seen as incompatible with legal requirements and professional standards. P2 stated outright that they would never agree to a collaboration involving an external party supplying medicines directly to patients. Their reasons stem not only from concerns about legality, but also from concerns about patient safety, continuity of care and professional responsibility (P2 and P3). Pharmacists see themselves as necessary gatekeepers who check prescriptions, advise patients and ensure the proper use of medicines. These functions cannot be fully 'logisticised' without losing the healthcare component (P2 and P3). P3 therefore repeatedly emphasised:

*"Logistical efficiency cannot be viewed separately from pharmaceutical responsibility and ethical considerations."*

### 5.2.4. Potential models of collaboration

Although the idea of independent implementation by a 3PL was rejected, the interviews revealed that pharmacists consider more nuanced collaboration models feasible. In these models, the pharmacy remains central to the process, with the external party providing support services rather than taking over dispensing. For example, P2 proposed a scenario in which a logistics company could set up a centralised distribution system in collaboration with pharmacies. In this proposed project, the logistics company would manage a joint storage and distribution centre for medical devices under the author-

ity of the participating pharmacies. Notable, this idea was initially limited to non-medicinal products only (medical devices rather than prescription medicines) to avoid legal complexity. For prescription medicines, the interviewee considered a central warehouse acting as a distribution point for existing pharmacies to be the most realistic approach, which simply aligns with existing structures, such as centralised filling by wholesalers, which is a B2B service. As P2 summarises:

*"Feasible innovations in this area would be more likely to lie in the area of B2B distribution and delivery on behalf of wholesalers / pharmacists than in independent pharmaceutical fulfilment."*

### 5.2.5. Preconditions for collaboration

If cooperation is ever applicable, the pharmacists have drawn up a number of strict conditions that must be met for cooperation with a fulfilment partner to be acceptable. These conditions include:

- The ultimate responsibility of the pharmacist for dispensing medicines must remain clear and indisputable;
- All GDP requirements and procedural quality controls must be complied with;
- The service must deliver medicines quickly and reliably;
- Patients (especially vulnerable groups) must have continuous and accessible communication channels with the service.

If a 3PL cannot meet these criteria, the pharmacists believe it should not be involved in the delivery of medicines. In addition, they highlighted potential risks associated with any form of outsourcing that must be managed, such as delays or errors in delivery (e.g. packages being lost or arriving late), which could have serious consequences for patients, and reduced contact with or guidance for patients if the pharmacist is less involved in the delivery process. These concerns emphasise the importance of designing any operational model in a way that supports the pharmacist-patient relationship and the safety check inherent in the current system.

Another recurring theme that emerged from the interview with P3, was the need to build trust gradually when external parties are involved in delivering medicines. They recommended a cautious, step-by-step strategy for introducing a logistics partner into the pharmaceutical supply chain. P3 suggested:

*"Begin by only performing home delivery on behalf of pharmacies, with no independent fulfilment operations, strictly providing last-mile logistics. If this proves reliable and the necessary processes and trust are established, the partnership could slowly be expanded to include additional services, such as central warehousing or packaging tasks"*

## 5.3. Conclusion

This chapter examines the extent to which the Dutch pharmacy market offers opportunities for external fulfilment services, and how willing pharmacists are to outsource fulfilment activities (SQ3). The analysis reveals that, rather than being a widely accessible or easy-to-enter market, the market offers selective and conditional opportunities for third-party logistics providers.

The market is highly concentrated and integrated, with a limited number of major players dominating the sector. These mainly include pharmacy chains and wholesalers. These companies benefit from economies of scale, long-term contracts and well-established infrastructures, as well as advanced internal logistics systems. Consequently, direct entry into the market for a non-pharmaceutical 3PL company, particularly in the form of a broad, generic fulfilment proposition or as a substitute for existing wholesale structures, is challenging and seems to offer limited market potential.

At the same time, however, there are clear differences between market segments. Many local pharmacies, particularly smaller or independent ones, organise handling and delivery in a relatively inefficient manner. Pressure on operating costs and last-mile delivery, particularly in urban areas, is creating potential demand for external logistics support to improve efficiency without requiring pharmacies to develop their own fulfilment capabilities. While this does not translate into immediate large-scale outsourcing, it indicates potential for targeted, incremental logistics services that reduce operational burden without altering core pharmacy responsibilities.

The rise of online pharmacies is making the market more attractive. Although they currently represent

only a small proportion of the total market, online pharmacies are growing, particularly in the repeat prescription segment. This segment is characterised by predictable demand and high volumes, making it highly suitable for centralised processing. As such, online pharmacies, or hybrid pharmacies that combine physical locations with online operations, represent the most realistic short- to medium-term entry point for a 3PL. This growth, however, remains constrained by legislative conditions and the continued importance of physical pharmacies for acute care and direct patient interaction.

The analysis suggests that, while traditional community pharmacies may not actively pursue fulfilment outsourcing, structural developments such as increasing operational complexity, space limitations and the emergence of online pharmacy models may create conditions under which external fulfilment services become attractive. Given the operational pressures identified in the analysis of the theoretical motivations for outsourcing fulfilment, pharmacies are most likely to consider cooperation with external fulfilment providers when such arrangements relieve them of logistics-intensive internal activities such as storage, order picking or packaging. However, from the interviews, pharmacists' willingness to outsource varies depending on the activity. While there is considerable resistance to outsourcing core pharmaceutical processes, there is greater openness to outsourcing logistics-intensive tasks, such as last-mile delivery. This indicates that current market potential lies predominantly in partial outsourcing arrangements rather than full fulfilment takeovers, and that acceptance depends on the 3PL being positioned as a supportive extension of the pharmacy rather than as an independent distributor. Consequently, market potential is assessed based on the extent to which a scenario delivers overall efficiency benefits, rather than on whether specific internal logistical steps are fully outsourced.

Taken together, these findings suggest that the market potential for external fulfilment services is currently limited in scale but clearly identifiable in scope. Opportunities are concentrated in specific segments characterised by predictable volumes, digital ordering, and lower patient-criticality, rather than across the pharmacy market as a whole. These insights partly inform the scope of the scenario building in Chapter 6. Feasible scenarios should focus on large, predictable flows, such as repeat prescriptions. Additionally, the fulfilment company must be positioned as a supporting logistics partner within existing pharmacy-oriented structures.

The consolidated set of market conditions in the table below serves as a test of the commercial feasibility of the scenarios in Chapter 6. Scenarios that do not align with these structural market realities do not mean that they are not possible scenarios, but they are unlikely to be implemented in practice, even if they are legally permissible, hence the use of the term 'design criteria' instead of 'requirements', as stated in Table 4.3. The pharmacists' conditions for cooperation in subsection 5.2.5 are also included in the series of design criteria, as they are the focus group for cooperation. The table below leaves out the first two conditions, as they are already included in Table 4.3.

**Table 5.1:** Design criteria framework based on market potential analysis

#	Design criterion
DC1	All categories of medicine can be included in the work.
DC2	The scenario is based on a clearly defined and commercially viable pharmacy segment and does not depend on broad market-wide acceptance.
DC3	Focus on predictable, high-volume flows.
DC4	Clear legal and operational separation between pharmacy and fulfilment entity is ensured.
DC5	The scenario delivers clear operational efficiency benefits.
DC6	The service must deliver medicines quickly and reliably.
DC7	Patients must have continuous and accessible communication channels with the service.

# 6

## Scenario building

Building on the foundation laid in Chapter 3, Chapter 4 and Chapter 5, this chapter develops structured participation scenarios for non-pharmaceutical fulfilment providers. Chapter 3 identified a research gap at the intersection of pharmaceutical legislation, medicine dispensation and emerging e-commerce logistics. Specifically, as also mentioned in Section 1.2, there is a lack of academic and practical insight into how independent non-pharmaceutical fulfilment providers could operate within the Dutch pharmaceutical system and Chapter 3 further emphasised this. The scenario development in this chapter directly addresses the issue.

Chapter 4 provided a systematic analysis of the European and Dutch legislative framework, clarifying the legal responsibilities of pharmacists, wholesalers, logistics service providers and other actors under the Medicines Act, GDP guidelines, and supervisory authorities such as the IGJ. Chapter 5 supplemented this with empirical insights into market structure, outsourcing intentions, and operational bottlenecks. Together, these chapters resulted in a set of mandatory requirements that each participation model must comply with, as well as design criteria that the models should ideally satisfy to ensure commercial robustness. These are summarised in Table 6.1 as a framework for scenario analysis, distinguishing between mandatory legal-regulatory requirement (R1-R4) and non-mandatory market and organisational design criteria (DC1-DC7).

Table 6.1: Scenario feasibility framework

<b>Legal and regulatory requirements</b>	
R1	UR/UA medicines are dispensed exclusively by a licensed pharmacist.
R2	All the necessary permits are in place.
R3	Unlabeled medication is stored in legally recognised locations only.
R4	Full compliance with GDP rules is guaranteed for all storage and transport activities.
<b>Market potential design criteria</b>	
DC1	All categories of medicine can be included in the work.
DC2	The scenario is based on a clearly defined and commercially viable pharmacy segment and does not depend on broad market-wide acceptance.
DC3	Focus on predictable, high-volume flows.
DC4	Clear legal and operational separation between pharmacy and fulfilment entity is ensured.
DC5	The scenario delivers clear operational efficiency benefits.
DC6	The service must deliver medicines quickly and reliable.
DC7	Patients must have continuous and accessible communication channels with the service.

Based on this combined legislative and empirical foundation, a scenario analysis is performed. This analysis does not constitute a separate method of data collection; rather, it serves as an analytical step in the design process. Each scenario represents a different organisational configuration for participating in pharmaceutical logistics, and is systematically tested against the constraints outlined in Table 6.1.

This chapter addresses sub-question 4:

- **SQ4:** Which fulfilment scenarios can be developed for non-pharmaceutical fulfilment providers, and how feasible are they in legal logistical, and organisational terms?

The chapter is structured as follows: Section 6.1 outlines the brainstorming process for potential scenarios, including the evaluation of legally structured forms of cooperation against the constraints framework. Section 6.2 examines key legal ambiguities at the intersection of dispensing and logistics. Section 6.3 applies the generic scenarios to the specific organisational context of PostNL via a case study analysis. Section 6.4 concludes by reflecting on the overall feasibility of hybrid fulfilment models within the current legislative and market framework.

## 6.1. Scenario brainstorm

This chapter provides an overview of the various strategic options available to a non-pharmaceutical fulfilment company looking to enter the medical market. The scenarios cover both B2B and B2C options, ranging from collaborating closely with multiple existing pharmacies to building in-house pharmaceutical expertise. The aim is to outline potential models for entering the healthcare supply chain without ruling out any possibilities from the very beginning. Each approach offers opportunities such as efficiency gains and economies of scale, but also presents challenges in terms of legislation and acceptance. Rather than focusing on limitation, the emphasis is on how a fulfilment company could position itself within the strict framework. At the same time, more ambitious scenarios (e.g. dispensing medicines themselves) will require a creative approach to the legal division of roles or a more gradual approach. The exploration of scenarios in this chapter is therefore of a strategic nature. It identifies feasible options a fulfilment company can pursue. This approach avoids a purely legal rejection of new ideas.

The main text in this chapter provides a concise description of each scenario, emphasising the core of the organisational logic and its position within the previously introduced framework of constraints. A detailed elaboration of each scenario, including legal structures and responsibilities, logistical and operational structures, quality assurance, advantages and disadvantages, and assumptions and uncertainties, is provided in Appendix E in Section E.1. This separation increases readability while ensuring full transparency regarding the analytical reasoning behind the comparative assessment in Table 6.2.

First, a number of initial operational implementation scenarios that build on existing structures within the pharmaceutical chain are discussed. These scenarios are based on desk research and interviews with pharmacists. After that, based on legal considerations and other external expertise, the focus shifts towards more legally structured cooperation models. This phased approach enables both low-threshold entry models and more complex organisational forms to be analysed systematically.

To enhance readability, the term 'the company' will be used throughout this chapter to refer to a non-pharmaceutical fulfilment company.

### 6.1.1. Exploratory scenarios within existing structures

This section presents a series of exploratory scenarios based on the existing organisational and regulatory structures within the pharmaceutical supply chain. While not all scenarios depict full fulfilment models, they demonstrate the various ways in which logistics service providers could access or participate in the pharmaceutical market, depending on the range of activities undertaken and the level of regulatory involvement.

#### SI: Short-term storage and/or distribution only

In this scenario, the company acts as a logistics service provider for pharmaceutical products such as medicines and medical devices. It does not provide pharmaceutical care itself or become the owner of the medicines. The company transports medicines between parties in the supply chain, such as from a wholesaler to a pharmacy or from a pharmacy to a patient. The responsible license holder must release ('dispense') medicines for distribution before they can be transferred to the company. Short-term transshipment is possible, such as cross-docking, but long-term storage and order picking are not included in the service. The company specialises in medical distribution, and the legal responsibility for the medicines remains entirely with the license holders.

**S2: OTC medicines only**

In this scenario, the company provides fulfilment services for non-prescription health product, namely OTC medicine, on behalf of licensed pharmacies, drugstores and other licensed retailers. The company does not sell products under its own name or becomes the owner of the goods. Instead, it acts as an external fulfilment service provider, supporting the distribution activities of authorised sellers.

The company remains outside the scope of pharmaceutical care and dispensing. Its role is limited to storing, processing orders for, and distributing OTC medicines sold by pharmacies and drugstores through their own online channels. By focusing on non-prescription products, the company avoids the most stringent legal requirements for prescription medicines while operating within the regulated healthcare supply chain.

**S3: Pharmacy distribution point**

In this scenario, the company acts as a distribution centre for licensed pharmacies. This is a scenario that was also considered feasible by the pharmacists interviewed (subsection 5.2.4). The distribution centre is not an independent pharmacy and does not provide pharmaceutical care. Instead, it acts as an external distribution point, delivering medicines directly to patients' homes on behalf of pharmacies. This model applies to all categories of medicine, including prescription medicines, provided dispensing, labeling and pharmaceutical control are carried out entirely by the responsible pharmacy before transfer.

Similar distribution points already exist, such as automated collection machines, lockers or manned service points operated by pharmacies, which are intended to increase accessibility. In this scenario, the distribution function is integrated into a fulfilment centre and is strictly limited to home delivery, and no pick-up service.

All interaction with patients regarding the dispensing, advising on, and checking of medication remains the responsibility of the pharmacy. Medicines are transferred to the company in a sealed, patient-specific, pharmaceutically prepared form. The company's role is limited to physically delivering medicines to patients, acting as an extension of the pharmacy's delivery service rather than an independent healthcare institution.

**S4: Becoming a wholesaler (B2B)**

In this scenario, the company operates as a licensed pharmaceutical wholesaler, offering wholesale distribution services for prescription medicines to other businesses. It purchases medicines from manufacturers or other licensed wholesalers and supplies them to licensed customers, including pharmacies, hospitals and other healthcare providers. By obtaining a WDA the company becomes an official intermediary within the pharmaceutical supply chain.

This represents a clear shift from pure logistics to regulated pharmaceutical trade. Unlike pure fulfilment models, the company becomes the legal owner of the medicines and assumes responsibility for their quality, traceability and distribution. The wholesaler does not supply medicines to patients or assume the role of a pharmacy; its activities remain strictly B2B. When an existing fulfilment company expands its activities to include the wholesale distribution of medicines, two distinct legal roles are assumed within the same organisational entity. As a fulfilment company, it acts on behalf of third-party owners of products and does not own the goods. However, as a license wholesaler, the company purchases, owns and supplies medicines under its own legal and commercial responsibility. This dual role seems to be permitted by law, provided that the distinction between these activities is clearly defined and demonstrable at all times.

**S5: Becoming a central filling company (B2B)**

In this scenario, the company provides a central dispensing service, meaning that patient-specific prescription drugs are prepared, packaged and labeled on behalf of pharmacies at a central location. Pharmacies digitally forward prescriptions, usually for repeat or chronic medications, to the central filling centre. There, medicines are prepared for individual patients and then returned to the pharmacy.

Central processing is an established concept in the Dutch pharmaceutical supply chain and is already being used by existing market players (see Section 3.1). The model aims to increase efficiency and scalability by centralizing labour-intensive processing activities and utilizing highly automated systems.

This enables pharmacies to reduce their local inventory and manual processing, allowing them to focus more on pharmaceutical care. In this scenario, the company can extend its services beyond logistics to become an operational extension of the pharmacy's processing.

### 6.1.2. Legally structured forms of cooperation

This section examines the legal structures of cooperation between the company and pharmacies. These structures involve a higher degree of legal, organisational and administrative complexity than the exploratory scenarios discussed earlier, and move more clearly towards integrated, fulfilment-oriented models.

The in-house pharmacy model (S6) originated from an earlier brainstorming session with PostNL employees. This scenario has been included to demonstrate how the company can evolve towards more integrated, fulfilment-oriented arrangements within the pharmaceutical market.

The other scenarios presented in this chapter (S7 and S8) are based on an interview with a legal expert who specialises in corporate law. Although this expert does not specialise in healthcare or the pharmaceutical sector, this proved valuable for the purposes of this study, enabling a more creative exploration of organisational structure without the constraints of sector-specific assumptions or established interpretations of existing legislation. The resulting legal analysis yielded three potential collaboration models: joint venture, franchise and cooperative. As the franchise model does not align with the logistical and operational focus of this study, it is not considered in this section.

In addition, an interview was conducted with a fulfilment company that has been active in the distribution of medical devices and OTC medicines for a long time, operating with its own inventory and therefore holds a WDA. Recently, this company set up a new collaboration model in partnership with a pharmacy, through which it now also facilitates the home delivery of UR medicines. Under this arrangement, the fulfilment company's owner has a co-ownership stake in the newly established entity. Although this structure does not constitute a joint venture or an in-house pharmacy where the company is still a separate entity in the strict legal sense, the discussion provided valuable insights into how shared ownership and collaboration across organisational boundaries can be organised in practice. As such, it helped to highlight the potential relevance of joint venture-like arrangements as an interesting topic for further research.

#### S6: In-house pharmacy

In this scenario, a licensed pharmacy is established at the same address as a logistics centre by renting a clearly defined storage and operational space within the facility. The pharmacy operates as an independent legal entity and holds its own pharmacy license, under the responsibility of an appointed responsible pharmacist registered at that location. All prescription medicines stored at the site remain the legal property of the pharmacy.

The logistics company does not sell medicines under its own name and does not become the owner of the goods. Instead, it provides storage facilities and performs logistical fulfilment activities on behalf of the pharmacy after pharmaceutical release has taken place. Medicines are distributed directly to patients under the pharmacy license, with the logistics company acting as an outsourced service provider for non-pharmaceutical handling activities.

By embedding the pharmacy within the logistics centre, this scenario enables the distribution of prescription medicines without requiring the logistics company to enter the pharmaceutical retail or wholesale domain. However, the model relies on close operational integration and strict governance arrangements to ensure legislative compliance.

#### S7: Joint Venture

In this scenario, the company and a pharmacy establish a new legal entity together, typically in the form of a private limited company (Besloten Vennootschap (BV)). This joint venture (JV) is based at the company's address and acts as a central logistics entity. The JV has its own pharmacy license, with its own appointed pharmacist. Profits, investments and risks are distributed according to a shareholder and/or cooperation agreement.

**S8: Cooperative**

In this scenario, the company acts as a co-founder of a cooperative alongside one or more pharmacies. These pharmacies can then join the cooperative as members. The cooperative functions as a collective organisation for pharmaceutical logistics and related support services, while individual pharmacies retain their own pharmacy licenses and responsibility for patient care. Adopting a U.A. (Uitgesloten van Aansprakelijkheid) structure excludes members from personal liability for the cooperative's debts.

Under this model, the company is responsible for the cooperative's entire logistics operation, including warehousing, inventory management and distribution. The cooperative provides a governance and ownership framework that enables pharmacies to organise and control these activities jointly.

This collaborative model has already been shown to be operationally feasible, as demonstrated by initiatives such as Multipharma in Belgium [49]. In Belgium, a relatively large proportion of pharmacies operate independently, making cooperative ownership and centralised logistics a natural organisational form [71]. However, in the Netherlands, the pharmacy market is more consolidated, with many pharmacies belonging to chains or purchasing cooperatives that already offer integrated logistics solutions (subsection 5.1.3). Consequently its added value is less evident in the Dutch context, which explains its limited acceptance to date.

**6.1.3. Scenario evaluation against constraint framework**

Table 6.2 provides a structured overview of how each scenario relates to the feasibility framework introduced in Table 6.1. The table uses check marks, crosses and question marks to indicate whether a scenario complies with (✓), does not comply with (×), or involves uncertainty regarding (?), a specific requirement or design criterion. The detailed reasoning behind the assessments of '×' and '?' can be found in Appendix E in Section E.2.

It is important to distinguish between the nature of the design specifications. Requirements R1-R4 reflect mandatory legal and regulatory requirements derived directly from legal requirements and supervisory practices. Failure to comply with these criteria would make a scenario legally invalid. The remaining design criteria DC1-DC7 represent structural and organisational specifications that affect practical feasibility and scalability. Failure to meet these latter criteria does not automatically render the scenario unlawful, but it significantly reduces the likelihood of successful implementation.

**Table 6.2:** Compliance with the feasibility framework

Design specification	S1	S2	S3	S4	S5	S6	S7	S8
R1	✓	✓	✓	✓	✓	✓	✓	✓
R2	✓	✓	?	?	?	?	?	?
R3	✓	✓	✓	✓	✓	✓	✓	✓
R4	✓	n/a	✓	✓	✓	✓	✓	✓
DC1	✓	×	✓	✓	✓	✓	✓	✓
DC2	✓	✓	✓	×	×	✓	?	×
DC3	✓	×	✓	✓	✓	✓	✓	✓
DC4	✓	✓	?	?	?	?	?	?
DC5	✓	✓	✓	✓	✓	✓	✓	✓
DC6	✓	✓	✓	✓	✓	✓	✓	✓
DC7	✓	✓	✓	✓	✓	✓	✓	✓

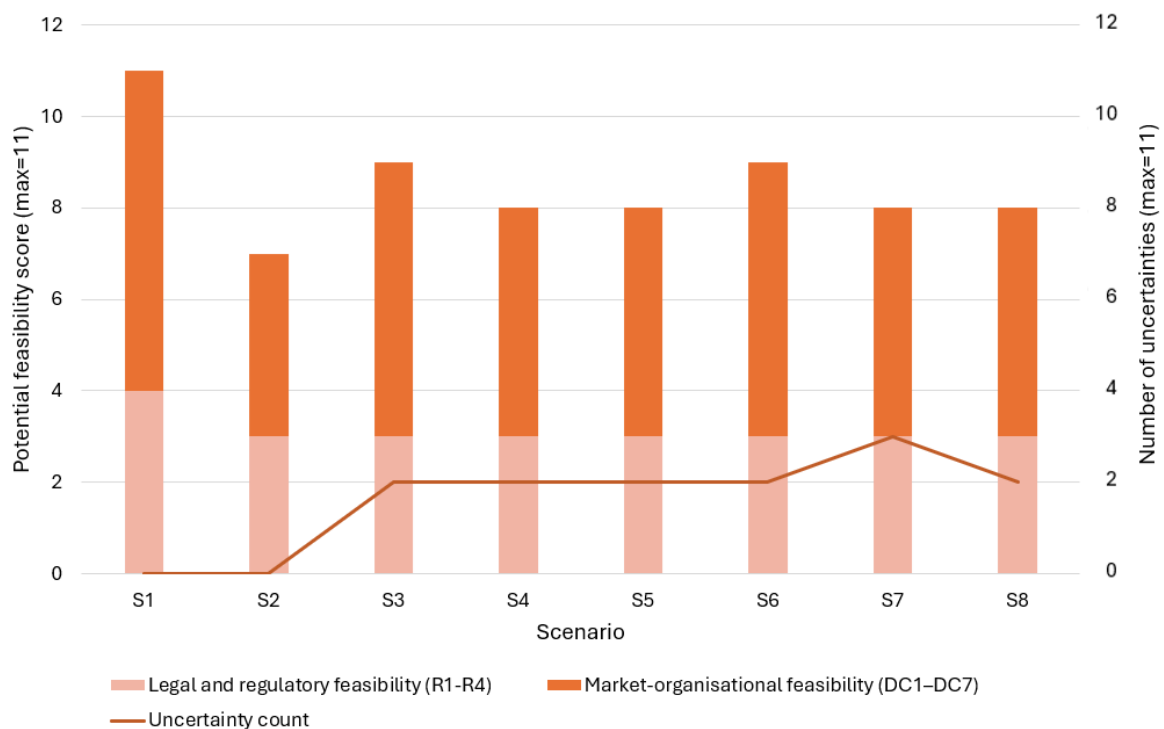
Table 6.2 clearly shows that the majority of question marks occur under R2 and DC4. These uncertainties are not coincidental. As discussed in Chapter 3, there is a gap in the literature and debate on legislation regarding the role of non-pharmaceutical executing fulfilment provider. Chapter 4 showed that existing legislation is designed around traditional, pharmacy-focused models and does not explicitly regulate hybrid fulfilment structures. Furthermore, Chapter 5 demonstrated through interviews (see Section 5.2) that pharmacists themselves experience uncertainty when interpreting how new organisational forms fit within the current framework. While Table 6.2 visualises structural compliance, the concentration of question marks requires deeper interpretation, which is addressed in Section 6.2.

Furthermore, none of the scenarios are currently excluded based on the legislative and regulatory requirements (R1–R4). All scenarios either meet these core requirements or are marked with a question mark, which indicates legislative and regulatory uncertainty rather than explicit incompatibility. However, a question mark does not confirm compliance. This indicates that, based on the available analysis, the scenario appears legally feasible, but its final viability depends on further clarification by the supervisory authorities. A more thorough regulatory assessment could ultimately clarify the situation, either confirming compliance or formally excluding the scenario.

From a market perspective, however, there are clear differences. S2, S4, S5, S8 do not comply with various market-oriented design criteria (DC1–DC7), which limits their structural market potential. While these models are legally possible, they are less attractive: S2, and S4 fail to reduce the operational workload of pharmacies. Furthermore, S2 operates in a non-profitable OTC stream, and S5 and S6 are subject to competition from wholesalers, chains, and formulas and S8 depends on the participation of multiple independent pharmacies, of which there are very few in the Netherlands.

Figure 6.1 provides a comparative overview of the eight scenarios by visualizing their potential structural feasibility within the framework of the constraints. Full compliance (✓) and legislative uncertainty (?) are both considered structurally feasible and therefore receive one point in the *Potential feasibility score*. Non-compliance (×) receives zero points.

This shows that legislative uncertainty does not necessarily mean incompatibility; rather, it indicates interpretative ambiguity. For transparency, the total number of identified uncertainties per scenario is shown on a secondary axis. Thus, the figure distinguishes between maximum possible structural feasibility and the degree of legislative uncertainty.



**Figure 6.1:** Comparative structural feasibility and uncertainty across scenarios

It is important to note that this visualisation is based solely on compliance with the legal, regulatory and market organisational specifications defined in Table 6.2. It does not assess other strategic dimensions, such as the degree of logistics outsourcing, operational integration or organisational complexity. Therefore, the figure should be interpreted strictly as a comparison of feasibility within the applied feasibility framework and not as a comprehensive ranking of strategic attractiveness. The PostNL case

study (see Section 6.3) addresses strategic considerations such as the degree of logistical outsourcing, operational integration and organisational alignment separately, assessing their feasibility in relation to specific boundary conditions and business objectives.

#### 6.1.4. Value creation for pharmacies

While Table 6.2 assesses the feasibility of fulfilment scenarios from legal and organisational perspectives, their practical relevance ultimately depends on the value they create for pharmacies. As discussed in subsection 5.1.4, pharmacies are under increasing pressure due to staff shortages, rising workloads and limited physical space. This is a key driver for outsourcing logistical activities.

Fulfilment solutions can create value by reducing labour-intensive tasks such as storage, order picking and packaging. This frees up personnel for pharmaceutical care, which is in short supply. In addition, centralised fulfilment can reduce local inventory requirements and alleviate space constraints while improving efficiency and scalability.

As shown in Table 6.2, the scenario evaluation indicates that this value varies significantly across the eight scenarios. S1 and S2 offer pharmacies only limited direct organisational relief, since most fulfilment activities remain internal. However, S1 can still create value at the supply chain level by improving distribution efficiency and reliability, which explains its practical applicability despite its limited impact on the internal workload. S3 offers partial value by outsourcing distribution, thereby reducing last-mile complexity while retaining core processing activities within the pharmacy. Scenarios S4 and S5 primarily operate at the B2B level. Their value lies in improving efficiency and standardisation upstream rather than directly reducing the B2C workload in pharmacies. Consequently, these scenarios offer pharmacies limited direct value, as they do not significantly alleviate internal operational pressures or reduce workload at the point of dispensing.

In contrast, S6, S7 and S8 transfer a greater proportion of logistical and processing activities outside the pharmacy, thus tackling labour and space constraints more effectively. These scenarios therefore offer greater potential value to pharmacies, particularly in terms of reducing workload and enabling a more focused approach to operations.

At the same time, the scenarios offering the greatest added value to pharmacies are accompanied by a higher degree of legal and organisational uncertainty, particularly in R2 and DC4. This highlights a central tension in the analysis: the models that most effectively address challenges at pharmacy level also require the most careful governance design.

Consequently, creating added value for pharmacies is an important factor in ensuring practical feasibility, but it is not an absolute prerequisite for implementation. While scenarios that significantly reduce internal workload and capacity constraints are generally more appealing, models offering only limited operational relief can still be implemented, especially if they can be easily integrated into existing structures and involve minimal organisational or regulatory complexity. For instance, distribution-focused scenarios such as S1 may not result in a substantial reduction in internal workload, yet they have been shown to be feasible in practice. Conversely, scenarios offering greater potential value are often accompanied by a higher degree of legal and organisational uncertainty, meaning their implementation depends on clarifying the identified ambiguities. Ultimately, the choice of scenario depends on aligning the preferences, constraints, and strategic objectives of the pharmacy and the fulfilment provider.

## 6.2. Legal ambiguities at the interface of legislation and practice

The large number of question marks under R2 and DC4 in Table 6.2 mainly stems from a central ambiguity: the distinction between delivery and logistics. This interpretative gap also affects issues such as scalability, where the division of responsibilities between the pharmacy and the fulfilment centre is not explicitly defined. The resulting legal uncertainty stems from this underlying interpretative gap in the current legislative framework, which is discussed below.

### 6.2.1. Boundary between dispensing and logistics

The first and most fundamental ambiguity concerns the distinction between the provision of medicines and logistical activities. As mentioned in subsection 4.3.1, the dispensing of prescription medicines is strictly the responsibility of licensed pharmacies. However, the Act does not provide a detailed

operational definition of where dispensing ends and logistics begin. This creates uncertainty about when a logistical task becomes an act of dispensing.

From a legislative point of view, this leaves room for interpretation. Activities such as order storage, picking, packaging (in this case, packaging the prepared medicine in transport-resistant packaging), transport preparation and last-mile delivery can be considered logistics support functions. However, what is also stated in subsection 4.3.1, is that current supervisory practice by the IGJ prohibits storage of unlabeled medicines outside an authorised wholesaler (B2B) or pharmacy (B2C). This constraint is not explicitly stated in the Medicines Act, but is enforced by the IGJ's interpretation of fulfilment and quality requirements, effectively limiting where unlabeled stocks can be stored. Moreover, while the GDP guidelines permit the outsourcing of certain logistical tasks through contractual agreements, they do not specify which tasks can be carried out by non-pharmaceutical entities without infringement responsibilities related to medicine dispensing.

Furthermore, the interviews revealed that this lack of clarity is particularly evident in practice. All three pharmacists emphasised that any activity resembling patient-specific preparation or final inspection is considered an integral part of dispensing medicines. For instance, while the Medicines Act explicitly refers to labeling as part of the dispensing process (subsection 4.3.1), the interviews reveal a significant practical difference: pharmacists primarily interpret this requirement as creating and checking the label rather than physically applying it. This use of speed fill systems illustrates this (Section 5.2), as the application of a pre-generated label can be performed by non-certified personnel or automated systems, while the pharmacist remains entirely responsible for generating, approving and checking the label.

Consequently, fulfilment models in which a non-pharmaceutical 3PL performs advanced logistics activities on behalf of pharmacies are in a legislative grey area. In principle, these activities comply with GDP requirements, but there is no explicit confirmation that they fall outside the scope of regulated dispensing. This uncertainty helps to explain the cautious attitude of pharmacists, who have consistently shown reluctance to adopt new models.

### 6.2.2. Centralised fulfilment for multiple pharmacies

A second important uncertainty relates to scalability, particularly in scenarios where a single fulfilment centre serves multiple independent pharmacies in a B2C context. While the legislative framework permits pharmacies to outsource logistics via GDP-compliant contracts, it implicitly assumes a direct relationship between a single pharmacy and its contracted service provider. Neither the Medicines Act nor the existing guidelines explicitly address scenarios in which a single external fulfilment centre processes medicines B2C on a large scale for multiple pharmacies simultaneously. Consequently, several unresolved questions arise, including; how is pharmaceutical responsibility divided when medicines from different pharmacies are processed within the same facility; does such a fulfilment centre begin to resemble a wholesaler from a legislative perspective; how can individual pharmacists meaningfully supervise shared, centralised activities?

The interviews show that, while pharmacists are not opposed to centralisation, they do organise it within clearly defined legal boundaries. All interviewees indicated that certain forms of centralised preparation are already common practice, such as using speed fill systems for prescriptions. However, these activities either take place within the pharmacy organisation itself, or are outsourced to parties operating within an established B2B framework. They do not take place within a shared B2C implementation model for multiple pharmacies. This uncertainty is not just theoretical. Interviewees said that they would find it difficult to interpret existing rules if such a model were introduced.

The absence of explicit legislation governing multi-pharmacy B2C fulfilment poses a direct obstacle to the scalability of 3PLs. Without clarity on how responsibility, supervision and licensing should be organised in a shared fulfilment environment, it is difficult to justify investments in large-scale infrastructure for multiple customers from a legal and commercial perspective.

## 6.3. Case study: PostNL Fulfilment

After developing the scenarios and assessed their overall feasibility based on the legal requirements and market design criteria, feasibility is now applied to a specific organisational context. To this end, as case study was conducted at PostNL Fulfilment.

This case study does not analyse PostNL Fulfilment as the primary research subject; rather, it uses the organisation as an empirical test case for the feasibility framework developed in this study. By applying the framework to a real fulfilment organisation, the study will evaluate whether the methodological approach, consisting of scenario development and feasibility assessment, can also be meaningfully applied in practice.

In previous sections, feasibility was evaluated in general terms. However, the practical implementation of fulfilment scenarios depends heavily on the strategic positioning, operational structure and organisational constraints of specific logistics service providers. It is important to note that the scenario that best fits the generic feasibility framework (Table 6.2) is not automatically the most feasible scenario for PostNL Fulfilment. Feasibility must therefore be assessed on the basis of PostNL Fulfilment's own preconditions, strategic positioning, and operational logic.

To enhance readability, the term 'PostNL' will be used throughout this chapter to refer to PostNL Fulfilment.

### 6.3.1. Boundary conditions

To translate the previously identified scenarios into a potential model for PostNL, the organisation has defined a series of boundary conditions. These reflect PostNL's strategic positioning and core competencies, and limit the feasible scenarios to those consistent with its role as a fulfilment service provider.

Firstly, PostNL's explicit aim is to remain solely a fulfilment service provider, aiming to take over most fulfilment steps in the process. This ambition is driven by both internal strategic positioning and signals from the pharmacy market. Feedback received by PostNL indicates that pharmacies are under increasing pressure due to staff shortages, limited physical space and growing administrative workloads. As discussed in subsection 5.1.4, similar structural developments have also been identified in the broader market analysis, where increasing operational pressure and the emergence of online-oriented pharmacy models were highlighted as potential drivers for outsourcing logistical activities. Although this broader operational pressure did not explicitly emerge as a dominant theme in the interviews with P1, P2, and P3 in Section 5.2, it does correspond with sectoral signals and practical experiences shared during exploratory discussions with PostNL and in the previous analysis. Many pharmacies indicate that they want to focus on core pharmaceutical care and patient-oriented tasks rather than storage, order processing, and distribution activities. This boundary condition therefore prioritises scenarios that maximise operational relief for pharmacies. This aligns with the value creation mechanisms discussed in subsection 6.1.4, in which reducing internal workload and logistical complexity was identified as a key driver of adoption.

From this perspective, partial outsourcing models that only cover transport or isolated logistics elements offer limited structural relief. For fulfilment to respond to an actual market need, it must significantly reduce internal workloads within pharmacies and alleviate capacity constraints. BC1 in Table 6.3 therefore reflects both PostNL's strategic ambition and the underlying organisational needs of pharmacies. In other words, comprehensive logistics support is a prerequisite for generating tangible value at the pharmacy level, not just a commercial preference.

Also, it does not intend to operate as a pharmaceutical wholesaler or engage in the commercial trade of medicines. This means that PostNL neither owns nor purchases or trades any medicines in its own name. While PostNL is willing to invest in obtaining a wholesale license if this is legally required to enable certain logistics activities, it does not intend to become a wholesaler, as owning stock is not part of its strategy.

Furthermore, PostNL does not intend to become a pharmacy. It will not apply for a pharmacy license or hire a pharmacist. Therefore, pharmaceutical responsibility, including processing prescriptions, checking medication and dispensing it, remains entirely with licensed pharmacies and pharmacists.

Also, PostNL has no intention of establishing new legal entities in which it has an ownership interest.

At the same time, PostNL considers it essential that the chosen scenario enables the home delivery of UR medicines to patients, since these medicines constitute the largest proportion of those dispensed by community pharmacies. Therefore, enabling UR delivery is crucial, both from a market perspective and to allow PostNL to support or take over the entire logistical process associated with pharmaceutical

home delivery. Although scalability is desirable in the long term, it is not a strict requirement for the initial development of the most promising scenario.

Taken together, these boundary conditions provide a clear framework, shown in Table 6.3, for selecting and further elaborating on the most suitable fulfilment scenario for PostNL.

### 6.3.2. Scenario alignment with PostNL's current framework

To assess which of the previously identified scenarios can be translated into an operational model, each one is evaluated against the boundary conditions set by PostNL. As subsection 6.1.3 demonstrated that S2, S4, S5 and S8 did not comply with various market-oriented restrictions, these have not been included in the evaluation for PostNL, as the scenario must have market potential. This evaluation can be found in the Table 6.3.

For scenario S7, which relate to the establishment of a new legal entity, it should be noted that the assessment of the boundary conditions is carried out exclusively from the perspective of PostNL as an organisation and not from the perspective of the newly established entity. This distinction is deliberate, as ownership of or participation in a new legal entity constitutes as separate boundary condition (BC5). Consequently, all boundary conditions are consistently assessed on the basis of PostNL's role, responsibility and strategic positioning.

**Table 6.3:** Boundary checklist for scenario selection for PostNL

Boundary condition	S1	S3	S6	S7
BC1. Enables coverage of the full logistical process (storage, order processing, delivery)	×	×	✓	✓
BC2. No ownership of medicinal products	✓	✓	✓	✓
BC3. No wholesale license required	✓	✓	✓	✓
BC4. No pharmacy license required	✓	✓	✓	✓
BC5. No ownership or participation in new legal entities	✓	✓	✓	×
BC6. Enables home delivery of prescription-only medicines (UR)	×	✓	✓	✓
BC7. Scalable in the longer term (desirable, not mandatory)	✓	✓	×	×

This assessment shows that scenario S6 (the internal pharmacy model) is the one that best aligns with PostNL's current framework. It provides comprehensive logistical support, while maintaining a clear distinction between pharmaceutical responsibility and logistical execution. Importantly, ownership of medicines remains with the licensed pharmacy.

However, this conclusion must be nuanced. While S6 complies with the formal preconditions, its implementation would require a high degree of operational integration between PostNL and the integrated pharmacy, and the uncertainties listed in Table 6.2 (R2 and DC4) would still need to be addressed. Co-location implies shared infrastructure, synchronised processes and closely coordinated governance mechanisms and this scenario also comes with certain disadvantages (see Appendix E). This raises strategic considerations that go beyond formal compliance:

- **Degree of logistics outsourcing:** In S6, PostNL would manage almost the entire physical flow after release, potentially even taking steps before pharmaceutical operations begin. This would require extensive logistics outsourcing by the pharmacy and strong contractual management and coordination in terms of quality;
- **Operational integration:** Although the legal entities remain separate, their day-to-day activities are closely intertwined. To avoid ambiguity about roles, process interfaces (e.g. release timing, and exception management) must be precisely defined;
- **Organisational alignment:** Cultural and procedural alignment between pharmaceutical and fulfilment organisation is becoming crucial. Differences in risk perception, documentation culture and quality management philosophy can cause problems.

In other words, the S6 model seems to be structurally feasible within the current boundaries of PostNL,

but only if it is implemented with a high degree of administrative maturity and carefully designed separation mechanisms. It also requires further validation of the uncertainties identified in Table 6.2.

### 6.3.3. Main bottlenecks

Analysis of the case reveals three key bottlenecks:

- **Separation of roles:** even in S6, the practical boundary between dispensing medicines and logistics remains a sensitive issue;
- **Scalability limitations:** S6 is feasible on the basis of a single location, but scaling up to multiple pharmacy partnerships could raise regulatory issues as more pharmacists would need to be accommodated as there will be different medicine flows.
- **Internal strategic rigidity:** The presence of boundary condition potentially excludes more integrated models (e.g., S7), even though such models could offer clearer governance structures in practice. This will be further elaborated in subsection 6.3.4.

### 6.3.4. Strategic flexibility and alternative trajectories

The analysis also shows that feasibility partly depends on PostNL's own boundary definitions and its commercial positioning as a profit-oriented fulfilment provider.

From an economic perspective alone, scenarios S1 and S3 in Table 6.3 are less attractive. Although they are legally feasible, they offer limited opportunities for value creation, operational optimisation and realizing margins. For a fulfilment company seeking scalable, integrated logistics propositions, these models lack strategic depth. Furthermore, as discussed in subsection 6.3.1, partial outsourcing configurations do not offer pharmacies substantial organisational relief, as they leave significant internal handling and coordination tasks within the pharmacy itself.

If certain internal restrictions were reconsidered, for example allowing participation in a joint legal entity and accepting deeper structural integration, then alternative scenarios (particularly S7, or maybe even S8, if there are enough collaborations to conclude) could become feasible. A joint management structure, for instance, could ensure better coordination between logistical implementation and pharmaceutical responsibility, potentially reducing legislative uncertainty by providing clearer institutional anchoring.

However, other scenarios are also not without structural uncertainties and its disadvantages (see Appendix E). Questions remain about the interpretation of licenses, how personnel will be distributed between parent companies and the joint entity, and how role distribution will be enforced in a shared operational environment.

Therefore, the current conclusion that S6 is the most suitable scenario remains within PostNL's existing strategic and commercial framework. This is not an absolute conclusion regarding overall feasibility, but rather the most coherent option given the current combination of legislative constraints and business preconditions.

### 6.3.5. Concluding reflection on PostNL feasibility

This case study demonstrates how the feasibility framework developed in this study can be applied to a specific organisational setting. The analysis shows that, by systematically testing previously developed scenarios against PostNL's strategic preconditions, the framework offers a structured method for translating abstract legal and market-related feasibility considerations into organisation-specific assessments.

However, the case study also emphasises that the framework should not be applied in isolation. While it provides a robust approach to identifying legally and structurally feasible implementation configurations, the suitability of a scenario ultimately depends on additional organisation-specific constraints, including strategic positioning, operational capabilities, and internal business priorities. As organisations differ in their strategic orientation and operational structures, the framework is most effective when combined with contextual requirements. This enables individual logistics service providers to determine which scenarios best align with their organisational characteristics.

Applying the framework shows that feasibility is inherently multi-layered. From a legal perspective,

various scenarios are ambiguous rather than explicitly prohibited. From an organisational perspective, the scenario that appears most compliant in abstract terms is not necessarily the most compliant in practice.

In Section 7.4 the additional implications for a fulfilment company when it participates in B2C medicine fulfilment are discussed in more detail.

## 6.4. Conclusion

This chapter answers sub-question 4: *Which B2C fulfilment scenarios can be developed for non-pharmaceutical logistics providers, and how feasible are they in legal logistical, and organisational terms?*

The scenario analysis shows that medicines could, in theory, be distributed by non-pharmaceutical fulfilment companies (B2B and B2C) if the activities took place within strict legal, organisational and contractual frameworks. Table 6.2 shows that none of the scenarios are explicitly excluded based on the mandatory legislative requirements (R1–R4). All scenarios either meet these core requirements or are characterised by legislative uncertainty rather than incompatibility. This suggests that participation is not prohibited by law, but rather depends on the interpretation and clarification of supervisory authorities.

At the same time, the degree of feasibility varies considerably between the different scenarios. The compliance assessment shows that most legal uncertainties fall under R2 (necessary permits) and DC4 (clear legal and operational separation between the pharmacy and the executing entity). These ambiguities stem from the unresolved boundary between dispensing and logistics, and extend to issues of scalability. As the scenarios become more closely integrated with core pharmaceutical sector activities, such as in-house pharmacies (S6), joint ventures (S7) and cooperation models (S8), the sensitivity to the interpretation of legislation and governance design increases.

From a market perspective, clearer differences emerge. While some models closely align with existing structures, other scenarios, particularly S2, S4, S5 and S8, face limitations under market-oriented design criteria (DC1–DC7). This reduces their structural appeal and scalability. Therefore, legal feasibility does not automatically translate into commercial robustness.

The continuing uncertainties reflect the fact that the examined scenarios represent organisational configurations that are not yet standardised within the Dutch pharmaceutical system. Existing legislation is designed around traditional, pharmacy-focused supply chains and does not explicitly regulate hybrid fulfilment structures.

As the PostNL case study illustrates, translating these scenarios into a concrete organisational context further limits the feasible options, as business boundaries and strategic positioning introduce an additional selection criterion. This confirms that the feasibility of a scenario depends not only on legislative compliance, but also on the extent to which a specific fulfilment provider is willing and able to offer logistics outsourcing, operational integration and organisational alignment.

Overall, this chapter demonstrates that innovative implementation models can be developed within the current legislative framework. However, the full outsourcing of pharmaceutical tasks is still limited by the legally protected role of the pharmacist and unresolved governance issues. Therefore, feasible participation depends on carefully structured hybrid arrangements, step-by-step integration within existing systems and a clear division of responsibilities. The ultimate feasibility of different scenarios depends on further clarifying the legislative uncertainties listed in Table 6.2, particularly those marked with question marks. Until these ambiguities are resolved through additional legal interpretation or supervisory guidance, the most realistic option for participation by non-pharmaceutical suppliers is step-by-step expansion rather than fully integrated end-to-end models.

# 7

## Systemic and actor-specific implications of participation in pharmaceutical fulfilment

Not only can the participation of non-pharmaceutical actors add a logistical player to the existing chain, it can also lead to a reconfiguration of the division of responsibilities, supervision and competitive dynamics within a pharmacy-focused system. As chapter 3 to 5 demonstrated, the Dutch pharmaceutical framework has traditionally been organised around clearly defined professional responsibilities. The introduction of hybrid delivery models therefore raises systemic question about oversight, liability, and institutional coherence.

Furthermore, Chapter 6 shows that, while participation seems not to be explicitly prohibited under Dutch legislative framework, it is characterised by interpretative uncertainty, particularly with regard to the boundary between dispensing and fulfilment logistics, licensing requirements, and the division of roles. Throughout the previous chapters, multiple structural and legislative ambiguities have been identified. This chapter systematically translates the previously identified ambiguities into actor-specific implications.

This chapter therefore analyses the implications both at system level and at the level of specific actors. It considers what participation would mean for regulatory and governmental agencies, pharmacies, fulfilment service providers, and for science and policy development more broadly. In doing so, this chapter answers sub-question 5:

- **SQ5:** What are the systemic and actor-specific implications of potential participation of non-pharmaceutical fulfilment providers in B2C medicine logistics?

This chapter is outlined as follows: Section 7.1 introduces the analytical framework for the implication analysis. Section 7.2 to Section 7.5 examine the systemic and actor-specific implications for regulators and governmental bodies, pharmacies, fulfilment service providers, and science an policy development, respectively. Section 7.6 provides a comparative overview of these implications.

### 7.1. Analytical framework for implication analysis

This chapter's analytical framework builds directly on the findings of chapters 3 to 6. The aim is to evaluate the systemic and actor-specific implications of the involvement of non-pharmaceutical fulfilment actors in a pharmacy-centered pharmaceutical system. The framework integrates three elements: (1) the structural characteristics of the Dutch extramural supply chain; (2) the applicable legal and regulatory framework; and (3) the constraint-based feasibility assessment developed in Chapter 6. Together, these elements provide a basis for evaluating the potential consequences of participation in terms of governance, responsibility allocation, and market structure.

Although this analytical framework appears broader than the limitations framework introduced in Table 6.2, it does not introduce any new evaluation criteria. Instead, it reinterprets and dissects the existing constraints from an actor-specific perspective. While Chapter 6 assessed feasibility at scenario level as integrated configurations, this chapter unveils the same legal and market constraints to analyse how they translate into responsibilities, risks and institutional implications for individual actors. In this sense, the framework presented here can be understood as a structured elaboration and synthesis of the constraints framework applied to systems and stakeholders rather than scenarios.

To clarify how the analytical framework for this chapter relates to the earlier scenario-based exploration, Table 7.1 offers a structured overview of its key components. As previously mentioned, it translates the same structural, legal and constraint-based elements into implications specific to each actor. This therefore serves as a bridging tool between the scenario analysis and the subsequent evaluation.

**Table 7.1:** Analytical framework for systemic and actor-specific implication analysis

<b>Analytical layer</b>	<b>Source chapter</b>	<b>Core principle</b>	<b>Relevance for implication analysis</b>
<b>Structural starting point</b>			
Structural system characteristics	Chapter 3	Pharmacy-centered extramural supply chain, pharmacist responsible for dispensing, wholesalers supply licensed actors only	Defines the basic governance structure and limits of third-party participation
Systemic challenges	Chapter 3	GDP continuity, role responsibilities, FMD traceability, data protection, shortages	Defines operational and compliance risks when introducing fulfilment participation
<b>Legal-regulatory boundaries</b>			
Legal responsibility	Chapter 4	“1 tent, 1 vent” (pharmaceutical responsibility tied to licensed pharmacist and location)	Clarifies that accountability cannot be outsourced
Regulatory boundaries	Chapter 4	Dispensing versus logistics distinction, wholesale qualification risks	Central source of ambiguity affecting role division
<b>Design specification-based feasibility</b>			
Legal requirements (R1–R4)	Chapters 4–6	Hard legal feasibility conditions	Define legal inclusion or exclusion of participation models
Market and organisational design criteria (DC1–DC7)	Chapters 5–6	Scalability, segment focus, flow separation, efficiency	Determine structural viability and systemic impact
Identified uncertainty areas	Chapter 6	R2 (permits) and DC4 (role separation)	Analytical lens for assessing governance and actor-specific risk

In summary, this chapter focuses on the systemic and actor-specific implications of participating in the fulfilment of pharmaceutical orders at warehouse and execution level. Any detailed operational design choices are beyond the scope of this chapter unless they have been specified in previous chapters.

## 7.2. Implications for regulatory and governmental actors

The potential involvement of non-pharmaceutical fulfilment providers in B2C pharmaceutical logistics would have significant implications for regulatory and government bodies, especially for the IGJ (see Section 3.6).

### 7.2.1. Core systemic implication

The most significant shift for regulators is moving from supervising clearly defined, traditional roles in the supply chain to supervising hybrid organisational models. Although legal responsibility for pharmaceuticals remains with licensed, BIG-registered pharmacists, logistical execution may be increasingly outsourced to independent fulfilment providers. However, as the existing legislative framework is largely designed for pharmacy-centric structures, there is room for interpretation when it is applied to hybrid fulfilment configurations.

### 7.2.2. Legislative and regulatory uncertainties affecting government

The various legal ambiguities mentioned in chapters 4 to 6 directly translate into challenges for supervision:

- **Licensing, qualification and role classification:** It is unclear at what point activities carried out by a fulfilment provider constitute wholesale activities. Interpretations by supervisory authorities, such as the 72-hours criterion, require clearer operational guidance for fulfilment environments;
- **Boundary between dispensing and logistics:** The legal framework does not provide an operational definition of where dispensing ends and logistics begins. This has implications for activities such as order picking, labeling and final checks prior to delivery;
- **Centralisation of multiple pharmacies:** Centralised B2C fulfilment for multiple pharmacies raises questions about oversight and supervision, and whether such a model is similar to wholesale activities in practice;
- **Data protection and information management:** Outsourcing can lead to processing and management relationships, or potentially joint management, under the GDPR. The division of responsibilities must align with the principles of pharmaceutical accountability.

### 7.2.3. Operational and governance implications for supervision

These developments mean that supervisory authorities need more explicit assessment criteria focused on:

- Contractual allocation of responsibilities;
- Verifiability and quality management systems;
- Demonstrable separation of pharmaceutical and logistical flows within shared facilities.

Supervisory attention is particularly required for FMD processes, as the verification and decommissioning of safety features are legally tied to the dispensing pharmacy. In hybrid fulfilment models, the legal moment of FMD deactivation may occur before the medicine is physically with the patient, which may cause a discrepancy between responsibility and physical control. This increases the need for explicit process controls and auditability.

### 7.2.4. Market and investment implications

Legislative uncertainty directly impact market development. As demonstrated in Chapter 6, uncertainties under R2 and DC4 reduce investment certainty. Without clear guidelines on qualifications and supervisory approval, the construction of large-scale infrastructure for multi-pharmacy B2C models becomes financially riskier and therefore can be less profitable.

### 7.2.5. Policy recommendations

To mitigate these systemic risks, the following governance measures could be considered:

- The development of implementation-focused guidelines to clarify delegation after medicine release, and multi-pharmacy delivery structures;
- Explicit definition of minimum governance requirements applicable to hybrid fulfilment configurations, including audit cycles, QMS standards and mandatory separation principles in shared environment;
- Facilitating controlled pilot projects with predefined monitoring indicators, such as temperature deviations, incident frequency, and FMD alerts.

## 7.3. Implications for pharmacies

The involvement of non-pharmaceutical fulfilment providers directly affects pharmacies, who are the central, legally responsible parties within Dutch pharmaceutical system. While outsourcing can improve operational efficiency, pharmacies remain fully responsible for pharmaceutical care, dispensing accuracy and quality assurance.

### 7.3.1. Core systemic implication

The main implication for pharmacies is that outsourcing logistical tasks does not absolve them of responsibility. Even when storage, order picking or distribution tasks are outsourced, the legally responsible parties remains the pharmacist registered with the BIG, who is accountable for correct dispensing, pharmaceutical checks and compliance with GDP requirements. Therefore, participation shifts operational tasks but not ultimate responsibility.

### 7.3.2. Legislative and regulatory uncertainties affecting pharmacies

Various legal and practical uncertainties can have direct consequences for pharmacies when they enter into fulfilment partnerships:

- **Delegating tasks after dispensing medicines:** it is unclear which activities can be carried out by non-pharmacy staff;
- **Inventory and storage location:** storage of unlabeled UR medicines outside the pharmacy may carry the risk of reclassification as a wholesale activity, which would limit the use of centralised inventory models;
- **GDPR role allocation:** Fulfilment providers are not permitted to process health-related data; however, the systems must be linked, which requires clear agreements with the processor or joint controllers, in accordance with pharmaceutical accountability.

### 7.3.3. Operational and governance implications

Participation in fulfilment models places greater demands on pharmacy management. Effective outsourcing requires:

- A robust contractual division of responsibilities;
- Clear coordination of quality management, including audit rights and KPI monitoring (e.g. temperature control, delivery performance and incident response);
- An explicit process design for exceptional situations, such as product recalls, lost shipments, temperature deviations and FMD warnings.

Special attention is needed for communication with patients. The interviews in Chapter 5 show that pharmacists are concerned about losing direct contact with patients. Collaboration is acceptable under certain conditions, provided that accessibility for patients and pharmaceutical responsibility remain demonstrably guaranteed.

### 7.3.4. Market and strategic implications

The willingness to outsource varies depending on the activity (Chapter 5). For example, pharmacies seem to be more open to outsourcing last-mile logistics than core processes within the pharmaceutical sector. Furthermore, the Dutch market structure, characterised by chains and purchasing formulas, reduces the likelihood of independent participation of a pharmacy in fulfilment models. Opportunities primarily lie in high-volume, digitally organised segments, particularly repeat prescriptions and online-oriented flows.

### 7.3.5. Strategic considerations and mitigation

To mitigate risks, pharmacies may wish to consider the following:

- A phased procurement strategy, starting with transportation and delivery before expanding to storage and, if possible, steps like order picking;
- An explicit definition of the point at which medicines are released and the logistics activities permitted after release;
- GDPR-by-design contractual agreements regarding data processing, tracking and subcontractor

management.

In general, participation in fulfilment offers operational relief, but increases governance complexity. The main challenge for pharmacies is to improve logistical efficiency without compromising pharmaceutical responsibility, patient trust and legislative compliance.

## 7.4. Implications for fulfilment service provider

The potential involvement of non-pharmaceutical fulfilment providers in B2C pharmaceutical logistics presents both strategic opportunities and structural risks. While fulfilment providers can add operational value through economies of scale, automation and process optimisation, they are entering a highly regulated domain in which compliance with GDP guidelines, licensing structures and clarification of roles are essential conditions for participation

### 7.4.1. Core systemic implication

The main implication is that, although they are permitted to carry out logistical execution, pharmaceutical responsibility remains external. This creates a structurally asymmetrical position: although the fulfilment service provider is permitted to manage a significant part of the physical process, they cannot take on pharmaceutical responsibility. The main systemic risks are therefore twofold:

- (Unintended) reclassification as a wholesaler pharmacy;
- Governance failure in complex configurations, particularly in multi-client or exception-driven flows.

### 7.4.2. Legislative and regulatory uncertainties affecting fulfilment providers

As was already clearly evident in the case study in Section 6.3, various legal ambiguities have direct consequences for fulfilment providers:

- **Wholesale license and the 72-hour criterion:** can be classified as wholesale activity, which may require a wholesale license, even if ownership remains with the pharmacy;
- **Permitted activities without a pharmacy license:** Patient-specific labeling, repackaging or activities similar to preparation or dispensing remain legally sensitive;
- **Centralisation of multiple pharmacies:** Serving multiple pharmacies from a single fulfilment centre raises questions about the separation of responsibilities and the risk of being considered a functional wholesaler;
- **Staffing and co-location:** In integrated facilities where pharmaceutical fulfilment takes place alongside regular commercial fulfilment, it is unclear how strictly the separation of operational activities and staff should be enforced, particularly when staff are employed by different legal entities.

These uncertainties correspond to the recurring ambiguities identified under constraints R2 and DC4 in Chapter 6.

### 7.4.3. Operational and governance implications

Participation in pharmaceutical logistics requires structural improvements in compliance capabilities for fulfilment providers. GDP-compliant QMS are becoming a core competency. Additionally, supervisory practice requires fulfilment providers to be demonstrably 'audit-ready', with clearly documented procedures, training materials and corrective measures.

From an operational point of view, strict separation of goods is essential, particularly when multiple pharmacies are supplied from a single warehouse. The physical and administrative separation of stock must be verifiable. Shared storage with fulfilment service providers outside the healthcare sector increases requirements further in terms of access control, hygiene standards and data separation.

### 7.4.4. Market and investment implications

Participation in pharmaceutical fulfilment requires significant capital investment. Compliance with GDP standards, infrastructure modifications, system integration and audit requirements necessitate significant initial investment.

Although fulfilment providers benefit from economies of scale, automation and process standardisa-

tion, these advantages only materialise when sufficient volume and long-term contractual stability are guaranteed. Therefore, the business case must be feasible for both the fulfilment provider and the participating pharmacies.

Legislative uncertainty directly impacts investment decisions. Without legislative clarity, large-scale infrastructure investments in B2C fulfilment for multiple pharmacies remain difficult to justify.

#### 7.4.5. Strategic considerations and mitigation

To reduce exposure to risk, fulfilment providers can consider the same factors as those stated for pharmacies in subsection 7.3.5.

From a strategic perspective, entering the market remains challenging due to the highly regulated structure of the pharmaceutical supply chain. This structure is dominated by well-established chains and purchasing formulas that already operate within tightly coordinated governance arrangements. This restricts access to economies of scale and makes it difficult for new entrants to obtain sufficient contract volume. Consequently, a viable entry strategy would likely necessitate targeted collaboration with independent online pharmacies operating within standardised, high-volume segments, where sufficient scale and operational predictability can be attained.

## 7.5. Implications for science and policy development

Research into new hybrid models has implications for science and policy developments.

### 7.5.1. Core implications

This study highlights a significant gap in the academic literature and policy debates surrounding the B2C delivery of prescription medicines by non-pharmaceutical 3PLs (see research gap in Section 1.2). While existing research primarily focuses on e-pharmacy chains, last-mile optimisation or broader healthcare logistics, it does not address the hybrid model in which a fulfilment provider performs multi-pharmacy B2C logistics within a pharmacy-focused legislative system.

The emergence of such configurations therefore raises new interdisciplinary questions at the intersection of pharmaceutical law, logistics management and governance theory. Scientific research and policy development are needed to assess not only operational feasibility, but also institutional coherence and legislation.

### 7.5.2. Legal-regulatory knowledge gaps

Several unresolved, recurring questions require further legal and empirical clarification:

- The operationalisation of the boundary between dispensing and logistics;
- Consistent interpretation of licensing routes;
- The distribution of responsibilities.

These issues show that, although the legislative framework is conceptually strict, it is not sufficiently detailed in relation to emerging fulfilment structures.

### 7.5.3. Operational research direction

From a logistical and operational perspective, several interesting new areas of empirical research are emerging:

- Fulfilment and last-mile optimisation within pharmaceutical constraints: although operational models demonstrate performance improvements through batching and synchronisation strategies, these models need to be validated within GDP-compliant pharmaceutical environments;
- Emerging delivery technologies, such as drone distribution, demonstrate the potential for improvements in service time and cost per item in pilot projects. However, they must first be integrated into pharmaceutical governance structures before they can be implemented on a larger scale.

Therefore, scientific research must go beyond pure optimisation models and integrate legislative feasibility as a core variable in the design.

### 7.5.4. Market and institutional implications for policy

Comparative insights point to strong context dependence. For instance, cooperative pharmaceutical logistics models in Belgium operate within a market structure characterised by a relatively high proportion of independent pharmacies (subsection 6.1.2). In the Dutch context, where chain and formula integration are more prevalent, cooperative or joint ownership structures may face structural barriers (subsection 5.1.3).

Therefore, policy development should take into account the institutional market structure rather than assuming the transferability of foreign organisational models.

### 7.5.5. Recommendations for science and policy

To promote legislative clarity and empirical insight, the following steps are recommended:

- Develop a structured evaluation framework for pilot projects, incorporating measurable indicators for GDP compliance, FMD integrity, patient accessibility, incident frequency, and demonstrable legislative compliance;
- Publish model contract provisions to standardise audit rights, data management arrangements, recall management, and the division of roles around responsibility for releasing and dispensing medicines;
- Conduct comparative institutional studies (e.g. NL–BE) to determine the influence of market structure, licensing practices and cooperative governance models on the feasibility of hybrid implementation configurations.

Overall, the implications for science and policy development extend beyond logistical innovation. They relate to the broader question of how highly regulated professional systems can adapt to platform-based and hybrid organisational forms without undermining accountability, safety and institutional legitimacy.

## 7.6. Actor-based implication overview

Table 7.2 provides an overview of the implications for the various actors identified in this chapter. It demonstrates that the same structural ambiguities have different legal, administrative and commercial consequences depending on their institutional position within the pharmaceutical system.

**Table 7.2:** Comparison of implications per actor

Domain	Regulators and government	Pharmacies	Fulfilment company	Com-	Science and policy
Key legal question	Operationalisation of dispensing vs. logistics; licensing route	Delegation without loss of legal responsibility	Avoiding unintended qualification as wholesaler or pharmacy	un-	Defining assessment frameworks and pilot structures
Biggest uncertainties	Multi-pharmacy B2C models, data handling	Dispensing and last check, FMD responsibilities, GDPR contracts	Storage duration and licensing, segregation of flows, exception handling		Limited empirical evidence and lack of uniform assessment frameworks
Governance focus	Inspection methodology, auditability, enforceability	Contracts, audits, patient communication and quality assurance	GDP-QMS, contract compliance, separation of flows and roles		Measurement frameworks, model clauses and comparative research
Commercial impact	Legislative uncertainty inhibits investment and innovation	Only feasible with efficiency gains without compromising care	Selective market dependent on predictable volumes and scale		Policy impact through pilots and dissemination of best practices

## 7.7. Conclusion

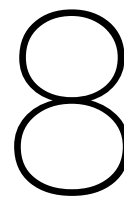
This chapter addressed sub-question 5: *What are the systemic and actor-specific implications of potential participation of non-pharmaceutical fulfilment providers in B2C medicine logistics?*

At the system level, the participation of non-pharmaceutical fulfilment providers adds a new logistics actor to the pharmaceutical chain and reshapes the distribution of responsibilities within a pharmacy-centric framework. This results in hybrid configurations where legal responsibility and operational control are institutionally separated. The main systemic implication is therefore increased governance complexity due to uncertainty surrounding the interpretation of role boundaries, licensing requirements and scalability.

At actor level, the implications vary:

- **Regulators and government actors** face the challenge of supervising hybrid models. This increases the need for clearer licensing, wholesale qualification, multi-pharmacy fulfilment and FMD control guidelines;
- **Pharmacies** remain fully legally responsible, despite outsourcing operational tasks. Participation can increase efficiency, but it also increases the requirements for contracts, quality management and data management.
- **Fulfilment service providers** face strategic opportunities and legislative risks. Economies of scale can only be achieved if sufficient volume and legislative clarity are present. The main risks relate to unintended reclassification as a wholesaler or pharmacy, and to governance failure in complex, multi-client environment;
- **Science and policy** development face a clear knowledge gap. There has been insufficient research into hybrid implementation models for multiple pharmacies, and these require further clarification of existing documentation, empirical validation and structured pilot evaluation.

In summary, participation within the Dutch legislative framework is not fundamentally prohibited, but it is sensitive to institutional factors. The feasibility of non-pharmaceutical delivery in B2C pharmaceutical logistics hinges on the legislation being interpreted clearly, roles being strictly separated, and investments being aligned with sustainable market structures.



# Discussion and limitations

This chapter provides a critical reflection on the study's findings, contextualising them within the broader legislative, institutional and practical landscape of pharmaceutical B2C deliveries. It also clarifies the study's contribution to the existing scientific literature. Furthermore, the chapter interprets the implications of the results, discusses their limitations, and provides recommendations for future research and practice.

## 8.1. Reflection on key findings

This study examined how the Dutch legal and institutional framework shapes opportunities and limitations for non-pharmaceutical fulfilment providers in the B2C medicine delivery sector. Rather than offering a black-and-white assessment of feasibility, the study provides a clearer, more structured understanding of the reasons why feasibility is fundamentally limited. It reveals that the root of the issue is a structural mismatch between a pharmacy-centric regulatory system, where responsibility is clearly defined, and a fulfilment logic that relies on centralisation, scalability and standardisation.

A key contribution of this study is that it clarifies a domain which is often characterised by ambiguity. It reveals that the primary obstacle is not an outright prohibition on outsourcing, but rather a series of unresolved issues concerning boundaries and accountability. While hybrid configurations are not explicitly prohibited by legislation, persistent interpretative uncertainties surround them, particularly regarding licensing, the scope of the license, and the required separation between pharmaceutical and logistics activities. These findings demonstrate that the current framework is not fully tailored to multi-actor hybrid models, resulting in institutional incompleteness rather than outright infeasibility.

This is further enhanced by three structural characteristics of the system: licenses are tied to both legal entities and locations, the dispensing of medicines remains legally anchored in the pharmacy, and regulatory practices restrict the storage of unlabeled medicines outside of licensed environments. Together, these elements constitute a significant barrier to outsourcing and limit the development of scalable fulfilment models. Furthermore, the study identifies the vague distinction between "logistics" and "dispensing" as a central source of uncertainty, which explains why operational activities can be interpreted as part of regulated pharmaceutical responsibility.

The study also shows that uncertainty actually increases precisely where fulfilment seeks its economic advantage: centralization across multiple pharmacies. The lack of a clear governance model for multi-pharmacy fulfilment environments constitutes a fundamental barrier to scalability, as efficiency gains come with an increased compliance risk.

Notably, despite the existing uncertainties, this study has succeeded in developing a structured evaluation framework that integrates legal and market-oriented perspectives. This framework enables different implementation scenarios to be assessed and compared systematically, while still allowing for company-specific preferences and strategic considerations to be taken into account. Thus, the research not only identifies limitations, but also offers a practical and flexible method for decision-making.

Thus, the research identifies limitations and offers a practical, flexible method for decision-making. The case study further supports this, demonstrating that the framework can be used to structure and evaluate real-world scenarios. However, further validation is needed. Furthermore, once the current interpretive ambiguities reflected in the remaining 'question marks' have been clarified or resolved, this framework will be a valuable tool for evaluating scenarios and designing strategies in this field.

Overall, the findings support the clear conclusion that, based on current interpretations, it is not possible to justify a scalable model in which a non-pharmaceutical service provider manages the entire B2C medication supply chain for multiple pharmacies on solid grounds. Furthermore, this study sheds new light on the ongoing debate. Rather than asking whether such models are feasible, the key question is how regulatory ambiguities can be reduced without compromising safety. The results suggest that further elaboration of the existing framework is the most promising path, rather than deregulation. Providing explicit guidelines for multi-pharmacy fulfilment, separation mechanisms and verifiable interfaces between actors could replace interpretive uncertainty with compliance-by-design, thereby reducing investment risk while safeguarding public health objectives.

## 8.2. Contribution to scientific literature

This study makes an important contribution to the literature on the intersection of regulated supply chains, institutional constraints and logistical innovation by explicitly analysing the interface between legislation and business operations (see research gap in Figure 1.1). Its main scientific value lies in its structured translation of dispersed legislative requirements and market realities into a feasibility framework comprising requirements and design criteria, and in its comparative assessment of multiple scenarios using this framework. This approach addresses an identified shortcoming: hybrid B2C fulfilment models for multiple pharmacies are inadequately defined in academic discourse and legislation, resulting in ambiguity regarding the division of responsibilities and the interpretation of licenses.

Secondly, the study reformulates feasibility as a multi-layered construct (legal ambiguity, organisational governance and strategic identity), thereby avoiding the overly simplistic interpretation of pharmaceutical innovation as 'the law allows/prohibits'. This is consistent with the broader observation that regulated systems often evolve through the specification of acceptable forms of organisation and accountability mechanisms rather than through deregulation.

A third contribution is the analysis of the implications for specific actors, which makes explicit how hybrid configurations redistribute operational control while legal responsibility remains concentrated. This leads to greater governance complexity for regulators, new contractual burdens for pharmacies and investment risks for fulfilment providers. By doing so, the study not only identifies obstacles, but also indicates where future research and policy clarification could have the greatest impact: licensing, separation design, multi-pharmacy governance and exception flows.

## 8.3. Limitations

The extent to which the findings can be generalised and the 'definitive' feasibility interpreted is determined by various limitations.

Firstly, the study is explicitly exploratory and based on scenarios. The development of these scenarios necessarily involves making assumptions about the interpretation of the law, the operational conditions in distribution centres and the willingness of stakeholders to outsource. When the legal framework contains ambiguities, the feasibility of the scenarios depends on future clarifications. This creates an external dependency beyond the control of the researchers that is central to the assessment of feasibility.

Another limitation concerns the scope of stakeholder input. Although interviews with regulators and healthcare decision-makers were originally planned, these could not be carried out as the relevant parties were unwilling to cooperate. This reluctance suggests that the subject matter is sensitive at an institutional level. However, this also restricts the ability to fully clarify interpretative questions, the answers to which ultimately depend on supervisory authorities rather than private actors. Furthermore, the empirical basis consists of a limited number of interviews with pharmacists. While their views were consistent due to common legislative conditions, this cannot replace validation by regulators, pharmacy

chains and wholesalers. Due to the concentrated market structure and different institutional interests at these levels, acceptance of implementation models may differ from the perspectives presented in this study.

Lastly, the case study design provides insight but restricts generalisability. The specific constraints that apply to PostNL may not be universal for all fulfilment providers. Other providers may accept joint entities, ownership interests or varying degrees of integration, which could alter the feasible scenario. Therefore, the conclusion that 'S6 is the best fit' should be considered dependent on PostNL's strategic identity and constraints rather than a general statement about dominance.

## 8.4. Recommendations

This section presents recommendations for future research, practice and for PostNL Fulfilment.

### 8.4.1. Recommendations for future research

Exploring scenarios naturally leads to a concrete research agenda, as most uncertainties are concentrated around identifiable points of contact. Future research would be most productive if it focused on design questions that transform ambiguity into testable governance configurations.

A first priority is researching legal and regulatory clarification through applied work that explicitly maps how Dutch legal concepts (including 'dispensing') interact with practical configurations such as co-location and centralised multi-pharmacy processing. As supervisory roles are crucial, research involving structured engagement with national supervisors and licensing authorities would be particularly valuable.

A second priority is governance models for multiple pharmacies. More comparative research could examine how other EU systems address online sales and delivery and whether specific governance instruments, such as licensing categories, cooperation models and contractual supervision models, can reduce uncertainty while maintaining accountability. The intention is not to 'import' foreign models wholesale, but rather to identify governance design patterns that are compatible with the Dutch institutional structure and market consolidation.

### 8.4.2. Recommendations for practice

For regulators and policymakers, the most useful recommendation is to treat hybrid implementation as a subject for legislation rather than as an ad hoc interpretation on a case-by-case basis. The findings of the study suggest that uncertainty is concentrated around licensing and separation requirements, implying that guidelines specifying acceptable separation mechanisms, and oversight models could reduce compliance uncertainty without relaxing safety standards. Such guidelines would also be consistent with the focus of supervision on compliance with the GDP guidelines and documented controls.

For pharmacies, the practical implication of outsourcing is that it is not just an operational choice, but also a commitment to governance. Even when tasks are outsourced, pharmacies remain legally responsible, so they need stronger contracts, quality management and information governance to ensure auditability and patient safety. In this context, professional guidance on dispensing and delivery, such as the KNMP guidance on 'Ter Hand Stellen' [35], is important not only for pharmacy operations, but also as a baseline for what fulfilment partners must be able to support.

For fulfilment providers, it is advisable to structure market entry based on the level of legislative and operational risk involved. Scenarios that closely resemble existing pharmacy-focused structures pose fewer interpretative and compliance risks. Conversely, models incorporating personalised processing and B2C activities for multiple pharmacies should only be pursued if the governance design can be validated by the relevant authorities. Furthermore, if a fulfilment provider intends to implement a model that competes with highly integrated pharmacy chain and formula structures, a broader market analysis is recommended to assess competitive dynamics, contractual dependencies and the strategic feasibility of entering such a consolidated market.

### 8.4.3. Recommendations for PostNL Fulfilment

If PostNL Fulfilment intends to participate in the pharmaceutical B2C fulfilment sector, it should adopt a phased, governance-driven entry strategy.

Within the parameters defined by PostNL (see subsection 6.3.1), S6 (the internal pharmacy model) was identified as the most coherent option (see subsection 6.3.2). The phased road map below therefore assumes the implementation of S6 (co-location of a single pharmacy) initially, explicitly indicating where considerations are more exploratory and relevant to possible future expansion. Given the layered feasibility identified in this study; legal, organisational and strategic, the following structure action plan is recommended:

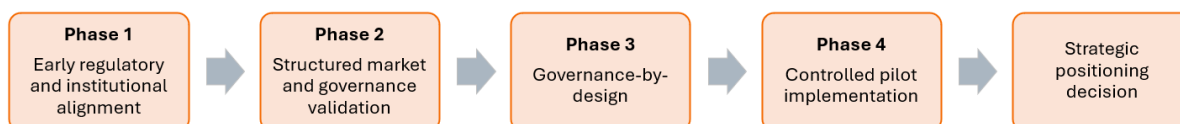


Figure 8.1: Implementation recommendations for PostNL Fulfilment

Importantly, the successful completion and validation of each phase should be treated as a prerequisite for progressing to the next. If a phase cannot be satisfactorily concluded, for example due to legislative non-acceptance, unresolved governance risks, or insufficient market commitment, this should be interpreted as a signal that implementation under the current configuration is not feasible. In that case, either redesign or strategic reconsideration would be required before further progression.

It should also be emphasised that this thesis primarily aimed to explore and compare different structural entry configurations within the Dutch legislative and institutional framework. The recommendations presented here move beyond exploration and focus specifically on implementation under S6 in the PostNL case. The greater level of operational detail in this section therefore reflects a shift from analytical feasibility assessment to practical governance design and execution planning.

#### Phase 1: Early regulatory and institutional alignment

Before finalising the operational design, PostNL should engage in structured dialogue with interpretative uncertainty in the context of an S6 configuration.

**Engage the regulatory and licensing authorities (IGJ and Farmatec)** Engage both parties in a dialogue, as clarification on hybrid S6 implementation requires both interpretative validation (IGJ) and formal licensing assessment (Farmatec):

- Clarify the operational boundary between dispensing and logistics within a co-location model, specifically for S6;
- Validate the separation mechanisms that are acceptable when the pharmacy operates within infrastructure owned or leased by PostNL (specifically for S6);
- Discuss the storage conditions for unlabeled medicines in a co-location environment. Under S6, unlabeled medicines remain under the pharmacy license at the same registered address. This significantly reduces ambiguity compared to centralised models with multiple pharmacies. However, clarification remains necessary because, although the pharmacy license remains with the pharmacy, the physical infrastructure may be owned by PostNL and operational control is institutionally separate. Therefore, the key question is not whether external storage is used, but whether the hybrid infrastructure demonstrably remains under the control of the pharmacy;
- Examine the expectations in terms of supervision in case it is considered in the future to extend beyond a single pharmacy;
- Confirm that S6 activities do not give rise to a wholesale reclassification;
- Clarify whether the intensity of processing or future scaling up for multiple customers could change requirements (e.g. for needing a WDA);
- Validate the interpretation of licenses in the context of co-location.

#### Consult the KNMP

- Align the S6 model with professional standards relating to the 'Ter Hand Stellen, KNMP-richtlijn' (guideline for dispensing) [35];
- Identify non-negotiable conditions for supervision by pharmacists;
- Assess the sector's acceptance of a hybrid fulfilment model with co-location.

#### **Perform a structured GDPR assessment**

- Conduct a Data Protection Impact Analysis (DPIA) for the processing of health data within a shared infrastructure;
- Validate the digital separation between the pharmacy and fulfilment systems;
- Clarify the assignment of controller and processor under the GDPR.

#### **Phase 2: Structured market and governance validation**

Chapter 5 of the thesis contains a structured market analysis, which includes interviews with pharmacists, an assessment of market concentration and segment differences, and an evaluation of the willingness to outsource. This provides initial validation of the structural feasibility of the market. However, if PostNL intends to implement S6, a further validation phase focusing on implementation is required. This phase would complement the existing analysis, providing a deeper strategic perspective on decision-making. This phase should result in a formalised S6 implementation feasibility dossier, containing: confirmed pilot partner(s), quantified operational relief, and initial integration of feedback from regulatory authorities.

**Validate S6-specific adoption conditions** Although the general conditions for cooperation were established, S6 requires confirmation that pharmacies are willing to participate in the co-location model. PostNL must therefore:

- Test the willingness to outsource storage and preparation within a shared location configuration;
- assess the acceptance of more intensive operational integration while retaining pharmaceutical responsibility;
- Identify candidate pharmacies suitable for a controlled S6 pilot, preferably with an emphasis on repeat prescriptions.

This shifts the focus from general market feasibility to concrete participation feasibility.

**Refine the pharmacy's value proposition** The study identifies organisational pressures, such as staff shortages, space constraints and non-core activities, as factors for acceptance (see subsection 6.3.1). With a view to implementation, PostNL must translate this into a quantified value proposition:

- Estimating the reduction in internal logistics processing under S6. This can be done by mapping out the current logistics process in the pharmacy and comparing it with the proposed S6 configuration. By quantifying the time spent per activity (e.g., hours per week), staffing levels, and space utilization, PostNL can estimate the reduction in internal logistics processing under S6. This estimate must distinguish between tasks that are fully transferred to the fulfilment partner and tasks that remain the responsibility of the pharmacy, so that the net organisational relief is transparent and measurable.
- Calculating the potential redistribution of space within pharmacy buildings;
- Clearly evidencing that pharmaceutical responsibility, decision-making authority and supervisory control remain with the licensed pharmacist, even when logistical tasks are outsourced under S6;
- Designing explicit governance mechanisms, such as auditability, intervention rights, and clearly defined escalation procedures, that ensure pharmacists retain practical oversight and do not experience a loss of operational control under S6.

This will convert analytical findings into a decisive proposal.

**Conducting a targeted structural market scan** Market concentration and vertical integration have already been described in the thesis (Chapter 5). For the implementation of S6, PostNL must supplement this with:

- Identification of pharmacies that are not contractually bound to vertically integrated logistics structures;
- Assessing independent or hybrid pharmacies with sufficient volume to justify co-location;
- Evaluating the density of repeat prescriptions in candidate regions;
- Analysis of whether vertically integrated pharmacies retain the contractual or operational flexibility to outsource specific logistics components independently, and mapping such flexibility where it exists.

#### Phase 3: Governance-by-design

Under S6, the design of the board becomes the central determining factor for feasibility. PostNL must design and formally document the following:

- A legally defensible “moment of release” that separates delivery and logistics;
- An explicit physical and digital demarcation of responsibilities;
- Verifiable access control systems;
- An interface for supervision by pharmacists that guarantees traceability and visibility.
- Clear FMD/NMVS verification tasks within the co-localized environment.

#### Phase 4: Controlled pilot implementation

Implementation must strictly begin under an S6 configuration with a single pharmacy. The pilot must:

- Focus on predictable repeat prescriptions;
- Be audited after 6-12 months;
- Be evaluated jointly with the pharmacy and the regulator.

Only after the following has been demonstrated: stable compliance with the GDP, clear and verifiable separation of duties, verifiable traceability, confirmed acceptance by the regulator, may expansion beyond S6 with a single pharmacy be considered.

#### Strategic positioning decision

Finally, PostNL must explicitly decide whether it intends to remain a pure logistics partner operating within governance structures determined by pharmacists (in accordance with S6), or to gradually work toward deeper structural integration within pharmaceutical governance.

The road map presented above is based on the first position and therefore prioritises institutional validation and compliance stability. An attempt to immediately achieve B2C fulfilment for multiple pharmacies without prior S6 validation would significantly increase the interpretative risk, licensing risk, and reputational risk. The recommended path therefore prioritises legislative certainty, clarity on governance, and step-by-step validation over rapid scaling.

# 9

## Conclusion

### 9.1. Conclusions

The thesis examined the institutional and legislative conditions that influence the opportunities and limitations for a non-pharmaceutical fulfilment company wishing to participate in B2C medicine delivery in the Netherlands. The scope was limited to warehouse activities in fulfilment centres, domestic distribution and coldstore/ambient temperature medicines, with the exception of special categories (Section 1.3). It transformed an under-researched fulfilment configuration into a structured feasibility exploration, mapping legal requirements, market design criteria and scenarios, while demonstrating that the outcome cannot be reduced to a definitive binary choice of 'possible or 'impossible'. Rather, the feasibility of this area is best characterised as conditional and dependent on governance. The main opportunities lie in pharmacy-led configurations with strict separation and demonstrable compliance. Conversely, the main limitations arise when the role of a fulfilment provider encompasses activities that could be perceived by regulators and other professionals as falling within the scope of medicine dispensing responsibilities.

#### 9.1.1. Conclusions of the sub-questions

*SQ1: How is extramural pharmaceutical care and medicine logistics organised in the Netherlands, and how does this compare to international approaches to B2C medicine delivery?*

Sub-question 1 was addressed in the analysis of the pharmaceutical supply chain in Chapter 3. This chapter mapped out the organisation of extramural pharmaceutical care in the Netherlands, placing it within an international B2C context.

The analysis revealed that the Dutch system is pharmacy-oriented and highly regulated, with the authority to dispense medicines and the associated legal responsibility firmly anchored within recognised pharmaceutical entities. Although digitisation and automation have improved upstream processes, the final B2C delivery phase remains operationally and institutionally sensitive. At the same time, demographic developments are driving the need for scalable home delivery models to increase. The complexity of this framework is reflected in the wide range of stakeholders involved, including pharmacies, wholesalers, manufacturers, supervisors, insurers and logistics providers. Their roles and responsibilities are closely interlinked.

Internationally, various B2C fulfilment/distribution models exist, including mail-order pharmacies, e-pharmacy platforms and DTP structures offered by logistics service providers. However, no international model has been found in which a non-pharmaceutical fulfilment provider acts as the complete logistics back office for multiple pharmacies while remaining outside the scope of pharmaceutical licensing regulations. Existing models remain embedded in pharmacy-controlled or formally recognised pharmaceutical structures.

Comparisons between countries are further complicated by differences in the national implementation and interpretation of European directives. Although legislative frameworks have a common basis,

national legislation and supervisory practices, such as the Dutch Medicines Act, lead to different institutional configurations. Consequently, international practice cannot be directly translated into the Dutch context.

Sub-question 1 therefore highlights a significant research gap: while the international literature describes various B2C and 3PL configurations, there is limited analysis of structurally independent, non-pharmaceutical back-office models within strictly regulated national systems. Chapter 3 clarifies this gap by mapping out the Dutch supply chain structure, thereby providing the necessary systemic basis for the subsequent legal, market and scenario analyses.

*SQ2: What do current Dutch medicines legislation and GDP guidelines prescribe regarding medicine logistics?*

Sub-question 2 was addressed through the legislative analysis in Chapter 4. This analysis systematically examined the Dutch Medicines Act, the EU GDP guidelines and other guidelines, as they are implemented in the Netherlands.

The analysis shows that Dutch pharmaceutical legislation and the GDP guidelines together form a multi-layered framework based on roles and locations that prioritises patient safety, responsibility and traceability. The most important legal principles can be summarised as follows:

- **Role- and location-based licensing structure:** Both wholesale and pharmacy licenses are legally bound to a specific legal entity and recognised physical location;
- **Exclusive authority to dispense:** Dispensing ('ter hand stellen') is exclusively covered by a pharmacy license;
- **Storage duration threshold:** A wholesale or pharmacy license is required for the storage of medicines for more than 72 hours;
- **Restrictions for unlabeled medicines:** Medicines without labels may not be stored outside a licensed pharmacy (B2C) or wholesale (B2B) environment.

These principles define the legal boundaries within which any logistics configuration must operate.

It is important to note that, as there is currently no model within the Dutch system whereby a non-pharmaceutical company takes on the entire logistical back office for one or multiple pharmacies, the legislation does not explicitly address such configurations. Consequently, the legislation offer limited clarity regarding the division of liability, the licensing structure and the division of roles in such hybrid arrangements. The legal framework was designed around clearly defined pharmaceutical actors rather than structurally external fulfilment entities. This lack of explicit provisions leads to uncertainty when attempting to fit new configurations into the existing licensing system.

Chapter 4 converted the legislative constraints into a mandatory checklist of requirements (R1–R4), turning compliance with legislation into specific prerequisites for scenario development. It clarifies that certain configurations are commercially and legally infeasible within the current framework, while others remain conditionally possible but are institutionally ambiguous. Sub-question 2 therefore establishes the non-negotiable legal basis of the study, explaining why feasibility in this area is primarily determined by licensing logic and legislative interpretation.

*SQ3: To what extent is there a viable market for external fulfilment services in the pharmacy sector, and how willing are pharmacists to outsource the fulfilment of medicines?*

This sub-question, which is addressed in Chapter 5, builds on the legal requirements previously established by analysing the economic structure and stakeholder attitudes. While sub-question 2 defined the mandatory legal requirements, this chapter set out the practical design criteria employed in the scenario exploration.

The analysis shows that the Dutch pharmacy market offers more selective than broad opportunities for third-party fulfilment. The sector is highly concentrated, dominated by large chains and wholesalers with advanced internal logistics infrastructures, which makes it difficult for generic replacement suppliers to enter the market. However, the market appears more viable in niche segments characterised by predictable volumes and digital orders, particularly repeat prescriptions, where outsourcing can be seen as logistical support rather than a replacement for core pharmaceutical responsibilities.

Pharmacists' willingness to outsource depends on the activity. They are most resistant to outsourcing when it could blur the authority to dispense medicines or clinical responsibility, but are more open to it for logistics-intensive pharmacy-related tasks such as delivery, provided reliability, governance and communication standards with patients are guaranteed.

Sub-question 3 therefore adds commercial and behavioral dimensions to the feasibility analysis, translating market realities into concrete design criteria for scenario development.

*SQ4: Which fulfilment scenarios can be developed for non-pharmaceutical fulfilment providers, and how feasible are they in legal, logistical, and organisational terms?*

Sub-question 4 focused on developing implementation scenarios for non-pharmaceutical providers and evaluating their legal, logistical and organisational feasibility. To avoid prematurely excluding potentially feasible configurations, a wide range of scenarios with varying degrees of integration and outsourcing intensity was deliberately developed. These scenarios were addressed using the structured scenario portfolio (S1–S8):

- **S1:** Short-term storage and/or distribution only;
- **S2:** OTC medicines only;
- **S3:** Pharmacy distribution point;
- **S4:** Becoming a wholesaler (B2B);
- **S5:** Becoming a central filling company (B2B);
- **S6:** In-house pharmacy;
- **S7:** Joint Venture;
- **S8:** Cooperative;

It explored using an integrated framework combining mandatory legal requirements (R1–R4) and market/organisational design criteria (DC1–DC7). Importantly, in line with the overall shift in the research, this chapter adopted an exploratory rather than definitive approach: rather than seeking final approval from the regulatory authorities, the aim was to identify the feasibility limits and sensitivities of the different configurations.

The analysis shows that none of the developed scenarios were explicitly excluded by mandatory legal requirements. Differences in feasibility mainly stem from the degree of integration with core pharmaceutical activities, and from uncertainty surrounding the interpretation of licenses, the separation of roles, and the governance structure. The scenarios differ significantly in terms of the extent to which implementation steps are outsourced. Logistics-related configurations involving limited outsourcing (e.g. delivery-focused models) appear less sensitive, while more integrated models, particularly those in which a fulfilment provider takes on the entire logistics back office, require complex governance structures and carefully designed mechanisms for legal separation. Such configurations would not resemble conventional commercial outsourcing arrangements, but would instead require hybrid models that are structurally embedded.

The case study at PostNL Fulfilment further illustrates that feasibility has multiple layers: in addition to compliance with laws and regulations, the identity of the organisation, its strategic positioning, and its risk appetite also influence which scenarios can realistically be applied. Even when abstract compliance with laws and regulations is feasible, practical implementation depends on validation by the board and institutional acceptance.

Sub-question 4 therefore forms the integrative core of the study. It translates the legislative restrictions and market design criteria into concrete, comparative configurations. It shows that participation is possible under certain conditions, but full back-office integration requires complex institutional coordination rather than straightforward commercial cooperation.

*SQ5: What are the systemic and actor-specific implications of potential participation of non-pharmaceutical fulfilment providers in B2C medicine logistics?*

Sub-question 5 examined the systemic and actor-specific implications of introducing a non-pharmaceutical fulfilment provider to the logistics of B2C medicine. Based on the scenario analysis, this question assessed the broader network-level impact. The main implications are summarised in Table 7.2.

At the system level, incorporating a non-pharmaceutical supplier results in hybrid configurations, where operational control and legal responsibility are institutionally distinct, thereby complicating governance. This means that regulators need greater clarity on licensing structures and oversight of hybrid models involving multiple pharmacies. For pharmacies, outsourcing logistics does not transfer responsibility; legal responsibility remains with the pharmacy, requiring robust contracts, quality management and data management. Participation in such models offers fulfilment providers both strategic opportunities and legislative risks, with scalability dependent on institutional clarity. In terms of science and policy, there is still a lack of empirically validated governance models for such hybrid configurations.

This sub-question is important because it links feasibility to consequences, clarifying not only whether participation is possible, but also its structural implications for the pharmaceutical network as a whole.

### 9.1.2. Conclusion of the main research question

The main research question of this study was formulated as follows

*How does the Dutch legislative and institutional framework influence the possibilities and limitations for non-pharmaceutical fulfilment providers in B2C medicine fulfilment?*

This thesis demonstrates that this influence operates through three reinforcing processes.

Firstly, the legislative framework limits participation structurally by embedding the fulfilment of medicines in a role-based system, in which authority, accountability and licensing are concentrated around pharmacies and other formally recognised pharmaceutical entities, with licenses linked to specific legal entities and locations. While this design protects patient safety and traceability, it severely limits the extent to which 'fulfilment' can be outsourced before a non-pharmaceutical provider engages in activities that entail additional licensing requirements or could be interpreted as part of the dispensing responsibility. In practice, viable participation begins with pharmacy-led configurations: logistical execution can be delegated, provided there is demonstrable compliance with GDP, strict quality systems and clearly defined control measures at the point of release and responsibility.

Secondly, the institutional framework, comprising supervisory practices, professional standards and stakeholder governance, determines the feasibility of actions beyond what is written in the law by influencing how ambiguous boundaries are interpreted and enforced. The study's scenario evaluation shows that the main feasibility bottlenecks lay in the interpretative grey areas (in particular, the boundary between dispensing and logistics, and centralisation of multiple pharmacies). Such ambiguities increase compliance and investment risk, thus constituting an indirect barrier to entry. In a regulated sector, it is difficult to responsibly scale up what cannot be unambiguously regulated and controlled, even if this appears operationally feasible.

Thirdly, the market structure combined with legislation ensures that practically accessible opportunities remain limited. As large companies already have integrated infrastructures and pharmacies are legally responsible even when outsourcing, the realistic market for non-pharmaceutical fulfilment providers focuses on specific segments and partial outsourcing agreements, particularly those involving predictable volumes and digital orders. In these cases, a fulfilment provider can be seen as an extension of the pharmacy rather than an independent distributor.

Overall, while the Dutch legislative and institutional framework does not fundamentally prohibit non-pharmaceutical participation, it does impose strict conditions. The framework only permits involvement through carefully regulated hybrid arrangements that maintain the pharmacist's responsibility, enforce strict separation and operationalise compliance through verifiable interfaces. At the same time, however, the framework limits the feasibility of fully outsourced, scalable, end-to-end fulfilment models. This is because the safety-oriented licensing logic and institutional interpretation of the system currently leave insufficiently specified governance paths for such configurations. The following five points summarises the research:

- **Pharmacy-centered foundation:** The Dutch system is structurally pharmacy-oriented: licensing, authority and legal responsibility are role- and location-based and anchored to recognised pharmaceutical entities;
- **Possibilities: conditional and pharmacy-led:** Participation is not explicitly prohibited, but is only feasible in carefully designed, pharmacy-led configurations with strict role separation, GDP

- compliance and demonstrable control mechanisms;
- **Institutional limitations: licensing logic and interpretative uncertainty:** Limitations arise when fulfilment activities approach dispensing responsibilities or trigger additional licensing requirements. Interpretative ambiguities (e.g. R2 & DC4) increase compliance and investment risk;
- **Market limitations:** Due to chain integration, existing logistics infrastructures and pharmacists' retained responsibility, realistic opportunities are limited to selective, predictable high-volume segments rather than scalable end-to-end outsourcing models;
- **Not a binary outcome:** Feasibility cannot be reduced to "possible" or "impossible"; it is conditional, governance-dependent, and limited to specific segments.

## 9.2. Reflection

This section outlines my reflections on the study in terms of its research design and outcomes, its relevance to the Master's program, and my personal experience.

### 9.2.1. Reflection on the research design and outcomes

The original aim of this study was to assess the feasibility of a non-pharmaceutical fulfilment provider participating in B2C pharmaceutical logistics. However, during the research process, it became clear that it would not be methodologically justifiable to provide a definitive assessment of feasibility at this stage. The Dutch pharmaceutical distribution system is characterised by a complex interplay between legislation, the interpretation of legislation, professional standards and operational practice. Therefore, feasibility is determined not only by legal provisions, but also by how these provisions are interpreted and implemented within the institutional environment. Furthermore, the sensitivity of the subject matter made it difficult to validate assumptions directly with regulatory authorities.

Consequently, the research shifted from a strictly evaluative objective to a more exploratory design. Rather than making a binary judgement on whether participation is 'possible' or 'impossible', the research examines how the Dutch legislative and institutional framework shapes the opportunities and limitations for non-pharmaceutical fulfilment providers. This shift ultimately proved valuable, as the debate on third-party involvement in pharmaceutical fulfilment is often characterised by considerable uncertainty. Legal provisions, institutional interpretations and operational practices are closely intertwined, making it difficult to determine where the real limitations and opportunities lie. By systematically unraveling these layers and structuring them into legal requirements, market and organisational design criteria, scenario configurations and actor-specific implications, the research brought analytical structure and clarity to a discussion that is often perceived as complex and vague.

To support this objective, a scenario-based methodology was employed. This allowed possible configurations of pharmaceutical logistics to be analysed without committing to a single institutional interpretation prematurely. These scenarios were then evaluated using a feasibility framework consisting of binding legal requirements and practical design criteria. Distinguishing these two dimensions explicitly proved particularly valuable, as it enabled the study to separate formal legal constraints from organisational and market considerations. Thus, the study developed a structured analytical approach to help translate abstract legislative constraints into concrete logistics configurations. This methodological contribution offers a systematic way to examine institutional feasibility in a highly regulated logistics domain.

A significant part of the research consisted of desk research. The Dutch pharmaceutical sector is subject to an extensive and complex web of legislation, policy documents, supervisory guidelines, parliamentary debates and academic literature. These sources are not coherent, often being scattered across different legislative layers and institutional interpretations. By systematically analysing and summarising these materials, the research identified the most relevant legal principles and regulatory boundaries in sources such as the Medicines Act, regulatory guidelines and supervisory communications. Extracting and structuring these key elements translated a fragmented collection of rules into a clear, coherent legal framework for assessing compliance scenarios. This process enabled triangulation of information and construction of a legally sound analytical basis, particularly in the absence of direct regulatory validation through interviews.

This desk research was supplemented with interviews with stakeholders involved in pharmaceutical practice. Pharmacists proved to be particularly relevant open interviewees, as any operational collaboration with fulfilment providers necessarily requires their participation. At the same time, the interviews confirmed that pharmacists have limited influence on the interpretation and enforcement of legislation, which ultimately lies with the regulatory authorities. This emphasises once again that feasibility is primarily determined at the institutional and administrative levels, rather than exclusively at the operational level.

Finally, while the defined scope of the study strengthened the analytical focus, it also limited the extent to which the findings could be generalised. By focusing on warehouse-related fulfilment activities, the study examined the area in which a non-pharmaceutical logistics service provider could potentially create the most organisational value. Consequently, the conclusions should be interpreted within this specific operational and product scope. Within these limits, the research provides a structured exploration of institutional feasibility and contributes to a clear analytical framework for navigating the legislative and organisational complexities surrounding pharmaceutical fulfilment. This framework could form the basis for future empirical validation and further clarification of legislative interpretations in this evolving area.

### 9.2.2. Position within the TIL Networks track

This thesis was written as part of the Master's program in Transport, Infrastructure and Logistics (TIL), focusing particularly on the network perspective. The research ties in with this program by analysing the pharmaceutical supply chain as a regulated logistics network, examining how goods flow, responsibilities and information are institutionally structured. Rather than focusing solely on operational efficiency, the study examines how legal framework and governance mechanisms influence network configurations and the interactions between its participants.

By examining hybrid fulfilment scenarios, the study shed light on how new actors can or cannot be integrated into strictly regulated distribution networks. Consequently it combines logistics system design with institutional analysis, reflecting the interdisciplinary nature of the TIL program. The research demonstrates that logistics innovation in healthcare cannot be valued solely in technical terms, but must be analysed within the context of a broader institutional network where legislation, accountability, and governance are structurally embedded.

### 9.2.3. Personal experiences

Reflecting on the process of writing this thesis, I feel positive about it. Initially, I found it challenging to decide on an approach to the research, particularly given the subject's strong legal dimension and my lack of formal legal expertise. However, this made the process intellectually stimulating, as it allowed me to explore new areas and deepen my understanding of legislative, regulatory and administrative structures.

Throughout the entire process, I felt very welcome at PostNL Fulfilment. Although the team did not have specialised pharmaceutical legal expertise, everyone was open and willing to help when needed. Although I had the option of working from home, I enjoyed going to the office because of the pleasant atmosphere. I also had the opportunity to observe operations on the work floor and attend meetings, making the experience both educational and enjoyable. I am very grateful for the insight I gained into how a professional logistics organisation functions.

The guidance I received from my TU Delft supervisors was invaluable. At times, it was necessary to carefully determine the direction of the research, and their expertise and constructive feedback helped me regain clarity and motivation whenever needed. They were also consistently willing to provide last-minute feedback as deadlines approached, which I found extremely valuable and reassuring throughout the process.

Overall, this research project has taught me how to conduct independent scientific research and structure complex, sensitive topics into coherent analyses. Although the original research design involved validating the developed scenarios through interviews with regulatory experts, this objective could not be fully realised due to a lack of participation. Despite this constraint, I am satisfied with how the research evolved and how, together with my supervisors, the project was reshaped into a robust and

meaningful study. I am therefore satisfied with both the learning process and the end result.

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*Note: AI-supported tools (such as ChatGPT) were used to assist with structural organisation and formatting during the preparation of this thesis. However, the intellectual content, analytical reasoning and final conclusions are the sole responsibility of the author.*

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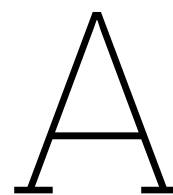
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Scientific paper

# Exploring the Feasibility of offering a GDP-Compliant Medicine E-Commerce Fulfilment Service

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**Abstract**—The home delivery of medicines to consumer (B2C) is under increasing pressure due to demographic changes, growing expectations of the convenience of e-commerce and the further digitisation of healthcare processes. Meanwhile, the extramural medicine sector in the Netherlands is highly regulated and organised around pharmacies, with legal responsibility for dispensing and patient safety remaining with the pharmacist. This study examines how the Dutch legislative and institutional framework determines the opportunities and limitations for non-pharmaceutical fulfilment parties in B2C medicine delivery. An exploratory, mixed-methods approach was taken, involving desk research, stakeholder analysis, semi-structured interviews, the development of eight delivery scenarios and a scenario evaluation based on a feasibility framework incorporation (i) hard legal requirement (R1-R4) and (ii) market- and organisation-oriented design criteria (DC1-DC7). The results show that, while participation is not explicitly prohibited, it is mainly limited by interpretive grey areas concerning the distinction between dispensing and logistics, uncertainty surrounding licenses and role qualifications, and requirements for demonstrable separation of responsibilities and auditable governance. The feasibility of a scenario decreases as it becomes more like an integrated 'logistical back office' of pharmacies, especially in cases of centralisation for multiple pharmacies. Phased implementation, strict contractual safeguards and further legislative clarification are crucial for implementation and up-scaling.

**Index Terms**— pharmaceutical fulfilment, medicine e-commerce, Good Distribution Practice (GDP), Dutch medicines legislation, third-party logistics (3PL)

## I. INTRODUCTION

### A. Context

Demand for the safe and reliable home delivery of medicines is growing due to an ageing population, increased medication consumption and a social movement towards longer independent living [1] [2]. At the same time, patients are becoming more accustomed to digital services such as e-health and e-prescriptions, and they now expect the same level of convenience in medicine delivery as they do with regular e-commerce [3]. This puts additional pressure on pharmacies to organise fulfilment processes more efficiently and in a scalable way, without compromising patient safety. Fulfilment refers to the outsourced logistical back-office of a company, encompassing stock management, order processing, picking and packing, delivery, and return handling.

In the current Dutch system, prescription medicines are dispensed to patients under the responsibility and supervision

of a licensed pharmacist (Art. 61, Gnw). In practice, manufacturers and wholesalers supply pharmacies, which then organise physical dispensing or delivery and remain legally responsible for dispensing, control and patient safety. Pharmaceutical fulfilment is therefore heavily regulated, and responsibility is tightly linked to licensed actors. In such a pharmacy-centric model, the role of non-pharmaceutical logistics parties is traditionally limited. At the same time, the potential entry of non-pharmaceutical logistics providers creates structural tensions: it challenges existing role boundaries and accountability, even though it could offer clear benefits such as economies of scale and efficiency gains in fulfilment operations.

Furthermore, new fulfilment concepts are emerging in which a 3PL is responsible for more than just last-mile transport. One example is central filling, where repeat prescriptions are processed in batches on behalf of one or more pharmacies [4]. This shift raises legal and administrative questions: which activities are still logistical, and which are implicitly or explicitly part of the dispensing process? How should licensing and supervision be organised when a single fulfilment environment serves multiple pharmacies?

### B. Literature and research gap

The literature shows that the Dutch pharmaceutical supply chain is a highly regulated, pharmacy-centered system, with the authority to dispense medicines, supervisory duties and legal responsibility firmly anchored in licensed pharmacies. Medicines are distributed from manufacturers to wholesalers and then to pharmacies, where prescriptions are validated, medicines are dispensed and patients are provided with advice [5]. Even when innovations such as robots, central filling or home delivery services are introduced, the pharmacy remains the legally responsible party [4] [6]. Therefore, logistical processes are not just operational functions; they are also institutionally intertwined with professional standards, compliance with Good Distribution Practices (GDP), traceability requirements and data protection obligations.

The existing academic literature reflects this structure. Studies on pharmaceutical logistics primarily concentrate on enhancing the efficiency of the existing pharmacy chain through automation, improved forecasting and centralised processing of repeat prescriptions. Research into B2C models primarily examines online or mail-order pharmacies, where medicine is

still dispensed from licensed pharmacies [7] [8] [9]. Other literature examines the optimisation of last-mile deliveries or the role of 3PLs in broader healthcare supply chains, often in B2B contexts between licensees [4].

However, an in-depth analysis of a configuration in which a non-pharmaceutical 3PL acts as a complete logistics back office for the delivery of B2C prescription medicines on behalf of one or multiple pharmacies is notably absent. The literature does not systematically examine how storage, order processing, picking, packaging and distribution can be organised outside the physical pharmacy environment, while ensuring legal responsibility for dispensing medicines is maintained, as well as GDP compliance, traceability and accountability structures.

Consequently, there is a clear knowledge gap at the intersection of health legislation, supply chain governance, and e-commerce: there is insufficient understanding of whether, and under what legal and legislative conditions, a non-pharmaceutical fulfilment provider can carry out B2C logistics for prescription medicines without this leading to uncertainty about responsibility, undermining oversight mechanisms, or compromising patient safety.

### C. Objective and main question

This study examines how the Dutch legislative and institutional framework influences opportunities and limitations for non-pharmaceutical fulfilment parties in B2C pharmaceutical fulfilment. Through a combination of legal and market analysis and scenario research, the study will translate an underexposed theoretical delivery structure into a series of practical, legally substantiated scenarios. The main research question is:

*'How does the Dutch legislative and institutional framework influence the possibilities and limitations for non-pharmaceutical fulfilment providers in B2C medicine fulfilment?'* The sub-questions to answer this main question are listed in "Fig.1".

## II. METHODOLOGY

This study employs an exploratory, mixed-methods approach due to the nature of the issue, which encompasses normative-legal aspects (e.g. what is permitted and how is it interpreted?), socio-institutional aspects (e.g. roles, supervision, and market acceptance), and operational aspects (e.g. process interfaces and exception flows). The research is structured around sub-questions that proceed step by step from the system context, through legislation and market potential, to scenario development and implication analysis (see "Fig.1").

### A. Desk research and document analysis

First, desk research was used to map out the extramural pharmaceutical chain in the Netherlands and analyse the relevant legislative framework, including GDP requirements and supervisory practices. The objective was to clarify the potential in the market and the structural 'rules of the game' within which scenarios must function.

### B. Stakeholder analysis and semi-structured interviews

Within this framework and the scope of the study, regulators and other stakeholders play a crucial role. This stakeholder analysis focuses on actors who have a formal role, decision-making authority or restrictive influence over the organisation of the fulfilment of medicines in B2C environments. The various stakeholders listed below are divided into regulatory and supervisory authorities, industry organisations and interest groups, operational actors and end users.

TABLE I  
STAKEHOLDER ANALYSIS

Stakeholder	Interest	Power
<b>Regulatory and supervisory authorities</b>		
EC	<b>Medium:</b> Sets the EU legislative framework.	<b>High:</b> Determines regulatory boundaries for member states.
CBG	<b>Low:</b> No role in distribution or fulfilment.	<b>Low-Medium:</b> Influence through product classification.
IGJ	<b>High:</b> Defines legal limits for distribution.	<b>High:</b> Can enforce or block fulfilment models.
Farmatec	<b>High:</b> Required for storage or distribution licences.	<b>High:</b> Licensing authority for fulfilment activities.
NMVO	<b>Medium:</b> Responsible for UR verification system.	<b>Medium:</b> Technical constraints on scanning processes.
AP	<b>High:</b> Regulates processing of health data.	<b>High:</b> Can prohibit data-sharing practices.
<b>Industry organisations and interest groups</b>		
KNMP	<b>High:</b> Protects professional responsibility and safety.	<b>Medium-High:</b> Influences sector standards and policy.
NPCF	<b>High:</b> Focus on accessibility and safety.	<b>Low-Medium:</b> Indirect influence via public opinion.
Insurers	<b>Medium:</b> Interest in efficient fulfilment models.	<b>Medium:</b> Influence through reimbursement structures.
<b>Operational actors</b>		
Pharmacist	<b>High:</b> Delegates logistics tasks to 3PLs.	<b>Medium:</b> Decisive for operational cooperation.
RP	<b>Medium:</b> Oversees operational compliance.	<b>Medium:</b> Can approve or block processes.
3PL	<b>High:</b> Directly affected by legal constraints.	<b>Low-Medium:</b> Dependent on licenses and pharmacists.
Wholesalers	<b>High:</b> Hybrid models affect distribution role.	<b>Low-Medium:</b> Market-based influence.
ICT suppliers	<b>Medium:</b> Provide digital infrastructure.	<b>Low:</b> Technical support role.
<b>End users</b>		
Patients	<b>Medium:</b> Interest in safe and timely delivery.	<b>Low:</b> Indirect influence through public opinion.

When introducing new fulfilment structures, it is important to consider the potential conflicts that may arise between different stakeholders. While cooperation between stakeholders such as pharmacies, wholesalers and logistics service providers is necessary to ensure compliance with legal frameworks such as GDP, their interests are not always aligned. For instance, pharmacies are legally responsible for dispensing and thus tend to prioritise patient safety and risk management, whereas other parties may prioritise efficiency, scalability, or cost reduction. Therefore, the feasibility of new B2C fulfilment models depends not only on legal permissibility, but also on the ability to manage these interdependencies and conflicting incentives within the pharmaceutical distribution system.

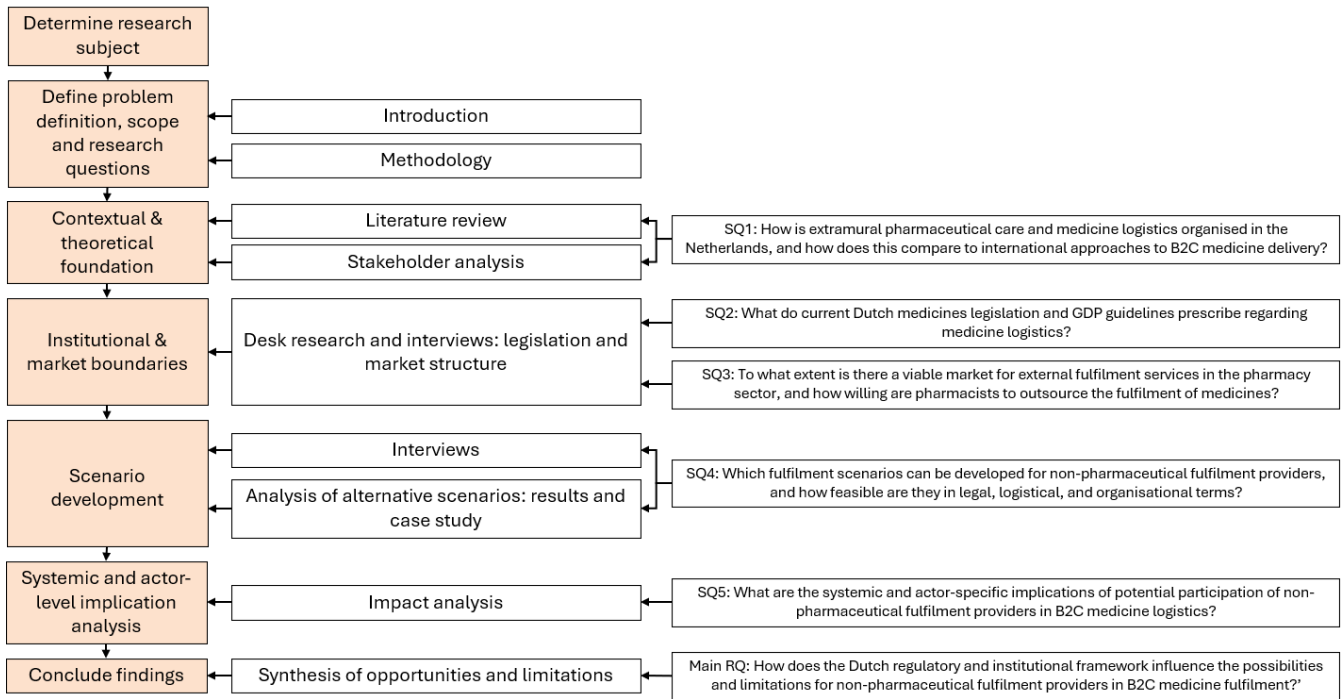


Fig. 1. Research flow; relation between methods and answering the research questions

Next, semi-structured interviews were conducted with important stakeholders to focus on interpretation and implementation issues. A total of five respondents were included ("TABLE.II").

TABLE II  
OVERVIEW OF INTERVIEWEES

Resp.	Type	Position
P1	Community / online pharmacy	Pharmaceutical manager; operationally responsible and in charge of all B2B clients
P2	Community pharmacy	Pharmacy owner (co-owner of all pharmacies within the partnership)
P3	Community pharmacy	Pharmacy owner; board member of BENU; former board member of KNMP
I1	Law firm	Legal counsel specialised in insolvency and corporate law
I2	Medical solutions company	Sales manager; responsible for commercial activities

Three pharmacy representatives from different organisations were interviewed about their practical experience of distributing medicines and their willingness to outsource fulfilment activities. Additionally, one legal expert specialising in corporate law was interviewed to explore alternative collaboration and organisational structures, and to evaluate the legal feasibility of new arrangements. Finally, an individual from a medical fulfilment/solutions company was interviewed to gain insight into the practical design of a recently implemented logistics construction and its operational implications.

The interpretations from the interviews were shared with the respondents for member checking, and the findings were triangulated with desk research and legal documentation to reinforce validity.

### C. Scenario Development

Based on market and legislative analyses and stakeholder insights, eight fulfilment scenarios (S1–S8) have been developed. These range from distribution-only configurations to more integrated collaboration and ownership models. The scenarios are deliberately broad in scope to avoid excluding innovative configurations prematurely and to systematically analyse where the legislative and institutional framework offers opportunities or imposes restrictions.

Thus, scenario development serves as a bridge between conceptual analysis and practical exploration, translating abstract legal and market conditions into concrete organisational configurations.

### D. Feasibility assessment

The developed scenarios were then systematically assessed against a two-part feasibility framework:

- Hard legal requirements (R1–R4): these were derived directly from the legal and legislative analysis. Failure to meet these requirements renders a scenario legally invalid;
- The design criteria (DC1–DC7) were derived from market potential and implementation logic. Failure to meet these criteria does not necessarily render a scenario illegal, but

it reduces the likelihood of successful implementation and scaling up.

The assessment is presented in a matrix with the following symbols: ✓ (compliant), × (non-compliant) and ? (interpretative uncertainty). (interpretative uncertainty), which makes legal certainty and institutional ambiguity visible.

#### E. Embedded case study and implication analysis

As an in-depth step within the scenario phase, a case study was conducted at a non-pharmaceutical fulfilment company. The aim was to assess how well the most promising scenarios fit within concrete strategic and operational boundary conditions set by the company.

This was followed by an analysis of the implications for each actor, in which the same legal and organisational constraints were reinterpreted for regulators/government, pharmacies, the fulfilment party and science/policy. This makes the governance, market and supervisory consequences explicit, revealing how the participation of a non-pharmaceutical fulfilment party could shift the institutional balance of power.

### III. ANALYTICAL FRAMEWORK

#### A. Legislative Foundation

The distribution of medicines in the Netherlands is subject to a strict, hierarchical legal framework. Unlike regular e-commerce logistics, where ownership, storage and distribution can be organised relatively freely, the pharmaceutical supply chain is explicitly regulated in terms of patient safety, product integrity and traceability.

The Medicines Act is central to this, stipulating that UR (prescription-only) and UA (pharmacy only) medicines may only be dispensed to patients by a licensed pharmacist, or under their direct responsibility (Art. 61.1, Gnw). Therefore, the legal responsibility for the supply of medicines lies explicitly with the pharmacist. Importantly, this license is not only activity-based but also location- and person-specific: a pharmacy license is tied to a registered physical establishment and to a designated responsible pharmacist (Art. 61.5, Gnw). This principle forms the core of R1 within the feasibility framework.

Furthermore, licensing requirements apply to organisations that store (>72 hours) or distribute medicines. Any organisation that physically manages medicines must have a Wholesale Distribution Authorisation (WDA) or a relevant trading license (Art. 18, Gnw). These authorisations are likewise location-bound, meaning that storage and distribution activities are only permitted at explicitly licensed sites under regulatory supervision. Storage or distribution without these licenses is not permitted. This constitutes R2 in the framework.

An additional structural restriction concerns the physical storage location. Unlabeled medicines (i.e. not yet packaged for specific patients) may only be stored in approved pharmacy or warehouse locations that are subject to GDP supervision (Art. 18.1, Gnw, in conjunction with Art. 61.1, Gnw). Storage outside these approved locations is not permitted. This constitutes R3.

In addition to the Medicines Act, the European and national guidelines on GDP also apply. These guidelines contain detailed requirements for:

- Storage conditions, including temperature control and monitoring;
- Transport (validated processes and secure chains);
- Documentation and traceability;
- Quality management systems;
- Staff training;
- Verification procedures, such as FMD/NMVS checks, are in place to prevent counterfeiting.

GDP means that the entire logistics chain, from storage to delivery, must be demonstrably controlled, documented and validated. This forms the basis for R4.

In the table below an overview is given to clarify the legal boundaries between pharmaceutical fulfilment activities.

TABLE III  
LEGAL PERMISSIONS PER ACTOR AND MEDICINE CATEGORY

Activity / Actor	Pharmacy	Drug-store	Wholesaler	Contract wholesaler	Carrier (transport only)
<b>UR medicines</b>					
Sell / dispense to patients	✓	×	×	×	×
Pharmaceutical release	✓	×	×	×	×
Patient-specific labeling	✓	×	×	×	×
Hold unlabeled stock	✓	×	✓	✓	×
Storage > 72 hours	✓	×	✓	✓	×
<b>UA medicines</b>					
Sell / dispense to patients	✓	×	×	×	×
Patient-specific labeling	✓	×	×	×	×
Hold unlabeled stock	✓	×	✓	✓	×
<b>UAD medicines</b>					
Sell / dispense to patients	✓	✓	×	×	×
<b>AV medicines</b>					
Sell / dispense to patients	✓	✓	✓	✓	×
<b>Regulatory status</b>					
WDA required	×	×	✓	✓	×
RP required	✓	×	✓	✓	×
GDP Guidelines	✓	✓	✓	✓	✓

When working with medicines, supervision is carried out by the Inspectie Gezondheidszorg en Jeugd (IGJ), which monitors compliance with GDP, licenses, and specific implementation rules, such as the so-called 72-hour rule for logistical transshipment. This enforcement makes the legislation not only formal but also operationally enforceable.

Although it appears to be a highly regulated system, the analysis also shows that the legislative framework was not designed with the concept of independent B2C handling by non-pharmaceutical actors in mind. Instead, it is based on clearly defined roles between pharmacist, wholesaler, and

carrier, each of which has its own legal obligations. This role-based structure significantly limits the extent to which fulfillment activities can be outsourced without additional licensing requirements. Not all elements offer the same degree of interpretative certainty, a distinction that becomes particularly relevant when assessing innovative fulfillment configurations. “TABLE.IV” provides a structured overview to distinguish between non-negotiable legal obligations and interpretative gray areas.

TABLE IV  
LEGISLATIVE CERTAINTY MAP BASED ON LEGAL AND REGULATORY ANALYSIS

Legislative domain	Hard must-comply (legal certainty)	Grey areas (interpretative uncertainty)
Dispensing authority	‘Ter hand stellen’ is exclusively reserved for a licensed pharmacy; legal responsibility remains with the pharmacist.	The operational boundary between logistics handling and dispensing-related activities is not explicitly defined in legislation.
Licensing structure	Licenses are legally bound to a specific legal entity and recognised physical location (pharmacy or wholesale).	The extent to which hybrid structures (e.g. joint ventures, cooperatives or embedded pharmacy models) satisfy the location-based licensing logic remains interpretative.
Storage duration	Storage of medicines for more than 72 hours requires a wholesale or pharmacy license.	The interpretation of structural transit storage within fulfillment-style hub operations may vary depending on supervisory practice.
Unlabeled medicines	Unlabeled medicines may only be stored within licensed pharmacy (B2C) or wholesale (B2B) environments.	The permissibility of centralised back-office processing for multiple pharmacies without triggering wholesale classification is not explicitly regulated.
Multi-pharmacy centralisation	Legal responsibility for dispensing remains with the individual pharmacy.	Whether central fulfillment models resemble in fact wholesale or a central pharmacy structure remains sensitive to legislative interpretation.
GDP compliance	Temperature control, traceability and quality management systems are mandatory for all storage and transport activities involving medicines.	The scope and depth of GDP expectations for non-pharmaceutical actors operating within hybrid fulfillment models are not exhaustively specified.
Data governance (GDPR)	Delivery data linking a patient to a specific medicine qualifies as health data under GDPR.	The allocation of controller and processor roles in integrated fulfillment models can be complex and interpretation-dependent.

In summary, the answer to SQ2 is that Dutch legislation and regulations require pharmacist supervision during dispensing, as well as licensing, traceability and GDP requirements. These conditions constitute the hard requirements (R1–R4) in the framework (“TABLE.V”). None of the scenarios may violate these hard preconditions.

### B. Market structure and potential

The Dutch pharmaceutical retail market is highly concentrated and integrated. A small number of chains and whole-

salers dominate the market, and many pharmacies are part of larger partnerships that have their own logistics infrastructure and IT systems [10] [11]. Consequently, pharmacies already benefit from economies of scale and existing distribution networks, limiting the need for external outsourcing. At the same time, pharmacies increasingly face operational pressure due to staff shortages and rising workloads, which may strengthen interest in outsourcing logistics-intensive activities such as storage, picking and packaging [12] [13] [14].

Therefore, outsourcing fulfillment to a non-pharmaceutical logistics provider is not an obvious market development. Pharmacists are strongly committed to professional autonomy, quality assurance and ultimate responsibility for delivering medicines. Market analysis and interviews show that a willingness to cooperate mainly exists when:

- Demonstrable efficiency gains are achieved;
- Operational capacity is increased without compromising quality;
- The pharmacist retains ultimate legal and professional responsibility.

Opportunities lie primarily in clearly defined and predictable segments, such as the provision of repeat prescriptions via e-prescriptions or the management of other large-scale, repetitive processes. These segments reduce operational uncertainty and enable economies of scale.

In short, the answer to SQ3 is that market potential is both selective and conditional. Collaboration is feasible within predictable, scalable segments, provided efficiency gains can be demonstrated and the pharmacist retains unequivocal final responsibility for all pharmaceutical matters.

This market analysis formed the basis for the design criteria (DC1–DC7) in the feasibility framework. While R1–R4 define the legal lower limit, DC1–DC7 operationalise the commercial and organisational viability of a scenario.

### C. Feasibility Framework

The feasibility framework in the table below was drawn up based on legislation and market analysis. The hard requirements (R1–R4) are legally binding under the Medicines Act, GDP, and other guidelines and must be enforced. The design criteria (DC1–DC7) reflect market and organisational factors and increase the likelihood of success, but are not legal requirements. This framework can be used to evaluate different scenarios.

TABLE V  
SCENARIO FEASIBILITY FRAMEWORK

Legal and regulatory requirements	
R1	UR/UA medicines are dispensed exclusively by a licensed pharmacist.
R2	All necessary permits are in place.
R3	Unlabeled medication is stored only in legally recognised locations.
R4	Full GDP compliance is ensured for all storage and transport activities.
Market design criteria	
DC1	All categories of medicine can be included.
DC2	The scenario is based on a clearly defined and commercially viable pharmacy segment and does not depend on broad market-wide acceptance.
DC3	Focus on predictable, high-volume flows.
DC4	Clear legal and operational separation between pharmacy and fulfilment entity is ensured.
DC5	The scenario delivers clear operational efficiency benefits.
DC6	Medicines are delivered quickly and reliably.
DC7	Patients can communicate with and access the service throughout the process.

## IV. RESULTS

### A. Scenarios

The study constructed eight scenarios, ranging from minimal logistical support to integrated business models. Together, these eight scenarios provide a structured answer to sub-question 4, which asked which B2C fulfilment scenarios can be developed for non-pharmaceutical logistics providers and how feasible they are in legal, logistical and organisational terms. The scenarios cover both B2B and B2C options. The aim is to outline potential models for entering the healthcare supply chain without ruling out any possibilities from the very beginning. To enhance readability, the term 'the company' will be used throughout this chapter to refer to a non-pharmaceutical fulfilment company. The following scenarios were constructed:

- **S1: Short-term storage and/or distribution only:** The company transports medicines between parties (e.g. wholesalers, pharmacies and patients), but does not store anything long-term or pick orders. The pharmacist remains fully responsible for release. It is a pure transport and provision service;
- **S2: OTC medicines only:** The company exclusively handles the fulfilment of over-the-counter (OTC) medicines on behalf of pharmacies and drugstores. By focusing solely on OTC medicines, it avoids the strictest legal requirements relating to the dispensing of prescription medicines. The company therefore has no additional professional responsibilities beyond standard supervision. This operational arrangement can be integrated in the same way as any other logistics partnership, with no need for a different governance or compliance structure;
- **S3: Pharmacy distribution point:** In this scenario, the company acts as a central distribution point for one or more pharmacies. Patient-specific processing, including pharmaceutical control, release and labeling, takes place

entirely within the pharmacy and is the responsibility of the licensed pharmacist. Then, the personalised medicine is physically transferred to the fulfilment company. This location then acts as a dispensing point recognised by the regulator, operating under the pharmacy's license. This adds an extra link to the distribution chain: after pharmaceutical processing in the pharmacy, the fulfilment company takes over for logistical transshipment and shipment to the patient;

- **S4: Becoming a wholesaler (B2B):** The company obtains a WDA wholesale license and purchases medicines from manufacturers. It becomes the legal owner for distribution to licensees (pharmacies, hospitals). The company continues to operate strictly at the B2B level (does not supply directly to patients). This means a dual role: on the one hand, performing fulfilment for third parties and, on the other hand, carrying out its own wholesale activities;
- **S5: Becoming a central filling company (B2B):** In this scenario, the company acts as a central preparation point in a B2B construction for one or more pharmacies. Pharmacies send repeat prescriptions and patient data to the company, where medication is picked in batches, packaged, and labeled specifically for each patient. The prepared orders are then returned to the pharmacy, which remains responsible for the final pharmaceutical check and formal dispensing to the patient. This working method requires an appropriate licensing framework, as the company performs activities that go beyond mere storage or transport. Depending on the exact setup, this means that the company must have a WDA and/or operate under a pharmacy license. In addition, the facilities must comply with GDP guidelines. The company thus has a dual role: logistics service provider and performer of preparatory pharmaceutical activities within a B2B relationship with the pharmacy. Although the pharmacist remains legally responsible, part of the operational control shifts to the company, which requires clear governance agreements;
- **S6: In-house pharmacy:** An independent pharmacy license has been established at the fulfilment centre, where there is a pharmacist on site. The pharmacy rents storage space from the company and remains the legal owner of the medicines. This in-house pharmacy is entirely responsible for the pharmaceutical assessment, release, and final responsibility. The fulfilment company then takes over as many logistical and operational fulfilment tasks as possible, such as storage, order picking, packaging and shipping, with the exception of pharmaceutical release. In this configuration, the pharmacy operates as an 'in-house' entity within the logistics centre, while the fulfilment company manages the executive logistics processes. This structure requires close cooperation, clear delineation of responsibilities and full auditability. However, it also offers maximum economies of scale and operational efficiency, as the pharmaceutical and logistics functions are physically integrated;

- **S7: Joint Venture:** The company and a pharmacy establish a new limited liability company (joint venture) with its own pharmacy license, registered at the fulfilment center’s location. The JV becomes the legal owner of the medicines and is responsible for purchasing them. The cooperative pharmacy within the joint venture manages the license and assumes pharmaceutical responsibility, with both parties participating in the management jointly. Profits and risks are shared contractually. This structure enables extensive integration without the company operating independently as a pharmacist. At the same time, it creates close organisational and financial integration of logistics and pharmaceutical functions, requiring explicit governance agreements, clear delineation of responsibilities and strict supervisory structures;
- **S8: Cooperative:** The logistics company sets up a cooperative together with pharmacists, with the necessary permits. Pharmacists join as members. The cooperative offers (GDP-compliant) fulfilment to these members, who retain their own permits. This enables up-scaling without one party having all the responsibility. It requires clear agreements and governance within the cooperative.

### B. Comparison of scenarios against the feasibility framework

“TABLE.VI” provides a structured overview of how each scenario relates to the feasibility framework introduced in “TABLE.V”. The table uses check marks, crosses and question marks to indicate whether a scenario complies with, does not comply with, or involves uncertainty regarding, a specific requirement or design criterion. It is important to distinguish between the nature of the design specifications. Requirements R1-R4 reflect mandatory legal and regulatory requirements. The remaining design criteria (DC1-DC7) represent structural and organisational specifications that affect practical feasibility and scalability.

TABLE VI  
COMPLIANCE WITH THE FEASIBILITY FRAMEWORK

Spec.	S1	S2	S3	S4	S5	S6	S7	S8
R1	✓	✓	✓	✓	✓	✓	✓	✓
R2	✓	✓	?	?	?	?	?	?
R3	✓	✓	✓	✓	✓	✓	✓	✓
R4	✓	n/a	✓	✓	✓	✓	✓	✓
DC1	✓	×	✓	✓	✓	✓	✓	✓
DC2	✓	✓	✓	×	×	✓	?	×
DC3	✓	×	✓	✓	✓	✓	✓	✓
DC4	✓	✓	?	?	?	?	?	?
DC5	✓	✓	✓	✓	✓	✓	✓	✓
DC6	✓	✓	✓	✓	✓	✓	✓	✓
DC7	✓	✓	✓	✓	✓	✓	✓	✓

As shown in “TABLE.VI”, most uncertainties are concentrated under R2 and DC4. This reflects legislative uncertainty rather than structural non-compliance. Existing legislation is primarily centred on traditional models involving pharmacies and does not explicitly address hybrid implementation structures incorporating non-pharmaceutical providers. Interviews

reveal that pharmacists are uncertain about how such organisational forms fit within the current legal framework.

Importantly, none of the scenarios are explicitly excluded on the basis of legislative requirements (R1–R4). Where question marks are present, these indicate interpretative uncertainty rather than direct incompatibility. Ultimately, therefore, the feasibility would depend on clarification by the supervisory authorities.

From a market perspective, however, the differences are more pronounced. Scenarios S2, S4, S5 and S8 perform poorly in terms of various market-oriented design criteria (DC1–DC7), which limits their structural viability. While these models are legally feasible, they fail to reduce workload (S2 and S4), they encounter commercial challenges, including limited profitability (S2), intense competition from existing wholesalers and chains (S5 and S6), and reliance on scarce independent pharmacies (S8).

“Fig.2” compares the eight scenarios by visualising their structural feasibility within the framework. Both full compliance and uncertainty are treated as potentially feasible and receive one point, whereas non-compliance receives zero points. Legislative uncertainty therefore reflects interpretative ambiguity rather than direct incompatibility. For transparency, the number of uncertainties per scenario is shown separately, distinguishing between overall structural feasibility and the degree of legislative ambiguity.

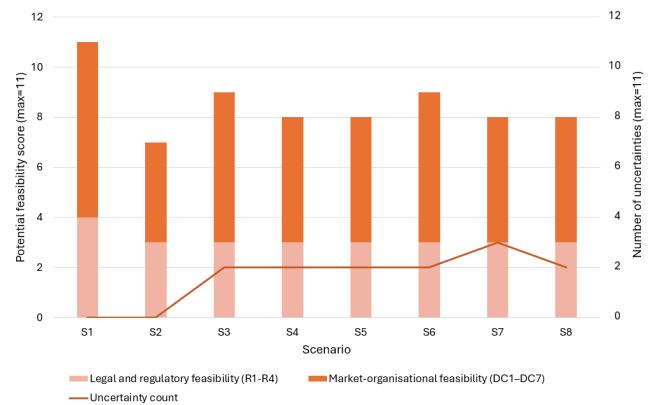


Fig. 2. Comparative structural feasibility and uncertainty across scenarios

It is important to note that this visualisation is based solely on compliance with the legal, regulatory and market organisational specifications. It does not assess other strategic dimensions, such as the degree of logistics outsourcing, operational integration or organisational complexity. Therefore, the figure should be interpreted strictly as a comparison of feasibility within the applied feasibility framework and not as a comprehensive ranking of strategic attractiveness.

In addition, the practical relevance depends on the value created for pharmacies. Although some scenarios (e.g. S1–S2) only offer a modest reduction in internal workload, they can still generate value at the supply chain level. Conversely,

scenarios such as S6–S8 offer greater potential for reducing labour and space constraints, but are associated with higher legal and organisational uncertainty. This highlights the trade-off between value creation and feasibility: the most beneficial configurations require the most careful governance design.

### C. Legal ambiguities that cause uncertainty

The concentration of question marks under R2 and DC4 highlights a fundamental ambiguity concerning the distinction between dispensing and logistics. This interpretative gap affects scalability, as responsibility allocation between the pharmacy and fulfilment centre remains unclear. The resulting legal uncertainties stem from this structural ambiguities in the current legislative framework:

- **Dispensing versus logistics:** Although dispensing is legally the responsibility of licensed pharmacies, legislation does not clearly define where dispensing ends and logistical support begins. This creates uncertainty around activities such as picking, packaging, transport preparation, and last-mile delivery. In practice, the IGJ prohibits the storage of unlabeled medicines outside authorised pharmacy or wholesaler environments, thereby limiting warehouse configurations. Although GDP permits the outsourcing of logistics, it does not specify which tasks fall outside the scope of dispensing responsibilities. Interviews confirm that pharmacists consider patient-specific preparation and final inspection to be integral to dispensing. Even when operational steps can be delegated, responsibility for approval and control remains with the pharmacist. Consequently, advanced fulfilment models operate in a legislative grey area, which explains the cautious adoption observed in practice.
- **Centralisation for multiple pharmacies:** A second bottleneck concerns scalability: fulfilling orders for multiple pharmacies in a single centre raises questions about the distribution of pharmaceutical responsibility, the separation of medicine streams, supervision, and whether the fulfilment centre will resemble a wholesaler in function. The lack of explicit rules on this makes investment decisions regarding large-scale infrastructure riskier.

### D. Case study: compliance with companies' boundaries

To assess which of the previously identified scenarios can be translated into an operational model, each one is evaluated against the boundary conditions set by fulfilment company. "TABLE.VII" shows the boundary conditions and their respective compliance. As "TABLE.VI" showed that S1, S2, S4, S5 and S8 did not comply with various market-oriented restrictions, they were excluded from the evaluation, since the scenario must have market potential. For scenario S7, in which a new legal entity is established, the preconditions are assessed exclusively from the company's perspective, rather than that of the newly established entity. This distinction has been made deliberately, since owning or participating in a separate entity constitutes an additional precondition

(BC5). All preconditions are therefore evaluated based on the company's role, responsibilities, and strategic position.

TABLE VII  
BOUNDARY CHECKLIST FOR SCENARIO SELECTION

Boundary condition	S1	S3	S6	S7
BC1. Enables coverage of the full logistical process	×	×	✓	✓
BC2. No ownership of medicinal products	✓	✓	✓	✓
BC3. No wholesale license required	✓	✓	✓	✓
BC4. No pharmacy license required	✓	✓	✓	✓
BC5. No ownership or participation in new legal entities	✓	✓	✓	×
BC6. Enables home delivery of prescription-only medicines (UR)	×	✓	✓	✓
BC7. Scalable in the longer term (desirable)	✓	✓	×	×

S6 (the in-house pharmacy) is the best fit for these conditions as it provides extensive logistical support while retaining pharmaceutical responsibility and ownership. However, the case study shows that 'best fit on paper' does not necessarily equate to 'easy to implement'. S6 requires: strong contractual safeguards and quality coordination; very precise process interface definitions; and cultural/procedural alignment between the pharmaceutical and fulfilment organisations. The main bottlenecks are role separation (which is also a sensitive issue in S6), limited scalability towards a multi-pharmacy model and internal strategic inflexibility if deeper governance integration (such as S7/S8) is ruled out in advance.

### E. Systemic and actor-specific implications

The system and actor implications are based on the analytical framework in the table below. The framework integrates three elements: (1) the structural characteristics of the Dutch extramural supply chain; (2) the applicable legal and regulatory framework; and (3) the constraint-based feasibility assessment. Together, these elements provide a basis for evaluating the potential consequences of participation in terms of governance, responsibility allocation, and market structure. It serves as a bridging tool between the scenario analysis and the subsequent evaluation.

TABLE VIII  
ANALYTICAL FRAMEWORK FOR SYSTEMIC AND ACTOR-SPECIFIC  
IMPLICATION ANALYSIS

Analytical layer	Core principle	Relevance for implication analysis
<b>Structural starting point</b>		
Structural system characteristics	Pharmacy-centered extramural supply chain, pharmacist responsible for dispensing, wholesalers supply licensed actors only	Defines the basic governance structure and limits of third-party participation
Systemic challenges	GDP continuity, role responsibilities, FMD traceability, data protection, shortages	Defines operational and compliance risks when introducing fulfilment participation
<b>Legal-regulatory boundaries</b>		
Legal responsibility	“1 tent, 1 vent” (pharmaceutical responsibility tied to licensed pharmacist and location)	Clarifies that accountability cannot be outsourced
Regulatory boundaries	Dispensing versus logistics distinction, wholesale qualification risks	Central source of ambiguity affecting role division
<b>Design specification-based feasibility</b>		
Legal requirements (R1–R4)	Hard legal feasibility conditions	Define legal inclusion or exclusion of participation models
Market and organisational design criteria (DC1–DC7)	Scalability, segment focus, flow separation, efficiency	Determine structural viability and systemic impact
Identified uncertainty areas	R2 (permits) and DC4 (role separation)	Analytical lens for assessing governance and actor-specific risk

The implications at system level is that the participation of non-pharmaceutical fulfilment providers adds a new logistics actor to the pharmaceutical chain and reshapes the distribution of responsibilities within a pharmacy-centric framework. This results in hybrid configurations where legal responsibility and operational control are institutionally separated. The main systemic implication is therefore increased governance complexity due to uncertainty surrounding the interpretation of role boundaries, licensing requirements and scalability.

At actor level, the implications vary:

- **Regulators and government actors** face the challenge of supervising hybrid models. This increases the need for clearer licensing, wholesale qualification, multi-pharmacy fulfilment and FMD control guidelines;
- **Pharmacies** remain fully legally responsible, despite outsourcing operational tasks. Participation can increase efficiency, but it also increases the requirements for contracts, quality management and data management.
- **Fulfilment service providers** face strategic opportunities and legislative risks. Economies of scale can only be achieved if sufficient volume and legislative clarity are present. The main risks relate to unintended reclassification as a wholesaler or pharmacy, and to governance failure in complex, multi-client environment;

- **Science and policy** development face a clear knowledge gap. There has been insufficient research into hybrid implementation models for multiple pharmacies, and these require further clarification of existing documentation, empirical validation and structured pilot evaluation.

This analysis directly addresses SQ5, clarifying the administrative and institutional conditions necessary for embedding such participation in the existing system in a responsible and structural manner.

## V. DISCUSSION

### A. Interpretation of key findings

The results show that the Dutch pharmaceutical distribution system is essentially pharmacy-oriented, with the licensed pharmacist and the registered pharmacy remaining legally responsible for dispensing medicines and ensuring patient safety. Logistical activities can be outsourced to external parties within this structure, but the central regulatory responsibility for dispensing medicines cannot be transferred. This study contributes to the academic debate on pharmaceutical logistics by demonstrating that the feasibility of hybrid fulfilment models depends less on the involvement of non-pharmaceutical parties than on how responsibilities, oversight and operational roles are institutionally separated and regulated.

Consequently, the focus of the discussion shifts from whether non-pharmaceutical providers can participate to how hybrid governance arrangements should be designed to maintain verifiable accountability structures. The results show that feasibility depends less on explicit legal prohibitions than on the interaction between legislative interpretation, governance design, and institutional oversight mechanisms.

The concentration of question marks under R2 and DC4 highlights this structural ambiguity. Although the legislative framework does not explicitly prohibit hybrid implementation configurations, it has historically been developed around traditional one-to-one pharmacy models. Consequently, it is unclear how licensing, dispensing responsibilities, and logistical activities should function in centralised or multi-client B2C environments. This research therefore reveals an important institutional gap: the legislative system lacks a clearly defined governance model for hybrid pharmaceutical implementation structures.

Essentially, the restriction on outsourcing is not an explicit legal prohibition; rather, it is the result of the interaction between licensing structures, the legal definition of dispensing medicines, supervisory practices (particularly with regard to the storage of unlabeled medicines) and the economic logic of scalable implementation. As models evolve towards the centralisation and integration of multiple pharmacies, they increasingly challenge the implicit governance assumptions embedded in the current legislative framework.

This institutional incompleteness can explain the legislative uncertainty observed in the scenario framework, as well as the cautious attitude of pharmacists and regulators. The findings

therefore suggest that feasibility should be considered in layers: it is legally ambiguous rather than explicitly prohibited, organisationally dependent on strict separation of responsibilities and transparent documentation, and strategically limited by the tension between safety-oriented pharmaceutical legislation and efficiency-oriented logistics systems.

### B. Limitations

This exploratory, scenario-based study is based on assumptions regarding legal interpretation, operational design and stakeholder willingness to outsource. Due to the existing ambiguities in the legislation, the ultimate feasibility of certain scenarios hinges on future clarification by the relevant authorities, which creates an external dependency beyond the researcher's control.

Access to empirical data was also limited. The number of interviews was limited, largely involving pharmacists operating under similar legislative conditions. Planned interviews with regulators and healthcare decision-makers were not possible, as these individuals declined to participate. While this reluctance points to institutional sensitivity and perceived risks in itself, it also limits the ability to definitively resolve interpretative ambiguities, which often depend on the interpretation of regulators rather than the expectations of the private sector.

Finally, the design of the case study limits generalisability. The identified 'best fit' scenario (S6) reflects the strategic boundaries and risk profile of the company in question and should not be interpreted as being universally optimal for all fulfilment providers.

### C. Recommendations for future research

Further development of hybrid implementation models requires both empirical validation and institutional clarification. Firstly, controlled pilot projects should be set up in predictable, high-volume segments, with predefined performance indicators such as GDP compliance, incident frequency, and traceability/FMD signals. A phased implementation approach allows for gradual scaling up while compliance risks are monitored.

Secondly, contractual frameworks and quality management systems should explicitly codify the separation of roles, audit rights, data management responsibilities and procedures for recalls and exceptional flows. Clear documentation and verifiable accountability mechanisms are essential to reduce ambiguity about the boundaries between distribution and logistics.

Thirdly, collaboration with regulatory authorities is crucial in developing implementation-oriented guidelines and pilot projects that address interpretative uncertainty, particularly with regard to licensing (R2) and legal–operational separation (DC4). Comparative institutional research could further clarify the influence of different governance models, such as cooperatives or joint ventures, and market structures on feasibility.

## VI. CONCLUSION

This study answers the main question by showing that participation is conceivable in principle, but is structurally limited by the allocation of responsibility and licensing logic.

The responsibility for pharmaceutical authority and licensing remains firmly anchored with pharmacies and specific legal entities and locations. Consequently, logistical implementation can be delegated, but responsibility for dispensing medicines cannot be transferred permanently.

Scenario analysis shows that none of the eight scenarios are explicitly excluded based on mandatory legal requirements (R1–R4). However, feasibility varies considerably, mainly due to uncertainty surrounding the interpretation of licensing requirements (R2) and the separation of pharmacy and operational functions (DC4), particularly in cases of centralisation involving multiple pharmacies. While these ambiguities do not constitute formal prohibitions, they create compliance and investment risks that limit scalability.

The framework exerts its influence through three reinforcing mechanisms. Firstly, the licensing logic places responsibility for compliance with the law on pharmacies, thereby limiting the extent to which they can outsource work without incurring additional legal obligations. Secondly, supervisory practices and professional standards determine the practical feasibility of activities beyond what is set out in the law by defining how grey areas, such as the boundary between dispensing medicines and logistics, are interpreted in practice. Thirdly, the existing market structure, characterised by integrated chains and concentrated market players, limits realistic entry opportunities to partial, segment-specific configurations.

Consequently, full end-to-end outsourcing of dispensing is not currently feasible without further legislative clarification. Realistic participation lies in carefully designed hybrid models, where pharmaceutical responsibility remains with the pharmacy and logistical tasks are delegated under strict supervision, with contractual safeguards and verifiable compliance mechanisms in place. Therefore, feasibility is not primarily an operational issue, but rather a matter of aligning legislation, governance design and strategic positioning within a safety-focused institutional system.

The conclusion can be summarised in the following five points:

- **Pharmacy-centered foundation:** The Dutch system is structurally pharmacy-oriented: licensing, authority and legal responsibility are role- and location-based and anchored to recognised pharmaceutical entities;
- **Possibilities: conditional and pharmacy-led:** Participation is not explicitly prohibited, but is only feasible in carefully designed, pharmacy-led configurations with strict role separation, GDP compliance and demonstrable control mechanisms;
- **Institutional limitations: licensing logic and interpretative uncertainty:** Limitations arise when fulfilment activities approach dispensing responsibilities or trigger additional licensing requirements. Interpretative ambiguities (e.g. R2 & DC4) increase compliance and investment risk;
- **Market limitations:** Due to chain integration, existing logistics infrastructures and pharmacists' retained responsibility, realistic opportunities are limited to selective,

predictable high-volume segments rather than scalable end-to-end outsourcing models:

- **Not a binary outcome:** Feasibility cannot be reduced to “possible” or “impossible”; it is conditional, governance-dependent, and limited to specific segments.

## VII. ACKNOWLEDGMENT

The author would like to thank the supervisors for their valuable insights, constructive feedback, and critical perspective that contributed to the final results.

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B

HREC

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## Plan Overview

*A Data Management Plan created using DMPonline*

**Title:** Assessing the Feasibility of offering GDP-Compliant Medicine E-Commerce Fulfilment Service

**Creator:** Romée Hoogeveen

**Project Administrator:** Jaap Vleugel

**Affiliation:** Delft University of Technology

**Template:** TU Delft Data Management Plan template (2025)

### **Project abstract:**

The objective of this thesis is twofold: firstly, to develop and evaluate scenarios for B2C fulfilment of medicines by non-pharmaceutical parties from both an academic and practical perspective; and secondly, to investigate whether there is a market to implement these scenarios. The present study

focuses specifically on:

- The identification of areas of ambiguity within legislation and regulations.
- To examine the pharmacy market and the willingness of pharmacies to outsource.
- The development of feasible fulfilment scenarios for external parties.
- The formulation of recommendations regarding propositions, risks, and preconditions.

**ID:** 191450

**Start date:** 01-10-2025

**End date:** 31-03-2026

**Last modified:** 25-11-2025

# Assessing the Feasibility of offering GDP-Compliant Medicine E-Commerce Fulfilment Service

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## 0. Administrative questions

**1. Provide the name of the data management support staff consulted during the preparation of this plan and the date of consultation. Please also mention if you consulted any other support staff.**

Lora Armstrong, Data Steward at the Faculty of Civil Engineering and Geosciences, has reviewed this DMP on 25-11-2025.

**2. Is TU Delft the lead institution for this project?**

- Yes, leading the collaboration – please provide details of the type of collaboration and the involved parties below

This research is conducted for my master thesis at the TU Delft in collaboration with PostNL Fulfilment.

## I. Data/code description and collection or re-use

**3. Provide a general description of the types of data/code you will be working with, including any re-used data/code.**

Type of data/code	File format(s)	How will data/code be collected/generated? <i>For re-used data/code: what are the sources and terms of use?</i>	Purpose of processing	Storage location	Who will have access to the data/code?
Audio/video recordings of interviews with stakeholders	.mp3/.mp4	If in person: audio recording with an iPhone. If online: audio recoding by microsoft teams after transcription, audio will be deleted.	identifying gray areas, proposition possibilities, market willingness	temporaly saved on my mobile phone + TU Delft Onedrive	Romée Hoogeveen

Personally identifiable information (PII) of interview participants (names, emails)	.docx, .pdf	Collect from participants sign-ups and interview scheduling	For administrative purposes: obtaining consent and communicating with participants.	TUDelft Onedrive	TUD project team TUD supervisors: Jaap Vleugel, Jan Anne Annema, Joyce Vleugel. Company supervisor: Quirin de Flines
Personally identifiable research data (PIRD) professional background and job title	.pdf	Data obtained from semi-structured interviews	To understand the different viewpoints.	Tu Delft Onedrive	TUD project team
Transcripts from interviews	.docx .txt	For online: directly transcribed in teams. For offline: recorded by phone, transcribed with MS Office.	Identifying gray areas, proposition possibilities, market willingness	Tu Delft Onedrive, will be anonymised and then deleted.	TUD project team and per transcript the corresponding interviewee
Informed consent forms	PDF	Informed consent forms signed digitally.	To obtain and document informed consent.	Onedrive, will be deleted after research. For longer storage: stored at Project Data Storage.	Romée Hoogeveen
Anonymized transcripts from interviews	.pdf	Anonymize interviews after transcription	Identifying gray areas, proposition possibilities, market willingness	Onedrive	TUD project team

## II. Storage and backup during the research process

### 4. How much data/code storage will you require during the project lifetime?

- < 250 GB

**5. Where will the data/code be stored and backed-up during the project lifetime? (Select all that apply.)**

- Another storage system – please explain below, including provided security measures
- TU Delft OneDrive

External recording device (iPhone): Used as a temporary storage location for recorded in-person interviews. Interviews will be deleted from device as soon as they are moved to OneDrive

### **III. Data/code documentation**

**6. What documentation will accompany data/code? (Select all that apply.)**

- Data – Methodology of data collection
- Other – please explain below
- Data – Data dictionary explaining the variables used

The dataset will not be shared in a data repository, but the methodology of data collection will be explained in the MSc thesis, which is made available in the TU Delft Education repository

### **IV. Legal and ethical requirements, code of conducts**

**7. Does your research involve human subjects or third-party datasets collected from human participants?**

***If you are working with a human subject(s), you will need to obtain the HREC approval for your research project.***

- Yes – please provide details in the additional information box below

I intend to apply for ethical approval from the Human Research Ethics Committee, but have not yet done so.

**8. Will you work with personal data? (This is information about an identified or identifiable natural person, either for research or project administration purposes.)**

- Yes

Interviewees will be reached by their e-mail and names. Because the interviews will be recorded, their voices will be recognizable in the recordings. However, all data relating to the identification of an individual will be deleted if possible.

**9. Will you work with any other types of confidential or classified data or code as listed below? (Select all that apply and provide additional details below.)**

***If you are not sure which option to select, ask your Faculty Data Steward for advice.***

- No, I will not work with any other types of confidential or classified data/code

**10. How will ownership of the data and intellectual property rights to the data be managed?**

***For projects involving commercially-sensitive research or research involving third parties, seek advice of your [Faculty Contract Manager](#) when answering this question.***

The intellectual property rights are framed by a graduation agreement between Delft University of Technology, myself and PostNL Fulfilment.

**11. Which personal data or data from human participants do you work with? (Select all that apply.)**

- Video materials
- Job title and/or employer
- Other types of personal data or other data from human participants – please provide details below
- Proof of consent (such as signed consent materials which contain name and signature)
- Audio recordings
- Telephone number, email addresses and/or other addresses as contact details for administrative purposes
- Names as contact details for administrative purposes

Company name

Opinions on the possibility of outsourcing fulfilment within the pharmaceutical supply chain.

**12. Please list the categories of data subjects and their geographical location.**

Interview participants are employees from pharmacies and PostNL Fulfilment in The Netherlands.

**13. Will you be receiving personal data from or transferring personal data to third parties (groups of individuals or organisations)?**

- No

**16. What are the legal grounds for personal data processing?**

- Informed consent

**17. Please describe the informed consent procedure you will follow below.**

The researcher will inform the potential participants about the goals and procedures of the research project. The researcher will also inform them about the personal data that are being processed and for what purpose. This information will be provided to the potential participants as follows: a digital copy of the information will be emailed to participants before the interview. All participants will be asked for their consent for taking part in the study and for data processing by signing a informed consent form before the start of the interview/experiment.

**18. Where will you store the physical/digital signed consent forms or other types of proof of consent (such as recording of verbal consent)?**

The proof of consent (digital copy of signed document) will be preserved on the TU Delft Onedrive. I will collect digital informed consent (securely stored), and store them on the TU Delft Onedrive, immediately data will be deleted, once transcribed.

**19. Does the processing of the personal data result in a high risk to the data subjects? (Select all that apply.)**

***If the processing of the personal data results in a high risk to the data subjects, it is required to perform a Data Protection Impact Assessment (DPIA). In order to determine if there is a high risk for the data subjects, please check if any of the options below that are applicable to the processing of the personal data in your research project.***

***If any category applies, please provide additional information in the box below. Likewise, if you collect other type of potentially sensitive data, or if you have any additional comments, include these in the box below.***

***If one or more options listed below apply, your project might need a DPIA. Please get in touch with the Privacy team ([privacy-tud@tudelft.nl](mailto:privacy-tud@tudelft.nl)) to get advice as to whether DPIA is necessary.***

- None of the above apply

**23. What will happen with the personal data used in the research after the end of the research project?**

- Anonymised or aggregated data will be shared with others

In the appendix of my master thesis.

**24. For how long will personal research data (including pseudonymised data) be stored?**

- Personal data will be deleted at the end of the research project

**25. How will your study participants be asked for their consent for data sharing?**

- In the informed consent form: participants are informed that their personal data will be anonymised and that the anonymised dataset is shared publicly

**V. Data sharing and long term preservation**

**27. Apart from personal data mentioned in question 23, will any other data be publicly shared?**

*Please provide a list of data/code you are going to share under 'Additional Information'.*

- Other – please explain below

information will only partially shared in the appendix of my thesis.

**29. How will you share research data/code, including those mentioned in question 23?**

*Select all that apply and provide additional details below.*

- I am a Bachelor's/Master's student at TU Delft and I will share the data/code in the body and/or appendices of my thesis/report in the TU Delft Repository

**30. How much of your data/code will be shared in a research data repository?**

- Not applicable - No data/code will be shared in a repository

**31. When will the data/code be shared?**

- As soon as corresponding results (papers, theses, reports) are published

**32. Under what licence(s) will the data/code be released?**

- Other - please explain below

No license.

Data are shared in my MSc thesis.

**VI. Data management responsibilities and resources**

**33. If you leave TU Delft (or are unavailable), who is going to be responsible for the data/code resulting from this project?**

My supervisor, Jaap Vleugel, from Civil Engineering and Geosciences, with email address J.M.Vleugel@tudelft.nl

**34. What resources (for example financial and time) will be dedicated to data management and ensuring that data will be FAIR (Findable, Accessible, Interoperable, Re-usable)?**

No additional budget is needed.

**35. Which faculty do you belong to?**

- Faculty of Civil Engineering and Geosciences (CEG)

C

Consent form

**Delft University of Technology**  
**HUMAN RESEARCH ETHICS**  
**INFORMED CONSENT TEMPLATES AND GUIDE**

You are being invited to participate in a research study titled “Exploring the Feasibility of B2C Prescription Medicine Fulfilment by Non-Pharmaceutical Logistics Providers.” This study is being conducted by Romée Hoogeveen as part of the MSc program at TU Delft, Transport, Infrastructure and Logistics, in collaboration with PostNL Fulfilment, under academic supervision from TU Delft. However, PostNL will not have access to the raw data or identifiable information you provide. Only anonymized and aggregated insights may be shared with them for analytical and reporting purposes, ensuring your confidentiality.

The purpose of this research study is to explore whether and under which legal, logistical and market conditions a non-pharmaceutical e-commerce fulfilment provider can play a role in the delivery of prescription medicines directly to patients (B2C) in the Netherlands. The interview will take approximately **30 minutes**. The data will be used for the completion of a Master’s thesis. We will be asking you questions related to your experiences with medicine distribution, your views on regulatory compliance, logistics partnerships, and your expectations or concerns regarding fulfilment outsourcing in the pharmaceutical sector.

As with any online activity the risk of a breach is always possible. To the best of our ability your answers in this study will remain confidential. We will minimize any risks by keeping your responses strictly confidential, not sharing any personal data in reports or publications, and securely store the data on the TU Delft OneDrive.

Your participation in this study is entirely voluntary and you can withdraw at any time. You are free to omit any questions. The interviews will be audio recorded and transcribed for analysis, the recordings will be deleted after transcription.

If you have any questions about this research you can contact Jaap Vleugel via [j.m.vleugel@tudelft.nl](mailto:j.m.vleugel@tudelft.nl) at the TU Delft.

By signing this form, you acknowledge that:

- You have read and understood all the information above.
- You agree with recording the interview
- You agree to participate voluntarily
- You understand that you can withdraw at any time, without providing a reason.

## Signatures

\_\_\_\_\_  
Name of participant [printed]

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date

I, as legal representative, have witnessed the accurate reading of the consent form with the potential participant and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

\_\_\_\_\_  
Name of witness [printed]

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date

I, as researcher, have accurately read out the information sheet to the potential participant and, to the best of my ability, ensured that the participant understands to what they are freely consenting.

Romée Hoogeveen

\_\_\_\_\_  
Researcher name [printed]

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date

Study contact details for further information:

Name: Romée Hoogeveen

Phone: +31 6 12 13 87 38

e-mail: r.a.c.hoogeveen@student.tudelft.nl

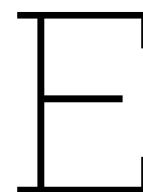
# D

## Interview participants

The table below lists the interviewees alongside the type of organization they represent, its characteristics, and their position within it.

**Table D.1:** Overview of interviewees

<b>Respondent</b>	<b>Type of Organization</b>	<b>Organizational Characteristics</b>	<b>Position of Respondent</b>
P1	Community / online pharmacy	Online-oriented pharmacy organisation, established in 2019, consisting of nine pharmacies, active in both B2C and B2B medicine supply, including international deliveries	Pharmaceutical manager; operationally responsible and in charge of all B2B clients
P2	Community pharmacy	Partnership of four community pharmacies; approximately 35 employees; broad medicine assortment and predominantly traditional, local patient population; responsible for hospital medicine supply	Pharmacy owner (co-owner of all pharmacies within the partnership)
P3	Community pharmacy	Pharmacist with extensive governance and sector-level experience; involved in national pharmacy chains and professional organizations	Pharmacy owner; board member of BENU; former board member of the KNMP
I1	Law firm	Law firm specialized in restructuring, insolvency, and corporate litigation	Legal counsel specialized in insolvency and corporate law
I2	Medical solutions company	Company supporting pharmaceutical organizations in a wide range of medical activities, specialized in medical fulfilment and direct marketing	Sales manager; responsible for commercial activities within the company



# Extended scenario elaboration

This appendix provides a detailed breakdown of the eight scenarios presented in Chapter 6. While the main text provides a structured overview and comparative analysis, this appendix offers a thorough examination of the internal configuration of each scenario.

The following aspects are systematically addressed for each scenario: legal structure and responsibility; logistical and operational structure; quality assurance; advantages and disadvantages; and key assumptions and uncertainties. This detailed breakdown enhances the transparency of the analytical process and supports the conformity assessment in Table 6.1.

The purpose of this appendix is to document the legal and organisational reasoning underlying the comparative scenario analysis in the main text.

## E.1. Elaboration on scenarios

### E.1.1. Exploratory scenarios within existing structures

#### SI: Short-term storage and/or distribution only

In this scenario, the company acts as a logistics service provider for pharmaceutical products such as medicines and medical devices. It does not provide pharmaceutical care itself or become the owner of the medicines. The company transports medicines between parties in the supply chain, such as from a wholesaler to a pharmacy or from a pharmacy to a patient. The responsible license holder must release ('dispense') medicines for distribution before they can be transferred to the company. Short-term transshipment is possible, such as cross-docking, but long-term storage and order picking are not included in the service. The company specializes in medical distribution, and the legal responsibility for the medicines remains entirely with the license holders.

**Legal structure and responsibilities** Provided that the company does not store on a long-term basis or purchase/sell medicines, it is not required to hold its own WDA or pharmacy license. The company operates under a contract with a license holder (e.g. a pharmacy or wholesaler), and the responsibility and GDP compliance requirements are set out in writing. The pharmacist remains responsible for dispensing, while the company is only responsible for the physical transfer. In other words: responsibility for product quality lies with the shipping license holder (manufacturer, wholesaler, or pharmacy), who ensures correct packaging and conditions prior to transfer. After transfer, the fulfilment company is responsible for maintaining the correct transport conditions. The IGJ supervises the license holder, but may become indirectly involved if the quality of transport is inadequate on a structural level.

**Logistical and operational structure** The company transports pharmaceutical shipments between different links in the supply chain. For example, it may transport goods from a wholesaler to a pharmacy, or from a pharmacy to a patient. These shipments can be transported via intermediate hubs or cross-docking centres, enabling short-term transshipment without the need for long-term storage.

Consequently, inventory management and pharmaceutical processing activities (e.g. order picking or dispensing medicines) are not part of the company's operations.

This operational model is already being applied in practice by specialised healthcare logistics service providers such as PostNL Health & Secure (Section 6.3), which operates a GDP-compliant distribution network for medicines and medical products. In such a setup, medicines are collected from the license holder after pharmaceutical release and appropriate packaging, and are transported via temperature-controlled vehicles and, where applicable, climate-controlled transshipment hubs. These facilities act solely as transit points, ensuring the continuity of the cold chain without taking on any responsibilities in terms of inventory management or ownership.

Although a pharmaceutical license is not required in this scenario, the company will usually obtain GDP certification to show customers that it complies with legislation and is reliable. Shipments are continuously monitored throughout the transport process using track-and-trace systems, which include temperature recording and delivery confirmation. Reliable and timely delivery is crucial, particularly for temperature-sensitive or urgent medications.

When delivering to patients, the company must ensure that deliveries are made correctly to the specified addresses in accordance with the pre-determined delivery instructions. Depending on the risk profile of the shipment, identity verification or a signature upon receipt may be required. If delivery is unsuccessful and there are no alternative instructions available (e.g. delivery to a neighbor or a secure drop-off location), the shipment will be returned to the pharmacy in accordance with the agreed procedures.

**Quality assurance** Although the company's role is limited, this scenario requires a robust quality system. Consider procedures for temperature monitoring, vehicle cleaning, security, contingency planning and staff training. GDP sets the standard here, providing guidelines on packaging validation, complaint handling, traceability and performance indicators such as timely delivery and incident frequency. Personnel such as drivers must be trained in handling medication, temperature sensitivity, patient delivery and emergencies.

**Advantages** This scenario offers the following advantages:

- No license is required, low entry barrier;
- Limited legal risk: the responsibility of the license holder;
- It is immediately scalable with existing logistics infrastructure;
- Demonstrable value in the final stage of medical deliveries.

**Disadvantages** This scenario offers the following disadvantages:

- No direct control over the flow of medicines;
- Dependence on pharmacies and wholesalers for orders;
- High-quality requirements without influence over the process;
- Potential liability in the event of incidents despite delegated responsibility;
- Added value is limited to transportation, not fulfilment tasks such as inventory management, order picking or packaging.

**Assumptions and uncertainties** This model reflects a practice that is already widely used within the pharmaceutical supply chain. Roles and responsibilities are clearly defined and can be effectively regulated through contractual and quality agreements. However, this structure is not yet commonly implemented within existing non-pharmaceutical fulfilment centres, particularly with respect to the organization and segregation of pharmaceutical products in cross-docking or transshipment environments.

#### S2: OTC medicines only

In this scenario, the company provides fulfilment services for non-prescription health product, namely OTC medicine, on behalf of licensed pharmacies, drugstores and other licensed retailers. The company does not sell products under its own name, operate a web shop or become the owner of the

goods. Instead, it acts as an external fulfilment service provider, supporting the distribution activities of authorized sellers.

The company remains outside the scope of pharmaceutical care and dispensing. Its role is limited to storing, processing orders for, and distributing OTC medicines sold by pharmacies and drugstores through their own online channels. By focusing on non-prescription products, the company avoids the most stringent legal requirements for prescription medicines while operating within the regulated healthcare supply chain.

**Legal structure and responsibility** Legal responsibility for the sale of OTC medicines remains entirely with the pharmacy or drugstore. As the company neither markets medicines under its own name nor sells directly to consumers, it does not qualify as a medicine supplier. Consequently, it is not required to register as an online medicine supplier, employ certified pharmacists or fulfill advisory obligations. These responsibilities remain with the contracting party, including compliance with requirements regarding sales categories, providing consumer information and advice, and complying with advertising legislation. In general, such collaborations are managed in a manner comparable to partnerships with non-healthcare clients, with responsibilities and liabilities primarily governed through contractual arrangements.

**Logistical and operational structure** In operational terms, the company acts as a centralized fulfilment hub for OTC medicines. It provides storage, inventory management, order picking, packaging and distribution services on behalf of its customers. Ownership of the inventory remains with the pharmacy or drugstore, and contractual agreements clearly define responsibilities relating to quality, recall procedures and information provision.

To ensure that products are distributed within their shelf life, the company must apply appropriate inventory management principles, such as FIFO or FEFO. Storage conditions must meet product-specific requirements, particularly with regard to temperature, humidity, and protection from contamination.

Depending on the customer's sales model, orders can be delivered to physical stores or directly to end consumers. In the case of direct delivery to consumers, the company acts solely as a delivery agent, while the authorized seller remains responsible for the legal transaction and communication with consumers.

**Quality assurance** Although the company is not responsible for dispensing or consumer advice, having a robust quality management system in place is essential. For OTC medicines, this includes among others, ensuring that they are stored appropriately, checking expiry dates, batch registration and reporting incidents to the contractual license holder. While GDP certification is not required for OTC products, adhering to GDP principles is considered good practice.

Personnel involved in handling healthcare products must be appropriately trained to recognise quality risks, comply with storage and handling procedures, and escalate deviations where necessary. In the case of established fulfilment companies, such training and quality management practices are typically already embedded in existing operational processes. For OTC medicines, no additional pharmaceutical qualifications are required for personnel, provided that adequate product-handling instructions and quality controls are in place. Internal audits and contractual performance monitoring support continuous compliance and operational reliability.

**Advantages** This scenario offers several advantages:

- No license is required, low entry barrier;
- Clear separation of legal responsibilities, which limits legislative exposure;
- Applicable to a wide range of customers;
- Less legislation compared to the supply of prescription drugs;
- Compatible with existing fulfilment models.

**Disadvantages** The scenario also entails limitations:

- Dependence on customers for order volumes;
- Relatively low margins, as OTC medicines represent only a small share of pharmacists' total expenditure.

**Assumptions and uncertainties** In terms of assumptions and uncertainties, this scenario largely corresponds to S1. This model reflects the logistics structures commonly used for consumer health products. The roles and responsibilities involved are clearly defined and can be effectively regulated through contractual and quality agreements. As a result, uncertainties are limited. The main uncertainties relate to practical situations, such as mixed orders containing both OTC and prescription medicines.

### S3: Pharmacy distribution point

In this scenario, the company acts as a distribution centre for licensed pharmacies. This is a scenario that was also considered feasible by the pharmacists interviewed (subsection 5.2.4). The distribution centre is not an independent pharmacy and does not provide pharmaceutical care. Instead, it acts as an external distribution point, delivering medicines directly to patients' homes on behalf of pharmacies. This model applies to all categories of medicine, including prescription medicines, provided dispensing, labeling and pharmaceutical control are carried out entirely by the responsible pharmacy before transfer.

Similar distribution points already exist, such as automated collection machines, lockers or manned service points operated by pharmacies, which are intended to increase accessibility. In this scenario, the distribution function is integrated into a fulfilment centre and is strictly limited to home delivery, and no pick-up service.

All interaction with patients regarding the dispensing, advising on, and checking of medication remains the responsibility of the pharmacy. Medicines are transferred to the company in a sealed, patient-specific, pharmaceutically prepared form. The company's role is limited to physically delivering medicines to patients, acting as an extension of the pharmacy's delivery service rather than an independent healthcare institution.

**Legal structure and responsibility** According to the Dutch Medicines Act, the pharmacy remains entirely responsible for dispensing medicines. The IGJ considers distribution points to be fixed delivery services that operate under the responsibility of a licensed pharmacist. Only medicines that have been prepared, checked, dispensed and labeled in the pharmacy may be distributed through these points. All pharmaceutical activities, including prescription checking, medication monitoring and labeling, therefore take place in advance at the pharmacy.

The fulfilment centre does not perform any independent pharmaceutical activities and has no decision-making authority with regard to the medication. Its role is strictly limited to logistics, namely the safe processing and storage of patient-specific, fully labeled medicines, and their home delivery.

Under Dutch legislation, distribution points are not subject to formal licensing requirements, nor are they required to have a physical service counter or a pharmacist on site, provided that the pharmacist's responsibility and supervision are demonstrably ensured. As such, a pharmacy license is not required for the company. Furthermore, medications are usually available at a dispensing point for up to 72 hours, which means that no WDA is required, but requirements regarding privacy, traceability and safe storage and transport apply.

**Logistical and operational structure** Following dispensing by the pharmacy, patient-specific, fully labeled medicines are transported from the pharmacy to the fulfilment centre as part of the distribution chain. The company acts as a distribution point under the pharmacy's responsibility and license, delivering medicines to patients' homes and eliminating the need to collect them in person from the pharmacy. However, this introduces an additional logistical step in the process.

The distribution centre does not repackage the medicines or apply new labels. However, it may place the sealed pharmacy packaging in transport-resistant outer packaging to protect the shipment during storage and delivery without affecting the original pharmaceutical packaging or labeling.

The company must have facilities that comply with GDP principles, including secure storage areas and temperature-controlled environments for refrigerated medicines. Provided that the company operates entirely under the pharmacy's license and does not carry out independent wholesale activities, storage of medicines in the fulfilment centre for a period shorter than 72 hours does not in itself constitute wholesale distribution. In such cases, the company is legally considered an extension of the pharmacy and not a separate distributor. Therefore, no WDA or legally responsible person (RP) is required for the company.

Nevertheless, companies operating under this model are typically contractually required by pharmacies or wholesalers to operate in accordance with GDP standards. In practice, this is usually achieved by designating an internal function responsible for quality or GDP. This function is responsible for overseeing internal GDP procedures, conducting audits, managing temperature control and incident handling, and acting as the first point of contact for customers and, where relevant, regulatory authorities. While this role promotes compliance and operational reliability, it does not constitute a legal RP as defined in the Medicines Act.

The company organizes the final stage of delivery in accordance with pre-established procedures agreed with the pharmacy. These procedures include instructions for handling temperature-sensitive medicines, as well as delivery control and traceability.

**Quality assurance** A basic quality assurance framework is required to ensure the integrity of medicine distribution. This includes the safe handling of medicines, environmental monitoring where applicable, and the accurate recording of transport and delivery events. Medicines must remain sealed throughout the entire process, and any deviation affecting product quality, delivery accuracy or patient safety must be documented and reported to the pharmacy for further assessment. Operational staff are trained in handling medicines and maintaining confidentiality, and compliance with agreed quality standards is monitored through internal controls and periodic pharmacy assessments.

### Advantages

- No license is required, low entry barrier;
- Scalable last-mile delivery model for pharmacies;
- Reduced operational burden on pharmacies' own delivery service;
- Highly suitable for repeat prescriptions.

**Disadvantages** The scenario also presents limitations:

- No service differentiation at the fulfilment level;
- Dependence on pharmacies for order volumes and service scope;
- Separate storage space required;
- Operational complexity related to temperature control;
- Extra step to the supply chain;
- Limited added value compared to transport-only scenario.

**Assumptions and uncertainties** In this scenario, the company acts as an external distribution point on behalf of a licensed pharmacy. It is assumed that the pharmacy carries out all pharmaceutical activities, after which the fulfilment company temporarily stores and delivers the medicines to patients. This model assumes that the company can operate entirely under the license and authority of the pharmacy, functioning as an operational extension of the pharmacy without making any clinical or pharmaceutical decisions. While this reflects the current practice of pharmacy-managed collection points, uncertainty arises when this role is performed by an independent external logistics service provider rather than pharmacy staff. It is unclear to what extent a separate legal entity can operate entirely under the pharmacy's license without incurring additional legal obligations.

Further uncertainties relate to scalability and operational design. As volumes increase or multiple pharmacies are served, it is assumed that drug flows, stock segregation and batch management can be strictly separated by pharmacy. However, it remains uncertain whether such segregation would be feasible in a high-throughput environment.

**S4: Becoming a wholesaler (B2B)**

In this scenario, the company operates as a licensed pharmaceutical wholesaler, offering wholesale distribution services for prescription medicines to other businesses. It purchases medicines from manufacturers or other licensed wholesalers and supplies them to licensed customers, including pharmacies, hospitals and other healthcare providers. By obtaining a WDA the company becomes an official intermediary within the pharmaceutical supply chain.

This represents a clear shift from pure logistics to regulated pharmaceutical trade. Unlike pure fulfilment models, the company becomes the legal owner of the medicines and assumes responsibility for their quality, traceability and distribution. The wholesaler does not supply medicines to patients or assume the role of a pharmacy; its activities remain strictly B2B. When an existing fulfilment company expands its activities to include the wholesale distribution of medicines, two distinct legal roles are assumed within the same organizational entity. As a fulfilment company, it acts on behalf of third-party owners of products and does not own the goods. However, as a license wholesaler, the company purchases, owns and supplies medicines under its own legal and commercial responsibility. This dual role seems to be permitted by law, provided that the distinction between these activities is clearly defined and demonstrable at all times.

**Legal structure and responsibility** In this scenario, the most important legal requirement is to obtain and maintain a WDA. This is done under the supervision of the IGJ. All requirements for obtaining and containing a WDA can be found in subsection 4.3.2.

From a legislative perspective, operating a fulfilment service alongside wholesale activities requires strict separation of responsibilities, ownership and documentation. Wholesale activities must be fully covered by a WDA and the associated GDP obligations, while fulfilment activities remain subject to contractual agreements with customers. Any ambiguity regarding ownership, responsibility or the applicable legislative framework may lead to non-compliance. During inspections, regulatory authorities will assess whether the company can clearly demonstrate the legal basis for each activity at any given time.

**Logistical and operational structure** From an operational standpoint, operating as a pharmaceutical wholesaler requires the implementation of a comprehensive quality management system that complies with GDP guidelines. Consequently, the company must provide adequate warehouse space and infrastructure to support its wholesale operations, including temperature-controlled storage, secure areas, and validated equipment.

Wholesale activities include receiving medicines from manufacturers or other authorized wholesalers and verifying deliveries, registering batches, and carrying out quality control checks. Storage and inventory management must meet product-specific requirements. Outbound activities consist of processing orders from authorized customers and distributing inventory to pharmacies or healthcare facilities under GDP-compliant transport conditions.

Combining wholesale activities with fulfilment services significantly increases operational complexity. Although physical infrastructure, such as packaging equipment, may be shared, the wholesale and fulfilment processes must be clearly separated. This requires separate inventory records, batch tracking, order flows and quality documentation, in order to prevent goods with different ownership and responsibility statuses from being mixed up. Staff can be deployed for both activities, responsibilities and training are clearly defined. This necessitates controlled access to storage areas, process-based separation of workflows, and robust IT systems that can consistently differentiate between wholesale and fulfilment inventory. While such a hybrid model seems to be operationally feasible, it entails higher compliance costs, strict governance requirements and a greater likelihood of inspections.

**Quality assurance** In this scenario, ensuring compliance with GDP is at the heart of quality assurance. The company must implement a comprehensive quality management system covering all wholesale activities. This includes documented procedures for receiving and storing goods, processing orders, transporting goods, handling deviations, dealing with complaints and handling recalls.

Continuous temperature monitoring, calibration and equipment maintenance are mandatory. IT systems must enable traceability at batch level, so that if a recall is necessary, it can be quickly determined who are affected. Personnel involved in wholesale activities must receive GDP training appropriate to their role.

The RP will supervise compliance, training and internal audits, and ensure that corrective and preventive measures are taken where necessary. Given the high value and sensitivity of medicines, security measures, including access control and theft prevention, are also part of quality assurance.

**Advantages** The advantages that this scenario offers:

- It enables the company to participate directly in the pharmaceutical supply chain and generate revenue from wholesale activities, rather than solely from logistics services;
- It allows the company to leverage its existing fulfilment infrastructure and logistics expertise for wholesale activities;
- Once legislative approval has been obtained, it offers scalability, with opportunities for differentiation through service quality, reliability or specialisation in specific product segments.

**Disadvantages** This scenario also has several disadvantages:

- A WDA has a high legislative threshold, requiring significant investment in compliance, facilities, qualified personnel and ongoing quality management to obtain and maintain one;
- It exposes the company to greater liability for product quality and legislative compliance, with the risk of penalties or license revocation in the event of non-compliance;
- It also requires significant capital investment in inventory, with risks of obsolescence or expired shelf life;
- The company must compete with established wholesalers and central filling providers that are often embedded within large pharmacy chains or purchasing cooperatives. These incumbents benefit from long-standing customer relationships, integrated procurement structures and significant economies of scale, making market entry for new and independent providers challenging.

**Assumptions and uncertainties** It is assumed here that the company itself obtains a WDA and acts as an official supplier of medicines to other healthcare institutions. It is implicitly assumed that a strict separation can be made between business operations, with a clear distinction between fulfilment activities (performed on a contractual basis on behalf of third parties) and wholesale activities (performed in the company's own name and ownership). This dual role seems to be legally permitted, provided it is clearly documented and managed separately. The main uncertainty concerns the practical implementation of this separation; stock and quality records must be kept separate to prevent resources being mixed up. As this scenario is exclusively B2B, questions about multi-pharmacy centralization (subsection 6.2.2) do not apply in principle.

#### S5: Becoming a central filling company

In this scenario, the company provides a central dispensing service, meaning that patient-specific prescription drugs are prepared, packaged and labeled on behalf of pharmacies at a central location. Pharmacies digitally forward prescriptions, usually for repeat or chronic medications, to the central filling centre. There, medicines are prepared for individual patients and then returned to the pharmacy.

Central processing is an established concept in the Dutch pharmaceutical supply chain and is already being used by existing market players (see Section 3.1). The model aims to increase efficiency and scalability by centralizing labour-intensive processing activities and utilizing highly automated systems. This enables pharmacies to reduce their local inventory and manual processing, allowing them to focus more on pharmaceutical care. In this scenario, the company can extend its services beyond logistics to become an operational extension of the pharmacy's processing.

**Legal structure and responsibility** According to Dutch law, only licensed pharmacies are permitted to dispense prescription medicines to patients. The central filling point operates as dispensing units under the professional responsibility of a licensed pharmacist. The central dispensing point carries out

dispensing activities on behalf of the originating pharmacy, rather than dispensing medicines independently to patients.

In the Dutch context, medicines used for central filling are usually stored and owned by the central filling partner, typically a pharmaceutical wholesaler or a specialised central filling pharmacy operating under its own license. They own the inventory, automated dispensing infrastructure and packaging process, and perform the physical picking, labeling and preparation of patient-specific medication on behalf of local pharmacies.

Although the central facility prepares and labels medicines, the original pharmacy remains legally responsible for dispensing to patients and communicating with them. In practice, this responsibility is maintained by either returning the patient-specific medication to the original pharmacy for formal transfer to the patient or operating the central filling facility under its own pharmacy license while dispensing on behalf of the original pharmacy through contractual delegation. Dutch pharmaceutical legislation permits the outsourcing of dispensing activities to another licensed pharmacy, provided patient safety is guaranteed, patients are informed and responsibilities are clearly defined in contractual agreements.

The IGJ considers central filling to be an integral part of the pharmacy care chain, supervising both the central filling facility and the participating pharmacies. This supervisory approach reflects the principle that responsibility for patient care and correct delivery remains with the authorised pharmacists, regardless of where the physical delivery activities take place.

**Logistical and operational structure** Operationally, central filling functions as a highly automated production process. Once the local pharmacy has validated the prescription, eligible orders are digitally forwarded to the central filling system, including product specifications and patient data for labeling. Quality controls, such as barcode scanning, vision systems and batch registration, are built into the entire process to ensure accuracy and traceability. Completed patient-specific packages are sorted.

Although the central filling partner is responsible for correct preparation, labeling and logistical handling, the local pharmacist is ultimately responsible for dispensing and providing pharmaceutical care to patients. Upon receipt, the pharmacy completes the handover to the patient and remains the primary point of contact for counseling, follow-up, and incident handling. Central filling is particularly suitable for standard, factory-produced medicines, while complex magistral preparations typically fall outside its area of expertise.

**Quality assurance** Due to the scale and critical nature of patient-specific dispensing, it is essential to have a robust quality management system in place. This includes batch traceability, compliance with the FMD where applicable, validated cold chain procedures and structured handling of deviations. While the central filling pharmacy is responsible for the accuracy of preparation and packaging, the original pharmacy remains legally responsible for final dispensing. This model of shared responsibility requires highly reliable processes, supported by audits, performance monitoring and clear escalation procedures.

**Advantages** The advantages that this scenario offers:

- Efficiency gains through automation and economies of scale;
- Reduced workload and inventory requirements for local pharmacies;
- High scalability once the central infrastructure is established.

**Disadvantages** This scenario also has several disadvantages:

- High upfront investment in facilities, automation and IT integration;
- Dependence on sufficient prescription volumes to remain viable;
- Strong competition from established central filling providers embedded in pharmacy chains or purchasing cooperatives.

**Assumptions and uncertainties** In this scenario, it is assumed that repeat prescriptions are sent digitally to a central dispensing institution that operates as a licensed pharmacy or a specialised central dispensing partner. In line with existing Dutch practice, medicines used for central dispensing are stored and owned by the facility itself, which operates under its own pharmacy license and professional responsibility. This facility is responsible for the physical preparation, labeling and sorting of patient-specific medication, while the original pharmacy retains legal responsibility for dispensing to and communicating with the patient.

Although central processing is an established and well-functioning model within pharmacy chains, uncertainties arise when this structure is adopted by an independent fulfilment company. A key assumption is that central processing activities can be organized and legally separated from other fulfilment or logistics services when carried out under one roof. In practice, however, it remains unclear how pharmacy and logistics activities within a single organisation can be sufficiently delineated without creating uncertainty about responsibility, supervision and compliance (subsection 6.2.1).

### E.1.2. Legally structured forms of cooperation

#### S6: In-house pharmacy

In this scenario, a licensed pharmacy is established at the same address as a logistics centre by renting a clearly defined storage and operational space within the facility. The pharmacy operates as an independent legal entity and holds its own pharmacy license, under the responsibility of an appointed responsible pharmacist registered at that location. All prescription medicines stored at the site remain the legal property of the pharmacy.

The logistics company does not sell medicines under its own name and does not become the owner of the goods. Instead, it provides storage facilities and performs logistical fulfilment activities on behalf of the pharmacy after pharmaceutical release has taken place. Medicines are distributed directly to patients under the pharmacy license, with the logistics company acting as an outsourced service provider for non-pharmaceutical handling activities.

By embedding the pharmacy within the logistics centre, this scenario enables the distribution of prescription medicines without requiring the logistics company to enter the pharmaceutical retail or wholesale domain. However, the model relies on close operational integration and strict governance arrangements to ensure legislative compliance.

**Legal structure and responsibility** Legal responsibility for the dispensing of prescription medicines lies entirely with the pharmacy and the responsible pharmacist. The pharmacist is accountable for prescription validation, pharmaceutical assessment, final release of medicines and compliance with all professional obligations under the Dutch Medicines Act and related healthcare legislation.

The logistics company does not qualify as a wholesaler, as it neither acquires ownership of medicines nor supplies them to other license holders. Its activities are limited to storage and logistical handling on behalf of the pharmacy, without independent decision-making authority regarding stock allocation, release or destination. As a result, the logistics company is not required to hold a WDA, provided that medicines are supplied exclusively to patients under the pharmacy license.

Although the logistics company is not the legal owner of the stock, it performs operational handling of prescription medicines, such as packaging and distribution. The pharmacy therefore remains fully responsible for ensuring that all outsourced activities comply with GDP. This responsibility is formalized through contractual arrangements, including a quality agreement that defines roles, responsibilities, audit rights and escalation procedures. While the IGJ formally supervises the licensed pharmacy, it may also assess the logistics provider insofar as deficiencies in storage or distribution could affect medicine quality or patient safety.

**Logistical and operational structure** Operationally, prescription medicines are stored within a physically and administratively segregated area of the logistics centre that is reserved exclusively for the pharmacy. This storage area must be GDP-compliant and meet all requirements regarding temperature control, access restriction, traceability and protection against contamination.

The company performs inventory handling, order picking, packaging for transport and shipment preparation, strictly in accordance with the pharmacy's standard operating procedures. Pharmaceutical activities, such as prescription review and release, remain the exclusive responsibility of the pharmacist. Personnel of the logistics company do not perform any pharmaceutical judgement and act solely as executors of predefined logistical processes.

Medicines may be stored for extended periods exceeding 72 hours. While prolonged storage increases the importance of robust quality controls, it does not in itself trigger wholesale qualification, provided that ownership and control remain with the pharmacy.

Distribution can take place directly to patients. In such cases, the company acts as a delivery agent on behalf of the pharmacy, while the pharmacy remains responsible for the legal transaction, patient communication and information provision.

**Quality assurance** Compliance with GDP principles is crucial in this scenario. The company must demonstrate that all storage and distribution activities are GDP-compliant. The logistics centre must therefore provide infrastructure and processes that meet GDP requirements, including temperature monitoring, deviation management, recall procedures and documentation.

The pharmacy retains oversight of quality assurance through audits, performance monitoring and incident reporting. All personnel involved in handling prescription medicines must be trained in GDP principles and instructed to recognize quality risks and escalate deviations. Clear procedures must be in place for complaints, recalls and cooperation with regulatory authorities.

**Advantages** This scenario offers several advantages:

- Distribution of prescription medicines without requiring a WDA;
- Legal separation between pharmaceutical responsibility and logistical execution;
- Direct delivery to patients under a pharmacy license;
- Reduced legislative exposure compared to wholesale models.

**Disadvantages** The scenario also entails significant limitations:

- High organisational complexity due to the need for in-housed pharmacists;
- Limited scalability, as each collaboration requires a dedicated pharmacy presence;
- Increased governance and oversight requirements;
- Personnel must receive additional training;
- Few independent and public pharmacies to collaborate with, as the majority are affiliated with a chain or formula

**Assumptions and uncertainties** As emphasized in subsection 6.2.1, this scenario highlights the ambiguity between dispensing medicines and logistics. While dispensing medicines remains the responsibility of the pharmacy from a legal standpoint, it is unclear which preparatory or processing activities can be delegated to logistics personnel once dispensing has occurred. In practice, the operational boundary between pharmaceutical judgement and logistical execution is difficult to define, particularly in highly integrated fulfilment environments. Therefore, the extent to which logistics personnel can be involved in post-dispensing processing remains uncertain and is largely based on assumptions rather than explicit legislation.

Although the model is conceptually clear, there are still uncertainties about its practical implementation and scalability. Each collaboration requires the establishment of a dedicated pharmacy, which limits scalability and increases organizational complexity. Finally, while the internal pharmacy model is theoretically robust, it needs to be clarified and validated in practice for independent fulfilment companies without existing pharmacy structures, particularly when pharmacy and fulfilment activities coexist within a single organisation.

#### S7: Joint Venture

In this scenario, the company and a pharmacy establish a new legal entity together, typically in the form of a private limited company (Besloten Vennootschap (BV)). This joint venture (JV) is based at the

company's address and acts as a central logistics entity. The JV has its own pharmacy license, with its own appointed pharmacist. Profits, investments and risks are distributed according to a shareholder and/or cooperation agreement.

**Legal structure and responsibility** The JV is a separate legal entity, offering limited liability to its shareholders [67]. As a holder of a pharmacy license, the JV is responsible for dispensing prescription drugs in accordance with the Dutch Medicines Act and related health legislation. The JV must appoint a responsible pharmacist who is personally responsible for compliance, professional standards, and cooperation with regulatory authorities.

The JV's pharmacy is responsible for pharmaceutical matters. This includes validating prescriptions, conducting pharmaceutical assessments, preparing and releasing medicines, and dispensing them to patients. While the company does not dispense medicines itself, as all pharmaceutical activities take place under the JV's pharmacy license, steps such as packaging for transport, and last-mile delivery can be outsourced. The roles, financing, ownership of inventory and profit sharing must be clearly defined in the shareholder and cooperation agreements.

The IGJ supervises the JV as a licensed pharmacy and may also assess logistics activities, insofar as shortcomings in storage or distribution may affect medicine quality or patient safety.

**Logistical and operational structure** From an operational perspective, the JV pharmacy is integrated into the logistics infrastructure. The JV leases business premises and storage space in the building from the logistics company, which is responsible for ensuring these facilities comply with all applicable GDP requirements. Medicines are purchased under the pharmacy license and stored in GDP-compliant conditions at the JV's location. The JV pharmacy legally owns the stock.

The logistics company provides storage facilities, inventory management, transport preparation and distribution as outsourced services in accordance with the pharmacy's procedures and quality agreements. While the logistics company is responsible for providing and maintaining GDP-compliant infrastructure and performing logistics processes, the responsible pharmacist remains solely responsible for pharmaceutical activities, including prescription validation and final release. Patients can be supplied directly from the joint venture's pharmacy, with the logistics company acting as a delivery agent on behalf of the pharmacy.

**Quality assurance** Quality assurance is overseen by the pharmacy's quality management system and professional standards. All outsourced logistics activities must comply with GDP and are subject to contractual quality agreements, audits and performance monitoring. Personnel involved in handling medicines must receive appropriate training for their role, while qualified professionals retain responsibility for pharmaceutical judgement.

### Advantages

- Direct delivery to patients under a pharmacy license;
- Shared costs and risks;
- Combining expertise;

### Disadvantages

- Upfront investment required to establish a new legal entity and to develop or adapt GDP-compliant storage and logistics infrastructure;
- High organisational and governance complexity;
- Requirement to appoint and retain a responsible pharmacist;
- Full legislative exposure as a licensed pharmacy;
- Can result in conflict of interest;
- Can result in cultural differences;
- Shared control and decision-making;
- Few independent and public pharmacies to collaborate with, as the majority are affiliated with a chain or formula

**Assumptions and uncertainties** This scenario assumes that the JV will operate as an independent pharmacy, with the parent company providing logistical operational support including storage, transportation and possible other fulfilment services. A key assumption is that pharmaceutical and logistical activities can be effectively integrated within a single licensed pharmacy while ensuring a clear distinction between pharmaceutical judgement and logistical execution. While this is legally feasible in principle, there are significant uncertainties surrounding the practical allocation of roles and responsibilities. In particular, it is unclear what involvement staff employed by the parent company (and not the joint venture) may have in logistics activities closely related to the dispensing of medicines, without compromising the pharmacy license's independence. It is unclear how this separation would be applied in daily practice, how transparency towards patients would be ensured, and how regulatory authorities would assess the separation between legal responsibility and operational implementation.

Overall, this scenario requires a high degree of contractual clarity and governance to prevent role confusion, conflicts of interest, and legislative non-compliance. Particular attention must be paid to quality assurance, and incident handling, as responsibilities are shared between two closely connected, yet legally distinct, entities. As with other integrated models, further practical validation is required to determine whether the separation of pharmacy, wholesale, and logistics activities can consistently and demonstrably be maintained within a joint venture structure.

#### S8: Cooperative

In this scenario, the company acts as a co-founder of a cooperative alongside one or more pharmacies. These pharmacies can then join the cooperative as members. The cooperative functions as a collective organisation for pharmaceutical logistics and related support services, while individual pharmacies retain their own pharmacy licences and responsibility for patient care. Adopting a U.A. (Uitgesloten van Aansprakelijkheid) structure excludes members from personal liability for the cooperative's debts.

Under this model, the company is responsible for the cooperative's entire logistics operation, including warehousing, inventory management and distribution. The cooperative provides a governance and ownership framework that enables pharmacies to organize and control these activities jointly.

This collaborative model has already been shown to be operationally feasible, as demonstrated by initiatives such as Multipharma in Belgium [49]. In Belgium, a relatively large proportion of pharmacies operate independently, making cooperative ownership and centralised logistics a natural organisational form [71]. However, in the Netherlands, the pharmacy market is more consolidated, with many pharmacies belonging to chains or purchasing cooperatives that already offer integrated logistics solutions (subsection 5.1.3). Consequently, while the cooperative model is legally feasible, its added value is less evident in the Dutch context, which explains its limited acceptance to date.

**Legal structure and responsibility** As a legal entity, the cooperative is responsible for its own debts, meaning that its members are not personally liable [66]. It has a pharmacy license registered at its place of business and appoints a responsible pharmacist, who is legally responsible for compliance with the Dutch Medicines Act and professional standards.

As the cooperative is a licensed pharmacy itself, it is legally authorized to perform pharmaceutical activities, including validating prescriptions, preparing, dispensing and delivering medications to patients. Affiliated pharmacies can contribute patients, prescriptions or operational capacity, but the cooperative pharmacy assumes responsibility for dispensing when medicines are supplied under its license. Medicines are procured under the cooperative's pharmacy license, typically through wholesale suppliers, and are legally owned by the cooperative.

The company itself does not perform any pharmaceutical activities. Its role is limited to providing logistical and operational support. Clear articles of association and cooperation agreements define the management, decision-making authority, financial contributions and profit distribution between the pharmacy members and the company. The IGJ supervises the cooperative as a licensed pharmacy and can also assess logistical activities insofar as they affect the quality of medicines or patient safety.

**Logistical and operational structure** In operational terms, the cooperative pharmacy is integrated into with the company's logistics infrastructure. The cooperative leases dedicated storage and operat-

ing space from the company, which is responsible for providing GDP-compliant facilities and maintaining them. The company performs all physical logistics processes on behalf of the cooperative, including storage, inventory management, transport preparation and distribution. Medicines can be dispensed directly to patients from the cooperative pharmacy through home delivery, with the company acting as the delivery agent.

**Quality assurance** Quality assurance is organized centrally within the cooperative pharmacy's quality management system. This system covers pharmaceutical processes and outsourced logistics activities. The company must operate in accordance with GDP requirements and contractual quality agreements, ensuring that logistics staff are properly trained.

The responsible pharmacist oversees pharmaceutical quality and patient safety, with support from audits, performance monitoring and deviation management. The cooperative governance structure enables members to oversee quality collectively, while centralization increases the importance of robust controls.

### Advantages

- Shared costs;
- Proved to be a workable structure outside the existing fulfilment environment;
- Collective scale advantages through shared logistics and procurement;
- Limited liability for members under a Coöperatie U.A.;

### Disadvantages

- Upfront investment required to establish a new legal entity and to develop or adapt GDP-compliant storage and logistics infrastructure;
- High governance and coordination complexity;
- Potentially slower decision-making due to collective control;
- Less direct operational control for the logistics company compared to a JV.

**Assumptions and uncertainties** In this scenario, it is assumed that the cooperative has a pharmacy license and carries out pharmacy activities on behalf of its affiliated pharmacies. The individual pharmacies remain responsible for patient records and pharmaceutical care.

A key assumption relates to the ownership of medicines. In accordance with general cooperative principles, pharmacies can contribute their stock to the cooperative, thereby transferring ownership to the cooperative entity. However, in the context of prescription medicines, it is unclear whether such a transfer of ownership is legally permitted under the Medicines Act. Unlike standard cooperative models, pharmaceutical legislation does not explicitly clarify how collective ownership of medicine stock should be structured, creating uncertainty around liability, accountability and regulatory oversight.

Even more uncertainty surrounds the outsourcing of logistics activities to a fulfilment company. While it is assumed that the cooperative can hire a logistics service provider for storage, processing and distribution, the exact boundary between pharmaceutical activities and logistics execution is unclear. As discussed in subsection 6.2.1 and subsection 6.2.2, delegating tasks in a centralized environment with multiple pharmacies raises questions about oversight, the separation of flows, and the risk that, from a regulatory perspective, the cooperative may in fact be functioning as a wholesaler. While the cooperative model offers an attractive framework for collective organisation in theory, its practical application in the pharmaceutical sector involves significant uncertainties.

## E.2. Elaboration on feasibility framework

This chapter provides brief explanations of all the question marks and crosses in Table 6.2. A copy of this table is shown below. Check marks indicate clear compliance with the relevant restriction and are explained in the individual scenario descriptions in Section E.1, so only these symbols are explained here.

**Table E.1:** Compliance with the feasibility framework (copy)

Design specification	S1	S2	S3	S4	S5	S6	S7	S8
R1	✓	✓	✓	✓	✓	✓	✓	✓
R2	✓	✓	?	?	?	?	?	?
R3	✓	✓	✓	✓	✓	✓	✓	✓
R4	✓	n/a	✓	✓	✓	✓	✓	✓
DC1	✓	×	✓	✓	✓	✓	✓	✓
DC2	✓	✓	✓	×	×	✓	?	×
DC3	✓	×	✓	✓	✓	✓	✓	✓
DC4	✓	✓	?	?	?	?	?	?
DC5	✓	✓	✓	✓	✓	✓	✓	✓
DC6	✓	✓	✓	✓	✓	✓	✓	✓
DC7	✓	✓	✓	✓	✓	✓	✓	✓

The explanations below clarify the reasons behind the legislative and regulatory ambiguity or structural misalignment of certain design specifications.

- **S2 - R4 (n/a):** The GDP-compliant storage and transport of prescription medicines does not apply in this scenario, which is limited to OTC medicines and does not involve the handling of prescription medicines requiring full pharmaceutical GDP supervision.
- **S2 - DC1 (×):** As it excludes prescription medicines, the scenario cannot include all categories of medicine, which limits its structural scope.
- **S2 - DC3 (×):** OTC products usually account for a relatively small proportion of total pharmacy sales (often around or below 20%, see subsection 5.1.3) and tend to be more demand-driven than repeat prescription flows. Consequently, they are less predictable and generate limited, fragmented volumes, which reduces the potential for stable, high-volume logistics.
- **S3 - R2 (?):** The fulfilment company acts as an external distribution point under the pharmacy's license. While the pharmacy retains responsibility for pharmaceutical activities, it is unclear to what extent an independent legal entity can operate entirely under that license without requiring additional licenses.
- **S3 - DC4 (?):** The model assumes a clear distinction between pharmaceutical responsibility and logistical execution. However, maintaining a strict separation and division of responsibilities can become complex (when activities are scaled up or the flows of multiple pharmacies are combined). This creates uncertainty over whether the legal and operational separation can consistently be guaranteed.
- **S4 - R2 (?):** Although a wholesale license (WDA) can be obtained, combining wholesale and fulfilment functions within a single entity raises questions about careful structural separation and approval by regulatory authorities.
- **S4 - DC2 (×):** This scenario relies on significant participation from the B2B market and does not target a specific niche segment. Furthermore, it would require direct competition with the well-established chains and large pharmaceutical wholesalers that already dominate the Dutch market, which would limit its structural market potential.
- **S4 - DC4 (?):** Having dual roles (wholesale and fulfilment) may make it difficult to separate responsibilities and create governance complexity.
- **S5 - R2 (?):** Activities involving central filling require clarification regarding the scope of pharmacy and/or wholesale licensing and supervision.
- **S5 - DC2 (×):** The model depends on widespread adoption by pharmacies to achieve economies of scale, making it structurally dependent on broad acceptance. Additionally, it would need to compete within the tightly regulated and well-established pharmaceutical supply chain, where existing wholesalers, chains, and central filling providers hold a strong position.
- **S5 - DC4 (?):** Preparing patient-specific items at a central site raises questions about the division between dispensing and fulfilment tasks.
- **S6 - R2 (?):** Although the in-house pharmacy has its own license, it remains unclear which activi-

ties can be delegated to fulfilment personnel after medicines have been dispensed. The boundary between pharmaceutical judgement and logistical execution is not clearly defined in the regulations, particularly in highly integrated environments. Furthermore, it is unclear whether a wholesale license is also required, given that the storage facility is owned by the fulfilment company and medicines must be stored under GDP conditions. The only practical example mentioned in subsection 6.1.2 concerns a party that already has a wholesale license, which makes it uncertain whether such a license would also be required in this configuration. As a result, additional investigation or clarification by the relevant regulatory authorities may be necessary.

- **S6 - DC4 (?)**: Integrating pharmacy and fulfilment activities physically under one roof requires strict legal and operational separation. In practice, maintaining this distinction can be challenging, particularly as volumes increase. This creates uncertainty over whether the separation of roles can consistently be guaranteed (also in scalable implementations).
- **S7 - R2 (?)**: The JV is expected to operate as an independent, licensed pharmacy with operational support from the parent company. However, it remains unclear how the regulatory authorities will assess the allocation of licenses and responsibilities, particularly in cases where parent company personnel are involved in activities closely related to the dispensing of medicines.
- **S7 - DC2 (?)**: Commercial viability depends on strong coordination between partners and sufficient volume within the joint structure. The model requires a high degree of coordination and long-term commitment to justify its organizational complexity. Furthermore, as this type of joint venture structure is unfamiliar in the Dutch pharmaceutical context, it is difficult to predict how it would be received or whether it would operate effectively within the existing regulated market.
- **S7 - DC4 (?)**: The shared ownership structure necessitates a clear distinction between pharmaceutical responsibility and logistical execution. In practice, maintaining this distinction, particularly in areas such as quality assurance, and incident handling, can be complex and requires robust governance and clear contracts. Furthermore, the extent to which personnel employed by the parent companies can be involved in operational activities without compromising the legal independence of the pharmacy entity remains unclear.
- **S8 - R2 (?)**: The scenario assumes that the cooperative holds a pharmacy license and conducts activities on behalf of its affiliated pharmacies. However, the collective ownership of the stock of prescription medicines and its relationship with the Medicines Act is uncertain. The regulatory implications regarding liability, accountability and potential classification as a wholesaler remain unclear.
- **S8 - DC2 (×)**: The cooperative model requires independent pharmacies to transfer their stock and operational control to a collective entity, and to participate in the cooperative. While this structure appears to work well in Belgium, relatively few independent pharmacies on the Dutch market could join such a cooperative autonomously. Due to the high level of consolidation and existing chain structures, the model has insufficient structural market potential in the Netherlands.
- **S8 - DC4 (?)**: Contractual agreements must ensure a clear separation between pharmaceutical responsibility and outsourced logistics. However, it remains unclear how multiple medicine streams from different pharmacies can be and must be strictly separated within a single centralized facility, especially when regular fulfilment activities are also carried out under the same roof. This creates uncertainty regarding oversight and accountability, and raises questions about whether such a structure could resemble wholesale activities in practice.